Website Content Analysis

Are you spending hours reading websites for a client, a prospect, or while conducting market research?

Oftentimes analyzing a website requires manually scanning dozens of pages, then taking screenshots, downloading PDFs, eventually writing a report of the website’s commonly used phrases and concepts.

An expensive, often complicated solution is to hire or develop a web scrapping solution.

Working with us, give us the domain names you’re interested in, and you’ll receive results in 48 hours.

Our service allows you to analyze an entire website in minutes by scanning a single text document with the extracted text from all HTML pages, PDFs, and images available in the website. We also provide the top 500 most-used phrases of 3, 4, 5, and 6 words (called “N-grams”) in that website.

You’ll be able to quickly learn the language of the website’s owner. To help you craft a better story. And to better understand a particular industry. While saving time. You’ll be able to better serve more clients.

## Benefits

\* Fully automated, done for you

\* Fast turnaround: 48 hours

\* No coding. No IT involvement.

\* Flat fee pricing: US$200.00 per domain name. PDFs and image files are available for an extra US$100.00 per domain name. (Note: PDFs locked behind registration forms are not available).

## Who do we serve?

Our website content analysis service allows

\* Marketing agencies to:

prepare better pitches for prospects by analyzing the prospect’s website

develop effective branding campaigns for a client by analyzing the websites of client’s own clients

\* Market research agencies to:

quickly analyze dozens, even hundreds of websites in a particular industry

## Deliverables

For each domain name that you define we’ll deliver to you:

\* a single text file with all text extracted from HTML, PDF, and image files

\* N-gram files (3, 4, 5, and 6 words)

\* PDFs and image files if desired

Please visit <https://DataSDR.com/website-content-analysis> to download free samples.

Contact:

José C. Lacal, CTO

Jose.Lacal@DataSDR.com

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Description  
  
This Word document contains all the text from the HTML files available at https://www.instem.com/  
  
You can literally "navigate" this entire website in this single file.  
  
Now you can analyze the entire contents of the website in your computer, even without an Internet connection.

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Join our panel of SEND experts to learn how to prepare for compliance with the newly required standard for Genetic Toxicology  
Wednesday August 28, 2024 at 3pm-4:30pm BST/10:00am-11:30am EDT  
Register Now  
  
  
CLINICAL DATA ANALYSIS:AVOIDING OBSTACLES TO SUCCESS  
Learn how to overcome disjointed systems, unprotected data, access mismanagement, validation issues, and much more in our webinar on September 11th at 2pm EDT / 11am PDT  
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White Paper: Polo-like kinase 4 (PLK4) Safety Review - Distilling the  
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What is the preferred approach for predicting carcinogenicity potency of N-nitrosamines?  
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Advance™ technology-enabled solution enables R&D organizations to cut study timelines, deliver cost savings and reduce animal experimentation.  
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Instem Now Part of ARCHIMED to Further Accelerate Growth and Impact  
Healthcare investment specialist ARCHIMED has the expertise, experience, enthusiasm and financial strength to fully back Instem’s ambitions.  
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Supporting Our Customers   
Many of our clients have been Instem customers for more than twenty years. Offering the highest level of community support is a vital mission for us.   
Every Instem customer has access to live global support to ensure their ongoing operational effectiveness and success. And when it comes to our Global Help desks, nothing can replace the responsive live person at the other end. These are seasoned experts who are well versed in our solutions and become a single voice for our users. When one of our help desk representatives takes a call, they stay with the call.  
“The result of Instem’s focus on delivering the exceptional client experience is seen through the extremely high customer satisfaction and retention rates”  
We also support our clients through our innovative and comprehensive Customer Involvement Program (CIP).   
 We want each and every user to feel connected, regardless of how much they have invested or the size of their organization. Our CIP provides our clients with opportunities to engage with us and other users in a variety of ways while optimizing their use of our solutions and help shape and influence roadmaps, including:  
  
Live Webinars  
On-demand videos  
Instem University CBT  
The Instem International Conference  
Special Interest Groups  
The Instem Customer Center   
Customer Advocacy Program   
  
  
  
  
  
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Cloud Services  
SaaS & Hosted Platforms - Access to Instem solutions on-demand from any location  
  
  
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Organizations of all sizes are accessing the power of Instem’s software solutions via our online platforms. Instem’s SaaS and Hosted Services deployment models give our clients simple, cost-effective ways to access software functionality, maintenance and support from any location that offers connectivity to their network or the Internet 24 hours a day; seven days a week.   
Instem Cloud Clients Enjoy:  
  
No upfront investment in hardware   
Reduced IT burden  
Flexibility and scalability to meet their changing needs  
Faster access to new software enhancements  
Inclusion of all 3rd party licenses such as Oracle, SAS, etc.  
Cost effective subscriptions that include validation, training & support  
100% network availability / 100% data protection  
  
  
  
Our professionally managed online platforms are run from centralized state-of-the-art data centers, which are being used by drug developers, contract research organizations, universities, research institutes and government agencies around the world.  
Staffed 24x7x365, Instem’s online solutions are located at international PCI Level One secure data centers managed by Rackspace, a global leader in managed IT solutions for the enterprise. Rackspace has established a prestigious record of excellence in customer support, technology and best practices and has won numerous awards and accolades including most recently being recognized as an industry leader by Forrester Research and by Gartner Research for Cloud-Enabled Managed hosting.  
Secure, Reliable. Proven.  
Learn more info@instem.com  
  
  
  
  
  
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Validation  
Satisfying the regulatory bodies, satisfying our clients’ high standards  
  
  
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We have a long history of working with the regulators and a wealth of hands-on experience of helping customers through the validation process. That's how we have been able to develop our highly valued in-house suite of Validation Services.   
Our services include:  
  
Requirements review & gap analysis  
Risk assessment & mitigation  
Database migration validation  
On-site installation and execution of the validation solution  
QA verification  
  
We utilize cost effective automated validation processes and test scripts to minimize the demands on valuable scientific staff and speed the validation process.   
Minimal disruption, fewer demands on client staff and a faster route to compliance, all delivered with a clear validation trail.  
Contact us at info@instem.com to learn more  
  
  
  
  
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Product Deployment  
Getting our clients into production faster, easier  
  
  
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Our aim is to deliver software that aligns 100% with user needs and to provide software solutions and services that deliver clear competitive advantages.   
Smooth installation is one of the surest ways to gain early user support   
It is the period when the project sponsor is really under the spotlight. At Instem, we have invested many years developing formal installation processes and professional services designed to safeguard the success of the project and to secure return on investment.   
Our Project Managers are highly skilled, hands-on individuals who have a thorough knowledge of our solutions and many years’ experience of successful Project and Program Management in the Life Sciences sector. They are well versed in all aspects of our governing Instem Project Method, including our proven Rapid  
Deployment Method for those organizations operating to rigorous timescales.  
We offer a range of training methods to suit our clients’ individual requirements, from virtual training sessions over the Web, to multi-day onsite courses and workshops at their facility or through use of Instem University, our new CBT system. Instem Training is a key element of ensuring our clients see immediate returns on their technology investment.  
  
  
  
   
   
  
Rapid & Tailored Deployments  
Instem offers a specialized program for clients needing a more tailored approach to implementation, training, validation and support services.   
Dedicated client specialists and extended customer care  
Perfect for:   
  
Smaller organizations or those needing to go live outside of normal timescales  
Academic or government research facilities  
Non-traditional research programs  
  
Ensuring our clients see value from their investment is priority number one, period.  
Clients stay connected with Instem when they need us the most, which often is for one year following the deployment of their solution.  
Learn faster, retain more  
  
  
ON-Demand Training Services  
Clients also have access to educational industry experts standing at the ready to help, can request more advanced learning or anything else that can maximize their use of our systems. Education services are available on-site or on-line, the client chooses.  
Once connected, always connected  
Once clients become proficient users, Instem becomes an extension of their business ensuring they receive the highest amount of value from our integrated software. Through our Relationship Managers and value-added tools such as our secure Customer Center, clients have access to a wealth of resources and support so they stay focused on their science, not their software.  
Tailored implementation plans can include:  
  
Business, industry & process consulting  
IT/technical assistance & support  
IQ, OQ, PQ & SOP services  
Go-Live assistance  
Application support  
Traditional on-site and On-line deployments  
  
  
  
  
  
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Industries we serve  
Empowering Today’s Research & Development Teams  
Pharmaceutical • Government Research • Chemical • Medical Device • Agrochemical • Academic Research  
  
  
  
Powering the processes that lead to safer more effective drugs  
The regulatory bodies’ preference for the electronic capture, storage and transfer of data for new drug submissions continues to grow, complementing the demand from pharmaceutical organizations and their collaborators to manage their compliance risk. Additionally, companies are increasingly keen to leverage vast volumes of historic data to help them to improve the suitability of drug candidates using.  
  
  
  
Instem has the unique ability to provide comprehensive software solutions and services across the R&D continuum to meet the needs of life science and healthcare organizations for data-driven decision making  
  
  
Key Industry Initiative Spotlight: The Standard for Exchange of Nonclinical data (SEND)  
Instem collaborates with regulatory authorities and industry consortiums around the globe to further their missions of increasing product safety while more rapidly introducing breakthroughs to improve todays’ way of life.  
The SEND standard was developed under the auspices of CDISC, a not-for-profit organization that establishes standards to support the acquisition, exchange, submission and archive of nonclinical and clinical research data and metadata. The introduction of SEND for both regulatory submission and the electronic exchange of toxicology data is having a significant impact on the industry...read more about SEND  
  
  
Government Research Community  
Instem’s government practice has been developed to consolidate and leverage our proven commercial experience, as agencies and their partners look towards technology to better investigate environmental risks as well as the causes, treatments, and cures for common and rare diseases and conditions.  
Our government program clients benefit from the heightened focus of an Instem team that tailors best practices for software development, support and services for what can be specialized research program requirements around the world.  
Some of our notable government clients include:   
  
National Center for Toxicological Research (NCTR)   
National Institutes of Health (NIH)  
United States Food and Drug Administration (US FDA)  
Health Protection Agency (HPA)  
United States Army Medical Research Institute of Infectious Disease (USAMRIID)  
National Institute of Environmental Health Sciences (NIEHS)   
National Institute of Allergy and Infectious Diseases (NIAID)  
Health Canada  
  
Instem additionally supplies enhanced indirect government support to a wide number of research programs throughout its customer community such as those being managed by Battelle or the independent nonprofit SRI International.  
Contact us for more information about our government practice at instem-gov@instem.com  
  
  
We also proudly support clients in the chemical, agrochemical and medical device R&D marketplaces.  
  
  
  
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Standard for Exchange of Nonclinical Data  
  
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Originally driven by FDA’s Critical Path Initiative to bring medical breakthroughs more quickly to market, the SEND standard was developed under the auspices of CDISC (www.cdisc.org), a not-for-profit organization that establishes standards to support the acquisition, exchange, submission and archive of nonclinical and clinical research data and metadata. The CDISC mission is to develop and support global, platform-independent data standards that enable information system interoperability to improve medical research and related areas of healthcare.   
SEND Status  
On December 17, 2017, the FDA SEND 3.0 Mandate for providing regulatory submissions in electronic format came into force. All organizations must use the appropriate FDA supported standards, formats and terminologies specified in the FDA Data Standards Catalog for NDA, ANDA, IND and certain BLA submissions.   
March 15, 2019 saw the requirement for SEND 3.1 for IND studies, which widened the scope to include Safety Pharmacology, for cardiovascular and respiratory studies. Additionally, in 2020, the SEND standard for animal rules studies, SENDIG-AR, was adopted. FDA have already begun the process of requiring SENDIG-DART, which is the SEND standard for Reproductive Toxicology Studies.  
   
  
Sensible SEND Blog  
Read Now  
  
The SEND format enables more efficient review of nonclinical data, offering improved data quality, accessibility and predictability.  
The standard itself has been developed by an expert team of sponsors, CROs and software vendor representatives over the last several years. It has been designed to provide a vehicle for transporting to regulators the results of the majority of standard regulatory toxicology study designs. The standard is constantly developing through the addition of support for more study types and the incorporation of changes arising from the practical use of the standard.   
  
  
  
Available Resources  
  
Have a SEND Question? Ask a SEND expert.  
Copy of the SEND Implementation Guide  
On-demand SEND Educational Videos  
Submit for SEND Literature  
Info about SEND data conversion services  
Case Study: Charles River Laboratories at the Forefront of SEND Compliance  
  
  
  
   
  
   
There are three principle components to the standard: the definition of the structure of the standard – domains, variables, etc., a library of controlled terminology (which controls the vocabularies that can be used in some of the variables) and a metadata file describing the source and content of a set of SEND datasets. The Controlled Terminology is managed by a CDISC team and disseminated through an NIH web portal, with new  
 releases of the vocabulary becoming available each quarter.   
The introduction of SEND for both regulatory submission and the electronic exchange of toxicology data is having a significant impact on the industry. Each organization in the pharmaceutical early development value chain is now touched by the implementation of this standard and will need to make changes to their systems and working practices.  
  
  
Did you know, noncompliance in SEND can result in refusal to file?  
 Learn how Instem can help.  
  
  
Instem has served the preclinical toxicology community for more than 30 years and recognized that the implementation of the SEND standard for regulatory submissions would have consequences for every organization that submits to FDA and for their suppliers and consultants. For the first time, all drug development sponsors would need to hold and manage electronic data that is subject to GLP (Good Laboratory Practices) and 21 CFR Part 11 regulations for electronic records.  
We have stood shoulder-to-shoulder with our partners in the pharmaceutical, contract research and regulatory communities to invest time and money in the creation of SEND since its inception. We have worked closely with SEND pilot organizations and the FDA, and have been part of various SEND industry teams in helping to further define the standard and align it with industry practices. We are proud to have worked with some of the brightest and most dedicated individuals to help create the SEND standard.  
Instem has been recognized by CDISC for our outstanding contributions toward the completion of the SEND Implementation Guide and was pivotal in helping draft guidance to be published by the FDA.  
Take the next step in becoming SENDReady™ and contact us today.   
  
  
  
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What makes Aspire™ Different?  
Aspire is a clinical analytics framework of flexible clinical components which allows you to focus on the meaning of your data by automating mundane tasks and providing a fit-for-purpose workflow. The platform is configured on an extendable cloud architecture. This allows you to rapidly add new capabilities while maintaining data integrity and traceability throughout the clinical data lifecycle.  
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Converting Information into Insight, Instem proudly offers solutions and services that help client research and development teams enhance and improve life.  
  
Study Management  
Software that empowers organizations to more efficiently collect, review, manage and report Discovery, Preclinical and Early Phase Clinical data.  
Discovery  
 Leading edge software for capturing and analyzing data in the laboratory that can easily be shared across scientific teams.  
BioRails® - A comprehensive system for workflow-driven data management  
Morphit™ - Providing unique abilities for reading, managing and visualizing data from instruments and transforming raw data into validated results  
BioHub™ - A single centralized location for storage and seamless access to all corporate research data  
Preclinical  
 Complete collection, management and reporting of safety evaluation study data in both GLP & Non-GLP environments.  
Provantis® Suite - The #1 on-line or on-premise toxicology study management software suite designed for single users to global multi-site organizations  
Logbook™ - Helping clients to replace paper forms across the laboratory resulting in reduced costs, increased efficiencies, and improved compliance   
GeneTox Suite - Image analysis and data management solutions helping users simplify the process of acquiring, managing and reporting genetic toxicology assay data  
NOTOCORD-hem™ - The leading telemetry-based safety pharmacology software platform for the seamless acquisition, display and analysis of physiological signals   
  
Regulatory Solutions  
Software, outsourced services, and consultancy for managing, storing, sharing and submitting and maintaining information compliant with FDA, EMA and other agency regulations.  
Preclinical SEND  
 Solutions and services that enables more efficient review of data, offering improved data quality, accessibility and predictability while helping clients generate value beyond compliance.  
Submit™ - Software for SEND dataset creation and version controlled file storage  
SENDView™ - Enabling simplified data review and quality control   
SEND Services - Outsourced study services, consulting and training   
Clinical Trial Transparency  
 Anonymization Services and software to meet EMA Policy 0070 and Health Canada public release of clinical information and support industry and internal sharing initiatives.  
De-identification Services - On-demand outsourced transformation services designed to measure risk, anonymize data and documents and meet strict regulatory sharing deadlines  
Blur™ - The leading transparency software that automates anonymization of both documents and data through Natural Language Programming  
Transparency Strategy - Consultancy and education that improve sharing processes for clients including global regulation education, disclosure defense, S.O.P development and training   
  
Clinical Trial Analytics Solutions  
Strategy, services and software to empower clinical innovation, create automation, enable open source and public cloud within biometrics, data science and clinical submissions.  
Accel™ - Cloud-based Statistical Computing Environment pre-loaded tools, applications & licenses for efficient statistical programming. Offers a validated connection between sponsors and CROS when sharing data, programs and analysis results  
Aspire™ - Modular clinical analysis framework that accelerates modernizations through non-proprietary code, applications and back-end services within the public cloud  
Analytics Strategy - Proven strategic consulting that delivers actionable plans for R&D IT, biostats, data science and product development teams.  
Analytics Services - Tailored enterprise services to build, customize or configure a fit-for-purpose clinical analysis system; integrating valued client legacy solutions and workflows with modern tools and practices, including the public cloud, to accelerate insight, analysis and submission.   
   
  
  
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Enabling researchers to generate new scientific insights through the identification, extraction and analysis of actionable information.  
Target Safety Assessment  
 Setting new standards in biological target profiling by helping organizations gather information about their targets during program development, find patterns in their research data, and put their own results into a broader scientific context to predict likely outcomes.   
KnowledgeScan™ - A technology enabled, informatics-based service to generate critical insights from immense and disparate scientific and medical ‘big data’  
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For more than 700 clients, Instem powers the processes that lead to safer, more effective healthcare solutions.  
  
  
Converting Information into Insight, Instem proudly offers solutions and services that help client research and development teams enhance and improve life.  
  
Study Management  
Software that empowers organizations to more efficiently collect, review, manage and report Discovery, Preclinical and Early Phase Clinical data.  
Discovery  
 Leading edge software for capturing and analyzing data in the laboratory that can easily be shared across scientific teams.  
BioRails® - A comprehensive system for workflow-driven data management  
Morphit™ - Providing unique abilities for reading, managing and visualizing data from instruments and transforming raw data into validated results  
BioHub™ - A single centralized location for storage and seamless access to all corporate research data  
Preclinical  
 Complete collection, management and reporting of safety evaluation study data in both GLP & Non-GLP environments.  
Provantis® Suite - The #1 on-line or on-premise toxicology study management software suite designed for single users to global multi-site organizations  
Logbook™ - Helping clients to replace paper forms across the laboratory resulting in reduced costs, increased efficiencies, and improved compliance   
GeneTox Suite - Image analysis and data management solutions helping users simplify the process of acquiring, managing and reporting genetic toxicology assay data  
NOTOCORD-hem™ - The leading telemetry-based safety pharmacology software platform for the seamless acquisition, display and analysis of physiological signals   
  
Regulatory Solutions  
Software, outsourced services, and consultancy for managing, storing, sharing and submitting and maintaining information compliant with FDA, EMA and other agency regulations.  
Preclinical SEND  
 Solutions and services that enables more efficient review of data, offering improved data quality, accessibility and predictability while helping clients generate value beyond compliance.  
Submit™ - Software for SEND dataset creation and version controlled file storage  
SENDView™ - Enabling simplified data review and quality control   
SEND Services - Outsourced study services, consulting and training   
Clinical Trial Transparency  
 Anonymization Services and software to meet EMA Policy 0070 and Health Canada public release of clinical information and support industry and internal sharing initiatives.  
De-identification Services - On-demand outsourced transformation services designed to measure risk, anonymize data and documents and meet strict regulatory sharing deadlines  
Blur™ - The leading transparency software that automates anonymization of both documents and data through Natural Language Programming  
Transparency Strategy - Consultancy and education that improve sharing processes for clients including global regulation education, disclosure defense, S.O.P development and training   
  
Clinical Trial Analytics Solutions  
Strategy, services and software to empower clinical innovation, create automation, enable open source and public cloud within biometrics, data science and clinical submissions.  
Accel™ - Cloud-based Statistical Computing Environment pre-loaded tools, applications & licenses for efficient statistical programming. Offers a validated connection between sponsors and CROS when sharing data, programs and analysis results  
Aspire™ - Modular clinical analysis framework that accelerates modernizations through non-proprietary code, applications and back-end services within the public cloud  
Analytics Strategy - Proven strategic consulting that delivers actionable plans for R&D IT, biostats, data science and product development teams.  
Analytics Services - Tailored enterprise services to build, customize or configure a fit-for-purpose clinical analysis system; integrating valued client legacy solutions and workflows with modern tools and practices, including the public cloud, to accelerate insight, analysis and submission.   
   
  
  
In Silico Solutions  
Enabling researchers to generate new scientific insights through the identification, extraction and analysis of actionable information.  
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Harnessing leading edge augmented intelligence capabilities, our pioneering, technology-enabled service is transforming the TSA process, driving quality, pace and insight in Research & Development.   
Built on a winning combination of fast, powerful computer-aided data acquisition and manipulation, automated workflows, and human expertise, KnowledgeScan gives clients detailed insight into the potential toxicological risks and challenges associated with modulating their drug targets, enabling them to make faster, better informed decisions.   
Using our proprietary KnowledgeScan Translational Informatics platform, we quickly and systematically review and distill millions of data records from a variety of published sources. These data are carefully curated, reviewed and interpreted by our team of expert life scientists and presented to our clients in a comprehensive, consistent report format.   
Key Highlights  
Comprehensive - KnowledgeScan systematically processes millions of records from numerous sources to ensure no key data are missed.   
Resource Efficient - By using automated data mining techniques, we can review and distill a huge wealth of data sources much faster than humans alone, enabling clients to spend 100% of their time making meaningful decisions.  
Unbiased - By deploying automated processes, KnowledgeScan removes the bias associated with manual literature searches, delivering a systematic, independent review of the published literature.   
Consistent - KnowledgeScan is based on reproducible, automated workflows, ensuring a standard approach across all TSAs. These standardized practices deliver accurate, high quality reports every time.   
High Quality - All data identified during the TSA process are reviewed and interrogated by our scientific experts to ensure data quality, accuracy and integrity.   
Flexible - By outsourcing your TSAs to Instem, you have a flexible, dependable resource that can be called on weekly, monthly or annually as needed to suit your TSA demands.  
   
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Remove Bias  
Minimize Risk  
Ensure Accuracy & Consistency  
Deliver Actionable Intelligence  
  
  
  
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To find out how KnowledgeScan can help improve Target Safety Assessment processes at your organization, why not take advantage of our free, no obligation 30 minute KnowledgeCall consultation?   
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Uniquely simplifying the QC review and exploration of SEND datasets all in one place  
  
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The SENDView™ application uniquely simplifies the review of SEND datasets; enabling the user to overcome hard-to-understand SEND concepts, view the data and its relationships in meaningful combinations and to easily keep track of their dataset review progress.  
Offering SEND solutions and services since 2004, Instem technical services staff relies upon SENDView as an essential part of the process when creating SEND datasets on behalf of its own clients. SENDView is now available as an independent solution functioning across any source that has produced a complete SEND dataset. Easy to deploy, SENDView offers organizations of all sizes the freedom to explore SEND data using intuitive and easy-to-navigate screens.  
Simplified SEND Review  
  
Easily address standards errors  
Easily see relationships between data in different domains   
See key SEND implementation guide and controlled terminology details in one place  
Take review notes directly in the application, eliminating additional paperwork   
See SEND data in a “days across” format commonly used during toxicology data review  
Track review status using domain and row status entries  
Easily generate group/sex group summary values including Incidence Counts, Mean, SD and N for comparison against the Study Report  
  
 Deployment made simple  
The SENDView solution is an easy-to-install/access product allowing clients rapid deployment after placing their activation order  
  
Remote installation support included  
Key-user Web-based training with on-site assistance when necessary  
Cost effective licensing model  
No risk trials available  
Can be installed on-site or accessed on-line (SaaS)  
  
   
Making the complex, simple  
  
Ensures a consistent review procedure for all datasets using task lists  
No data loading, warehousing or transformation needed  
No infrastructure needed – no database, no warehouse loading, no SAS installation  
SEND terminology can be hidden ensuring a wide range of staff can easily learn and use  
Focus on specific data points using advanced search and filter capabilities, and optionally export to excel for additional analysis  
Easily generate and view group/sex summary results for the SEND datapoints   
  
  
  
  
  
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Uniquely simplifying the QC review and exploration of SEND datasets all in one place  
  
In this section  
  
SEND Solutions  
  
  
SENDView™  
  
SEND  
  
   
The SENDView™ application uniquely simplifies the review of SEND datasets; enabling the user to overcome hard-to-understand SEND concepts, view the data and its relationships in meaningful combinations and to easily keep track of their dataset review progress.  
Offering SEND solutions and services since 2004, Instem technical services staff relies upon SENDView as an essential part of the process when creating SEND datasets on behalf of its own clients. SENDView is now available as an independent solution functioning across any source that has produced a complete SEND dataset. Easy to deploy, SENDView offers organizations of all sizes the freedom to explore SEND data using intuitive and easy-to-navigate screens.  
Simplified SEND Review  
  
Easily address standards errors  
Easily see relationships between data in different domains   
See key SEND implementation guide and controlled terminology details in one place  
Take review notes directly in the application, eliminating additional paperwork   
See SEND data in a “days across” format commonly used during toxicology data review  
Track review status using domain and row status entries  
Easily generate group/sex group summary values including Incidence Counts, Mean, SD and N for comparison against the Study Report  
  
 Deployment made simple  
The SENDView solution is an easy-to-install/access product allowing clients rapid deployment after placing their activation order  
  
Remote installation support included  
Key-user Web-based training with on-site assistance when necessary  
Cost effective licensing model  
No risk trials available  
Can be installed on-site or accessed on-line (SaaS)  
  
   
Making the complex, simple  
  
Ensures a consistent review procedure for all datasets using task lists  
No data loading, warehousing or transformation needed  
No infrastructure needed – no database, no warehouse loading, no SAS installation  
SEND terminology can be hidden ensuring a wide range of staff can easily learn and use  
Focus on specific data points using advanced search and filter capabilities, and optionally export to excel for additional analysis  
Easily generate and view group/sex summary results for the SEND datapoints   
  
  
  
  
  
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Technology-enabled approach for assessing carcinogenicity based on the ICH S1B WoE Addendum  
  
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Instem has developed Advance™ a NEW technology-enabled approach for assessing carcinogenicity based on the recently published ICH S1B Weight of Evidence (WoE) Addendum. If a WoE can be utilized, it can deliver huge benefits to organizations throughout the R&D pipeline including:   
  
Significantly decreasing animal usage in line with the 3Rs initiative.  
Potential to save $2-4 million in costs associated with the drug discovery process.  
Empowering researchers with the confidence to progress drugs to market faster, reducing time to market by 3 - 5 years.  
  
The Advance™ solution includes a comprehensive technology enabled carcinogenicity assessment report that mirror the six guideline-based WoE factors.  
 Target Biology  
   
  
 Secondary Pharmacology  
   
  
 Histopathology  
   
  
 Hormonal Perturbation  
   
  
 Genetic Toxicology  
   
  
 Immune Modulation  
   
  
Advance™ provides organizations with comprehensive, industry approved, evidence-based carcinogenicity assessments, enabling them to streamline their WoE submissions and ultimately get their life-enhancing products to market faster.  
Client Testimony  
"The Advance™ services are a living embodiment of more than a decade of effort from scientists and regulators across the globe. We now have an avenue for leveraging a scientific-based argument to reduce the emphasis on animal use in the post marketing space without compromising patient safety. It’s an opportunity for us to embrace innovation and to deliver medicines in a more efficient way."  
Advance™ Client - Global Pharma Organization  
  
  
  
Contact us for a Free Consultation  
To find out how Advance™ can help your organization why not take advantage of our free, no obligation consultation? Simply email us at insilico@instem.com to book your free consultation with one of our in silico team.  
  
   
  
  
  
Advance™ Weight of Evidence Assessments  
Download the Fact Sheet  
  
Instem Enables Clients to Leverage ICH S1B Weight of Evidence Guideline  
Read the Press Release  
  
Webcast - From Safety Testing to Success: ICH S1B and the Power of Data Sharing  
Watch the Webcast  
  
  
  
  
  
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Technology Solutions & Outsourced Services for Computational Toxicology  
Our leading computational toxicology products and services, originally developed by Leadcope Inc., and now part of the Instem solution portfolio, are helping organizations around the globe to unlock valuable knowledge contained in both public and proprietary sources of research data. Our advanced informatics and prediction technology, along with database solutions, enable clients to accelerate the drug discovery and development process to predict toxicity and perform expert reviews for genetic toxicity, skin sensitization, carcinogenicity, acute toxicity, reproductive and developmental toxicity, organ toxicity and environmental toxicity.  
Our innovative solutions allow researchers to combine their own proprietary data with publicly-curated toxicity databases. Clients searching our toxicity databases can access well over 600,000 toxicology studies for more than 200,000 chemicals, enabling fast, accurate, defendable and regulatory accepted predictions.  
Our computational tox solutions support a variety of applications including the ICH M7 pharmaceutical impurities guideline, assessment of extractables and leachables, and classification and labelling.   
  
  
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Latest Software Release Available Now!  
The latest edition of our leading computational toxicology software solution is available now. The release includes a comprehensive package of new and updated models and alerts to meet the growing market demand for in silico solutions.  
Highlights include:  
  
Updated Read Across Tool  
  
Enhanced Skin Sensitization Models   
  
Updated Skin Irritation and Corrosion Models   
  
Updated Endocrine Activity Models  
  
Improved Bacterial Mutagenicity Expert Alerts   
  
Models Predictive of Human Cardiac Events  
  
Updated Abuse Liability Profiler  
  
NEW Leadscope Model Applier™ N-nitrosamine CPCA Module  
  
Read our latest news release to learn more.  
Watch our On-Demand Launch Webcast  
  
  
Available Resources  
  
On-Demand Presentation: Predict™ In Silico Tox Service  
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Software & Technology Solutions  
Leadscope model applier: Easy-to-use software to apply prediction models, perform an expert review, and create reports.  
Genetic toxicity (Q)SARs: Complete solutions for the computational assessment of genetic toxicity, including statistical-based and expert rule-based models  
Advanced informatics and searching: Software to run computational models, perform read-across, advanced searching of chemicals and toxicity data, as well as capabilities for building QSAR models and automatically identifying expert alerts  
Flexible deployment: Options include a stand-alone client, client-server implementation, as well as web browser and web service access  
Predict GHS classifications: Computational solutions to predict acute toxicity, skin sensitization and irritation/corrosion classifications  
Hazard assessment: Computational models and databases to support hazard assessment of carcinogenicity, reproductive and developmental toxicity, and organ toxicity (cardiological, hepatobiliary, urinary, neurotoxicity)  
Toxicity databases: Access over 600,000 studies for over 200,000 chemicals covering genetic toxicity, cancer, reproductive/developmental toxicity, acute and chronic toxicity, sensitization, irritation/corrosion and many other endpoints   
Example applications of computational toxicology include:  
  
Genotoxic impurities  
Residues of plant protection products  
Extractables and leachables  
Classification and labelling  
Compound discovery  
Comprehensive computational toxicity assessments   
   
   
  
Outsourced Services & Consultancy  
Predict™ In Silico Tox ServiceA technology-enabled service delivering fast, efficient, comprehensive in silico toxicology predictions  
Consulting program   
This program supports independent consultants who wish to supply computational toxicology model results to their clients. The program has no up-front payments and includes unlimited training and support. Consultants pay a quarterly license fee, based on predictions made for their clients.   
In silico toxicology consortia   
This international collaborative effort includes over 60 organizations and is organized into a series of working groups addressing specific issues to support the acceptance and implementation of computational toxicology. These groups develop positions papers, create protocols for computational assessments, generate case studies, help to improve our understanding of structure-activity relationships and assesses whether state-of-the-art computational models are fit-for-purpose for different use cases.   
  
  
Ask an Expert: Free Resource  
Do you have any in silico questions? We encourage you to take advantage of this free industry resource. Simply drop an email to insilicoexpert@instem.com and one of our experts will respond ASAP and without any obligation.  
  
   
   
  
  
  
  
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Setting New Standards in Computational Toxicology  
  
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A technology-enabled service delivering fast, efficient, comprehensive in silico toxicology predictions  
  
  
Predict™ is a leading edge, technology-enabled service that delivers a combination of powerful computation models with expert scientific review, to help clients predict chemical safety more quickly, efficiently and comprehensively.  
The Predict™ In Silico Tox service builds on the power of world-leading computational models and databases developed by Leadscope, an Instem company, and combines them with expert scientific review, to deliver comprehensive, unbiased, high quality, regulatory-accepted assessments of chemical safety.  
   
  
Visit our Blog - In Silico Insider  
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Key Highlights  
Domain Expertise – The Predict™ service is delivered by expert scientists with vast experience in computational methodologies, toxicology and chemistry, ensuring high quality scientifically robust assessments every time.  
Comprehensive Approach – All assessments leverage the latest information, including historical databases of toxicity studies, giving you peace of mind that your assessments are always current and up to date.   
Finely Tuned Process – Assessments and expert reviews are based on a standard operating procedure, ensuring comprehensive, consistent assessments time after time.  
Actionable Information – Our comprehensive documentation summarizes the main conclusions, as well as detailed reports on the data used and the prediction model results, enabling you to make clearer, quicker decisions.  
Scalable – The Predict™ service is cost-effective and scalable for organizations of all sizes. For organizations without the necessary resource to perform an expert review, Predict™ offers a complete (Q)SAR solution to satisfy regulatory requirements. For organizations with in-house expertise and technology, Predict™ can be used to augment existing capabilities or in times of peak demand.  
Faster Turnaround – Quality assessments delivered on time, every time. Our experts will ensure we deliver what you need, exactly when you need it, enabling you to make faster, better informed decisions.  
Accepted by Regulators – The Predict™ team has a deep understanding of applicable guidelines and regulatory agency processes, giving you complete confidence that your assessments will be accepted by all of the key industry regulators.  
  
  
  
Contact us for a Free Consultation  
To find out how Predict™ can help your organization assess chemical safety quickly, efficiently and comprehensively, why not take advantage of our free, no obligation consultation? Simply email us at predict@instem.com to book your free consultation with one of our in silico team.  
  
  
  
Ask an Expert: Free Resource  
Do you have any in silico questions? We encourage you to take advantage of this free industry resource. Simply drop an email to insilicoexpert@instem.com and one of our experts will respond ASAP and without any obligation.  
  
   
  
The Predict™ service is delivered by an experienced team, in conjunction with external consultants, who have a deep understanding of applicable guidelines and regulatory agencies’ processes, as well as extensive experience in computational methodologies, toxicology, and chemistry. All assessments and expert reviews are based on a documented standard operating procedure and leverage an infrastructure that ensures the latest information is being used, including historical databases of toxicity studies.  
Supporting a Variety of Applications  
The Predict™ service supports a variety of applications including the ICH M7 pharmaceutical impurities guideline, SD file generation to include in the Electronic Common Technical Document, assessment of extractables and leachables, and classification and labelling.  
  
Mutagenicity (Q)SAR assessment   
Establishing Acceptable Limits for N-nitrosamines – NEW!  
SD File Generation – NEW!  
Abuse Liability Assessment – NEW!  
Bioactivation Assessment – NEW!  
Comprehensive\* (Q)SAR assessment   
Bespoke\*\* (Q)SAR assessment  
\*Includes carcinogenicity, mutagenicity, reproductive/developmental toxicity, endocrine activity, acute oral toxicity, skin sensitization, irritation/corrosion, organ toxicity, bioactivation, abuse liability   
 \*\*Choose any of the following (Q)SAR assessments: carcinogenicity, mutagenicity, reproductive/developmental toxicity, endocrine activity, acute oral toxicity, skin sensitization, irritation/corrosion, organ toxicity, bioactivation, abuse liability  
  
The Predict™ Process  
Flexible Options to Suit Your Needs  
Clients can select either the Core or Full Predict™ service option to suit their needs. With both options, clients no longer have to spend multiple days searching and analyzing the data they need. Instem rapidly and systematically undertakes searches on multiple sources of data, peforms regulatory-accepted in silico predictions and provides a summary of the results.  
Clients selecting our Full Predict™ service will also receive an expert review by a team of experts with deep knowledge of computation modelling, toxicology and chemistry.  
  
Feature  
Full  
Core  
Relevant toxicity studies identified  
•  
•  
Applicable in silico predictions performed  
•  
•  
Full study and in silico reports included  
•  
•  
Executive summary of data and predictions  
•  
•  
Expert review of data and in silico results  
•  
   
Expert reviewed overall assessments  
•  
   
  
  
  
  
  
  
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Genetic toxicology in silico protocol  
Principles and procedures for implementation of ICH M7 recommended (Q)SAR analyses  
In-Silico toxicology protocols  
Transitioning to composite bacterial mutagenicity models in ICH M7 (Q)SAR analyses  
Principles and procedures for handling out-of-domain and indeterminate results as part of ICH M7 recommended (Q)SAR analyses  
Skin sensitization in silico protocol  
Developing structure-activity relationships for N-nitrosamine activity  
Implementation of in silico toxicology protocols within a visual and interactive hazard assessment platform  
   
   
  
  
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Blur Clinical Anonymization - New!   
Comet Assay IV™  
Cyto Study Manager  
Computational Toxicology Solutions  
Logbook™ ELN  
Morphit™ for Discovery Data Visualization - New!  
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The most comprehensive and widely deployed set of tools and services supporting SEND  
  
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SENDView™  
  
SEND  
  
  
  
The submit™ platform provides a suite of integrated tools and services for the creationand management of SEND datasets and associated documents forContract Research Organizations (CROs) and Sponsors.   
  
  
Submit serves the needs of both producers and consumers of SEND data. But, we have developed submit knowing that many organizations both create and consume SEND data in the course of their operations. The platform also supports the very wide range of demands that span the needs of the largest multi-national pharmaceutical organizations and CROs to the smallest organizations and their advisors.  
Whether you are simply using SEND to get to a regulatory submission in order to move your R&D program forward or you see it as the vehicle to enable you to leverage your safety data to generate new insights, Instem can provide the support you need. Our data management and analytics products are sophisticated and designed to support regulatory queries as well as data mining. The workflow management aspects of SEND can automate the flow of SEND data into a data repository and/or onwards to your regulatory submissions system as required.   
With a wealth of unparalleled experience in supporting companies to prepare for the standard, Instem provides organizations with clear SEND guidance at any stage of readiness with pragmatic, practical and proven solutions. Instem’s submit suite of tools and outsourced services is now the most widely adopted SEND solution in the market across 15 countries.  
  
  
WEBCAST: Introducing SEND Advantage™ Services  
Register Now  
  
  
   
  
  
  
Features & capabilities of submit™ include:  
  
SEND dataset generation: Import data from any source and convert it into SEND  
DefineNow™: Quickly create and edit CDISC compliant and submission-ready define.xml files - also available as a standalone tool  
SEND checker: Ensuring datasets conform to the IG rules  
SEND editor: Secure, fully-audited bulk dataset edits  
SENDView™: Simplified data review & QC checking - also available as a standalone tool  
SEND Workflow & File Management: Fully automated workflows for securing & processing SEND datasets  
Secure storage: Fully version controlled file store of all data files & SEND datasets  
  
  
  
  
  
  
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Whether you run your own studies, outsource everything or a blend of the two, our efficient and compliant solutions have been designed to streamline your operations and minimize the costs of compliance.  
The submit™ platform provides configurable components that enable you to create workflows to match the study data sources and processes that support your mission-critical submission processes.  
CRO-sourced datasets can be:  
In-house data can be:  
Retrieved from a secure location  
Converted to SEND using one of our source-specific adapters  
Checked using either your specific SEND checker rules or the OpenCDISC checker  
Merged with SEND or data from other sources  
Queried more efficiently  
Supported with automatically generated DEFINE.xml files and Study Data Reviewers’ guide  
Combined with data from other sources  
Visualized in our purpose-built QC tool, SENDView™  
Stored in the secure file store along with meta data and SDRG  
Passed into the submission workflow or onwards to other systems and recipients  
  
  
  
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Whether you are creating FDA-ready SEND datasets or SEND datasets to meet the specific requirements of a sponsor, Instem’s submit™ platform offers both software and professional services to support the efficient and commercial creation and management of datasets.  
We understand that the time required to create final study documents is crucial for the success of CROs. Our consultants work with you to make sure, whether you are using our software or our services, that the workflows we implement provide you with excellent value for money as well as ensuring that you are able to meet the expectations that you have set with your customers.  
For CROs, the submit™ platform provides tools to accept data from any electronic source system and to convert that data into SEND datasets. We can blend together data collected in standard In-Life collection systems with those from specialized analysis systems and data provided by, for example, contract pathologists to generate a single combined dataset.  
The submit™ platform has been designed to support CROs of all sizes and specializations, which means that you can select components that:  
  
Create SEND direct from leading toxicology software solutions  
Create SEND from a wide range of electronic source formats  
Execute standard and configured SEND validation tools  
Manage and track the QC process for SEND datasets  
Store and manage contributing datasets from a range of internal and external data sources  
Store and manage SEND datasets and associated metadata and documents  
Forward datasets to specified locations  
  
SEND Price Check  
CROs, has one of your sponsors asked if their study can be returned in SEND ahead of you being SEND-Ready™? Touch base with us and we can give you an immediate quote for converting the study.  
  
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Conformance checks, dataset verifications and remediation services performed by our team of SEND experts.  
Tailored on-site or remote consultancy and education programs.  
Transforming legacy data into structured datasets that provide value beyond compliance.  
Flexible SEND partnership programs that offer professional staff augmentation, partial or full outsourcing services.  
  
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DefineNow™: Quickly create and edit CDISC compliant and submission-ready define.xml files - also available as a standalone tool  
GuidePro™: Reduce the time for nSDRG development by up to 50% with our automated guide generator   
SEND checker: Ensuring datasets conform to the IG rules  
SEND editor: Secure, fully-audited bulk dataset edits  
SENDView™: Simplified data review & QC checking - also available as a standalone tool  
SEND Workflow & File Management: Fully automated workflows for securing & processing SEND datasets  
Secure storage: Fully version controlled file store of all data files & SEND datasets  
  
  
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The introduction of SEND for the submission of study findings to the FDA presents the industry with opportunities and challenges alike. Instem's SEND experts help organize, educate and guide clients to be coming SEND-Ready, identifying specific approaches so as to maximize the benefits of SEND while ensuring they comply with regulatory guidance.  
Clients can choose from one or more services that will help them in their journey towards SEND compliance while minimizing the impact within their organization. This includes the option for organizations to completely turn to Instem as their fully-outsourced SEND department.  
  
  
SEND Advantage Services include:  
  
SEND Deliver™: Leveraging new processes, a larger team, and leading proprietary technologies, Instem rapidly turns manual or electronic data into SEND with all supporting documentation & metadata.  
SEND Comply™: Conformance checks, dataset verifications and remediation services performed by our team of SEND experts.  
SEND Advise™: Tailored on-site or remote consultancy and education programs.  
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Replace GLP & Non-GLP Paper Data!  
The Logbook ELN is helping clients across the globe reduce and even eliminate the vast number of paper forms that are used in their laboratories, resulting in reduced costs, increased efficiencies and improved compliance.   
Logbook offers Laboratories a single, searchable, secure repository for their data, and utilizing an easy-to-navigate interface and a flexible form designer, users can quickly and easily re-create paper forms on the spot.   
Logbook provides a safe, secure repository for a wide range of information that would traditionally be kept on paper notebooks and forms such as Study Diaries, Vet Alerts, Facility Management logs, Sampling, Histology, Husbandry Checks and many more.  
Why Replace Paper Data Collection?  
  
Paper information is static and cannot be searched or shared  
Paper is less GLP compliant  
Difficult to build in automated workflow  
  
Solution Benefits  
  
Save time and improve data quality  
Increase productivity and accuracy  
Flexible form designer - build forms to suit your workflow and data   
21 CFR part 11 compliant  
  
   
  
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Support, Forums, Roadmaps & More  
  
  
  
“Reduce or even eliminate paper while increasing productivity and accuracy”  
  
  
  
Capabilities  
  
Full GLP compliant audit trail  
Electronic archiving  
Comprehensive search capabilities  
Lists can be populated from external data sources  
Label creation including barcodes and pictures  
Send alerts via email or SMS text messaging  
Output to Word, Excel, Web pages or raw XML  
Publish information to intranet or Internet  
Store any type of file (eg Excel, Word, pictures, video etc)  
  
& Many More!!!  
Application Areas  
The Logbook functionality offers a wide range of uses including  
  
Histology Tracking  
Cleaning/Temperature/Humidity Logs  
Dose pump calibration  
Vet Consultations  
Treatment Plans  
Clinical Observation Reference Library  
Husbandry Checks  
  
& Many More!!!  
Easy to deploy. Simple to Use.  
  
  
  
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Automatic image analysis for life and material sciences  
Sorcerer Image Analysis is a powerful, automatic system with a wide range of applications in both the life and material sciences.   
Our image analysis solution is a fast, versatile analytical tool for research and quality control. A high-quality industrial-standard camera which relays a live digital video image to your computer screen is used to view the sample either with a microscope, Petri-viewer, or macro stand and lens. Various optical and illumination techniques are available to ensure an optimal picture is presented for analysis. The system detects and measures objects by contrast differences. Sorcerer utilizes a specialized object detection algorithm for situations where shading is encountered, either induced by the sample or the illumination used.  
Wide range of customizations & measurement parameters  
Sorcerer is a powerful tool which can be used for a number of imaging applications – talk to us today to see whether Sorcerer Image Analysis is suitable for your application!   
Circular, rectangular and user-drawn measurement frames are available to suit the sample type and to select particular regions for analysis. An easy-to-use and customizable “macro builder” allows you to create a sequence of operations for your analysis, for example to prompt the user to enter sample details, perform image processing functions, measure and transfer the data.  
Sorcerer can measure both field and feature specific measurements and can analyze individual objects, so you can classify items according to their size, measure areas of images, count specific items and measure features of your image.   
Instant, live data transfer to multiple formats  
Image analysis data from Sorcerer is transferred directly to Excel (or an Oracle database) and can be processed as required. It is also possible to instruct Sorcerer to perform a measurement from within Excel or other applications. For easy import into third party applications, Sorcerer can also export data in CSV (comma separated values) file format. Images captured by the camera can also be saved for future retrieval and transfer to document processing software.  
Flexible use for multiple applications  
Sorcerer can be used for many applications within one lab. Using different system configurations, you can control how Sorcerer detects objects and how data is handled and reported. Example applications include:   
  
Inhibition zone measurements  
Multipoint plate scanning  
Plaque counts  
Antibiotic susceptibility and MIC assays  
Unscheduled DNA synthesis (UDS)  
Particle size and shape analysis  
ELISPOT assay  
Pulp and paper quality  
Chemotaxis  
Direct Epi-fluorescent filter technique  
Colony counting and sizing  
  
  
  
  
  
  
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We offer a free one week trial of the Comet Assay IV software. This trial is provided free-of-charge strictly for non-commercial evaluation purposes only. You agree not to use the demonstration for collation of any data used as part of a research project or commercial test or study.  
Please complete the form below to receive your trial link:  
  
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Data Extractor  
Data Extractor is a powerful optional module for viewing, searching and filtering comet data that has been scored with Comet Assay IV and stored in an Oracle database. This system is commonly utilized in GLP-regulated environments to ensure study data security and integrity.   
Data Extractor also gives authorized users the power to approve and reject data, archive studies and export result and audit data. For full genetox study management, including experimental set-up and automatic reporting, please visit our Cyto Study Manager solution.   
Features of Data Extractor:  
Control your data - Within Data Extractor you can browse, sort and filter your result and audit data within the Oracle database. What’s more, you can also review and approve or reject your data.  
Flexible and efficient data transfer and processing - Users can export study data to Excel, then analyze it with the spreadsheet generator or any other data processing/reporting tool. Result files and images can be exported in batches. This means you can export all the results for a study in one group! These files can be named automatically for easy identification.   
Increase your data security - Our solution allows for ultimate portability, integration into existing data management systems and security of data.   
Verify your scoring process - Whether you want to “spot check” or “verify” a process, you can access images of scored cells via Data Extractor. Each cell image is stored with result data and information on exactly how the user scored the cell. These images can be opened in Comet Assay IV and re-scored to verify the data.  
Easily find specific study data - Data Extractor makes it easy to locate any past data for review or statistical analysis. Data can be sorted and grouped quickly by clicking on column headings, and the “filter builder” offers powerful data filtering capabilities allowing the creation of complex search criteria for selecting data in any conceivable way. Filters can also be saved for future use.   
Archive your data in accordance with OECD guidelines - Sophisticated electronic signatures and archiving tools allow you to annotate data as “archived” within the database. This not only helps ensure the integrity of your data by avoiding any potentially dangerous export and purge operations, but also means you can still view the study and reconstruct reports for auditing and verification.   
Ensure regulatory compliance - System Access Manager allows complete 21 CFR Part 11 compliance. All audit data collected during the use of Comet Assay IV can be viewed by authorised users within the Data Extractor and exported, if desired.   
You work to GLP and so do our genetox solutions…  
   
All of Instem’s genetox solutions are designed with reference to the OECD and S2(R1) guidelines. We ensure our solutions are fully compliant with the principles of Good Laboratory Practice (GLP) and the FDA 21 CFR part 11 rule on electronic signatures.   
  
  
  
  
  
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System Access Manager   
Key Features   
  
Secure user administration module  
Manages unique electronic signatures  
Full and detailed audit trails  
Highly configurable user account rules  
Enforces password changes and rules on password re-use  
Login timeouts and lockouts to prevent unauthorized access  
  
Manage users in a compliant environment  
System Access Manager strengthens compliance by managing and maintaining user access. The System Access Manager solution is required for use with Ames Study Manager & Cyto Study Manager, and can be used alongside Comet Assay IV & Sorcerer Colony Counter to achieve a fully compliant arrangement.   
System Access Manager supports compliance for organizations that adhere to Good Laboratory Practice (GLP) or Good Manufacturing Practice (GMP) regulations, or for companies who comply with the FDA 21 CFR Part 11 Final rule on Electronic Records and Electronic Signatures.   
Password rules and electronic signatures  
Individual users are assigned unique user IDs and access rights to each product. The program manages user access via a wide range of password rules including expiry, length, use of characters & numbers, etc. User Administrators can add new users to the database and assign them a unique User ID, a User Name and duration of password validity, as well as defining a specific access level and time-out to each product.   
Comprehensive audit trails   
System Access Manager provides comprehensive security and full audit trails that record all login attempts and changes to a user’s account validity or access permissions. The audit trails can be filtered on any field, such as User ID, event description or date. Audit trails can be exported to Excel for printing or review. System Access Manager is built around a secure Oracle database, providing complete security of user and audit data.  
You work to GLP and so do our genetox solutions…  
   
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Specialised study management and data capture for genetox assays   
Many the world’s leading pharmaceutical and contract research organizations use Cyto Study Manager to help them increase productivity and improve compliance with GLP regulations. Compatible with all types of study designs and offering flexible, customizable reporting, Cyto Study Manager can be used ‘out of the box’ with the following assays.  
  
Ames in-vitro assay  
Comet in-vitro and in-vivo assay  
Micronucleus in-vitro and in-vivo assay  
Chromosome Aberrations in-vitro and in-vivo assay  
Neutral Red Uptake in-vitro assay  
Transgenic Rodent Assay (Watch Demo)  
  
Because Cyto Study Manager has been designed to work with any assay that shows a dose-response relationship, we have experience in configuring the system to meet individual client needs. Email help@instem.com to discuss how your assay workflow could benefit from integrating your data acquisition, auditing, reporting and study management into one easy-to-use solution.   
Ames Assay  
  
Instant capture of automatic plate counts when combined with the Sorcerer Colony Counter – simply hit the space bar and the plate is automatically scored and data saved  
Accommodates multiple experimental designs  
Versatile sharing of concurrent controls  
Plate observations for contamination, precipitation, manual count etc.  
View and filter all historical controls data  
Automatic generation of CTD (dose ascending or descending), OECD and Japanese reports included as standard  
Reports can be customized to meet your needs   
Chromosome Aberrations Assay  
  
Suitable for in-vitro and in-vivo  
Score total cells and all chromatid, chromosome, and other aberrations via an intuitive user interface  
Customize the metrics you want to score and formula to include in your reports   
Integrates with 4 or 8 button tally counters  
Accommodates multiple experimental designs  
Versatile sharing of concurrent controls  
Ability to add individual sample, culture (vitro) or animal (vivo) comments and/or observations  
Supports blind scoring via automated random culture/animal code generation, and slide coding and decoding (where appropriate)  
View and filter all historical controls data  
Automatic generation of reports showing cytotox, mitotic index, RICC/RPD polyploid and chromosomal aberrations data for chromosome aberrations in-vitro and OECD report for chromosome aberrations in-vivo included as standard  
Historical control reports available for both in-vitro and in-vivo  
Reports can be customized to meet your needs   
  
Micronucleus Assay  
  
Suitable for in-vivo and in-vitro  
Score coulter counts, replication index and vitro/vivo micronucleus data  
Customize the metrics you want to score and formula to include in your reports   
Suitable for micronucleus flow: 96 well plate layouts included as standard, with ability to import data straight from your existing instrument  
Integrates with 4 or 8 button tally counters  
Accommodates multiple experimental designs: completely configurable plate layouts, ability to import data, or score manually – either with or without a tally counter   
Versatile sharing of concurrent controls  
Ability to add individual sample, culture (vitro) or animal (vivo) comments and/or observations  
Supports blind scoring via automated random culture/animal code generation, and slide coding and decoding (where appropriate)  
View and filter all historical controls data  
Automatic generation of reports showing cytotox, CBPI and RICC/RPD data for micronucleus in-vitro & %PCE, and %MN-PCE for micronucleus in-vivo included as standard  
Slide decoding, slide labelling and historical control reports available for both in-vitro and in-vivo  
Reports can be customized to meet your needs  
  
Comet Assay  
  
Suitable for in-vivo and in-vitro  
Automatic capture of key metrics: % Tail Intensity, Olive Tail Moment, and % Hedgehogs when combined with Comet Assay IV. Alternatively, you can quickly and easily import data from your existing instruments with just a few clicks.   
Accommodates multiple experimental designs  
Versatile sharing of concurrent controls  
Slide observations for contamination, lost slide, not scorable, manual count etc.  
Supports blind scoring via automated slide coding and decoding  
View and filter all historical controls data  
Automatic generation of comet data, slide decoding, slide labelling and historical controls reports for both in-vivo and in-vitro included as standard  
Reports can be customized to meet your needs  
Neutral Red Uptake Assay  
  
Suitable for in-vitro   
Effortlessly manage multiple plates and samples   
Import data to CSM directly from your existing lab equipment  
Plate layouts for OECD and Health Canada methodologies available by default  
Accommodates multiple experimental designs with fully configurable plate layouts  
Versatile sharing of concurrent controls  
Ability to add individual sample or culture (vitro) comments and/or observations  
View and filter all historical controls data  
Automatic generation of OECD and Health Canada reports, including automatic calculation of relative survival rate, included as standard  
Reports can be customized to meet your needs   
   
   
  
Transgenic Rodent Assay   
  
Suitable for in-vivo  
Comprehensive support for the most common TRAs: MutaMouse and Big Blue   
Easily manage data from all the different tissues in one place   
Simple set up and tracking of DNA packaging locations   
Data automatically flagged for review, sparing Study Directors from manually reviewing every line   
Automatically report and run stats on mutant frequency   
End result: Faster data interpretation and assay throughput   
  
  
Transgenic Rodent Assay Demo  
Watch Demo  
You work to GLP and so do our genetox solutions…   
All of Instem’s genetox solutions are designed with reference to the OECD and S2(R1) guidelines. We ensure our solutions are fully compliant with the principles of Good Laboratory Practice (GLP) and the FDA 21 CFR part 11 rule on electronic signatures.   
  
   
  
  
  
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Experimental set up, data acquisition & reporting for regulatory genetic toxicology assays  
Cyto Study Manager integrates genetox data acquisition, auditing, reporting and study management into a single system. Our GLP compliant solution is revolutionizing genetox study workflows and helping clients to reduce costs, increase efficiencies, and improve regulatory compliance.  
Cyto Study Manager is a comprehensive and configurable solution, hosted on your servers or in the cloud, allowing you to manage all your genetox assays from one study management system, thereby increasing data reliability and traceability whilst saving time and resources.   
Suitable for:  
  
Ames in-vitro assay  
Comet in-vitro and in-vivo assay  
Micronucleus in-vitro and in-vivo assay  
Chromosome Aberrations in-vitro and in-vivo assay  
Neutral Red Uptake in-vitro assay  
Transgenic Rodent Assay (Watch Demo)  
Any assay that is used to show a dose-response relationship  
  
Features include:   
  
Comet, micronucleus, chromosome aberrations & customizable modules  
Data acquisition from flow cytometers, tally counters, Comet Assay IV & other genetox scoring platforms  
Automatic, customizable reporting & statistics  
Flexible study design  
  
  
   
  
Cyto Study Manager Assays  
Find out more about available assays  
  
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Flexible experiment design  
Reusable experiment & study templates   
Sample coding & decoding  
Extensive genetox data collection (from multiple sources and platforms)  
Effortless data review   
Straightforward data approval  
Customizable reporting & statistics  
Extensive GLP audit trail functionality  
Excellent user control (delivered by System Access Manager)  
Comprehensive data archive capability  
Historical control data management   
GLP & 21CFR Part 11 compliant  
  
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“Cyto Study Manager’s reporting function ensures that data entered into the system is seamlessly exported and converted into statistical reports that cannot be changed once generated. This saves us time and significantly reduces our validation burden. This feature, used within a fully secure and GLP-compliant environment, gives the regulatory authorities full confidence in our processes and reporting.” Study Director, Global Pharmaceutical Company  
  
  
Key Benefits   
Improves workflows - Around the world, Cyto Study Manager is replacing multiple genetox systems with one comprehensive, easy to use solution. Cyto Study Manager combines experimental set up, data collection and automatic report generation, which saves you time and streamlines your genetox workflows!  
Get results sooner - We are helping clients reduce paperwork and get the answers they need faster than ever before. Study templates allow you to copy previous study designs, so you don’t need to re-configuring, re-type or re-enter setup information. Integrated data collection and reporting means you can report on your data as soon as it is collected, helping you interpret results faster.  
Flexible study design - Our solution is designed to work with the regulatory Genetox assays, including ames, comet, micronucleus chromosome aberrations and NRU. Cyto Study Manager can also be configured to work with any other Genetox assay that shows a dose-response relationship, ensuring we can meet your specific Genetox needs. Experiments can have multiple stages, multiple test items, several or no control groups! Cyto Study Manager can deal with your unique experimental set-up, whatever that might be.  
Ensures compliance & increases data traceability - All actions that are carried out within Cyto Study Manager, such as creating, editing and deleting data, are recorded within an audit trail. Cyto Study Manager has been designed with reference to the OECD and S2(R1) guidelines. It is fully compliant with the principles of Good Laboratory Practice (GLP) and the FDA 21 CFR part 11 rule on electronic signatures.  
Increases productivity within your Genetox team - Access Cyto Study Manager anytime, anywhere! Our solution is a secure, web-based system; you can log in from anywhere using the standard version of Google Chrome.Multiple users can log in simultaneously - each can be working on the same or different experiments.  
Produces customized reports & statistics automatically - Reports are generated securely and automatically from within the system. Available reports include sample coding/decoding information, results tables, historical data ranges and audit information. Reports can easily be customized to match your own corporate style and data interpretation needs. Because all of this is achieved within one system, there is no risk of transcription errors, no import/export, no file transfers and no copy and paste, saving you time and reducing errors.  
Removes experimental bias - When scoring your Genetox assay, Cyto Study Manager can present the scorer with a list of coded samples to remove scorer bias. Coded samples are configurable and can be any letter-number combination you need. The sample details are handled invisibly by Cyto Study Manager and the scorer remains “blind” to all experimental information. Cyto Study Manager stores data against the appropriate sample automatically, so study directors can review, approve, and reject data in real time.  
You work to GLP and so do our genetox solutions…  
   
All of Instem’s genetox solutions are designed with reference to the OECD and S2(R1) guidelines. We ensure our solutions are fully compliant with the principles of Good Laboratory Practice (GLP) and the FDA 21 CFR part 11 rule on electronic signatures.   
  
   
  
  
  
  
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What if you could score a comet slide in two minutes?  
Comet Assay IV is a live video imaging system designed for fast, accurate and reproducible comet slide scoring.  
Comet Assay IV's unique single-click scoring method and instant live video technology make it the most efficient and easy-to-use system available for measuring DNA damage using single cell gel electrophoresis. Comet Assay IV is easy to install and use – simply connect the camera and start scoring.  
Comet Assay IV can score many different types of cell; regardless of species, cell size and level of DNA damage. Comet Assay IV uses the parameters defined by Olive et al on the principle of DNA damage and comets are scored appropriately.  
When using Comet Assay IV you click on each cell in turn and key comet assay parameters, including % Tail Moment, Tail Length and % hedgehogs will be recorded. Typical time taken to score each slide is less than two minutes.  
Comet Assay IV is used across the globe by contract research organisations and pharmaceuticals. It is the market-leading comet scoring system used by academics, with over 66% of comet assay publications written by our customers. Read more about how Comet Assay IV is helping academics create respected, peer-reviewed, scientific investigations & publications.   
Comet Assay IV can be used standalone, or together with our genetox study management solution, Cyto Study Manager, to seamlessly bring study management and automated scoring together, as well as a comprehensive audit log to ensure GLP compliance and automated reporting.  
You can try Comet Assay IV for one week for free when you download our trial version of the software.   
  
   
  
Download a Free Trial!  
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Read more about using Comet Assay IV in academic environments  
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“I have been using the Comet Assay IV software – it is great! During my software validation, I realized how much easier and precise it is compared to our old software. It makes analyzing the comet slides more enjoyable.” Scientist, Medical Research Centre, USA  
  
  
Key Highlights   
Integrated study management – Combine Comet Assay IV with our world-leading genetox study management solution: Cyto Study Manager for fully integrated data collection, management and reporting.  
Increase speed – Single click automatic scoring in Comet Assay IV enables you to score comets from a live video. This makes Comet Assay IV the fastest and easiest way to score comets, increasing your laboratory’s productivity.  
Boost accuracy – With no adjustable settings or configurations to modify, you can remove subjectivity from the scoring process. Comet Assay IV automatically compensates uneven backgrounds or varying levels of brightness, ensuring comparable and reproducible results across a wide range of slides.  
Comprehensive data analysis – Capture and record all the parameters you need for your analysis, including Tail % DNA, tail moment, tail length and % Hedgehogs.  
Reporting – When using Comet Comet Assay IV as a standalone, you can use our Excel-based tool to chart your Comet assay data, together with powerful macros to compare data across dose ranges. When using Comet Assay IV together with Cyto Study Manager, reports are created automatically, ensuring you can quickly and easily interpret your results.  
Ensure compliance – Work securely in the knowledge that your system is GLP and FDA 21 CFR compliant. For full data security when using Comet Assay IV as a standalone, consider adding Data Extractor and look at the ‘packages comparison’ section of our fact sheet. Data extractor allows you to browse, sort and filter your result and audit data, you can also review, approve or reject your data.  
You work to GLP and so do our genetox solutions…  
   
All of Instem’s genetox solutions are designed with reference to the OECD and S2(R1) guidelines. We ensure our solutions are fully compliant with the principles of Good Laboratory Practice (GLP) and the FDA 21 CFR part 11 rule on electronic signatures.   
  
  
  
  
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Helping academics create respected, peer-reviewed, scientific investigations & publications  
  
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What if we told you Comet Assay IV is the leading scoring platform for all comet assay publications?   
In addition to a well-established home in the contract research and pharmaceutical laboratories, Comet Assay IV is used every day in hundreds of research laboratories around the world. An ever-growing number of academic institutions and universities rely on Comet Assay IV for their genetox analysis and the majority of comet-related publications are written by our users.  
 Driven Research with Comet Assay IV  
Pharmaceutical companies may conduct a routine experiment, but an academic laboratory or research institute might have a different approach…   
 Comet Assay IV is used in hundreds of scientifically novel publications every year. Each one unique, each one peer-reviewed and each one answering a question which has never been asked before.   
When the answers are not expected, routine, or predictable, researchers turn to Comet Assay IV for reliable interpretation of their results. With a reputation they can trust, Comet Assay IV gives researchers confidence in their science.   
  
  
  
Leaders in Comet Assay Scoring for Academia  
  
250 universities in 40 countries are currently using Comet Assay IV   
1,500 peer-reviewed publications feature Comet Assay IV  
66% of all current comet assay publications are written by our customers!  
  
Comet Assay IV teaches future generations  
Not only a tool for research, Comet Assay IV can be used as a tool for teaching. With hundreds of systems in universities, it is no surprise that thousands of researchers are using Comet Assay IV to gain valuable experience.  
We have seen Comet Assay IV used in continuing education initiatives and expert workshops. The comet assay is used in many diverse scientific fields, and gaining experience in the technique, and in using Comet Assay IV, is a valuable addition to a researcher’s CV.   
Totally free, no-obligation trial of Comet Assay IV  
You can try Comet Assay IV for one week for free when you download our trial version of the software.  
If you want to enjoy the single-click functionality and excellent reputation of Comet Assay IV permanently, we will be happy to provide a quote for you.   
Comet Assay IV comes in three versions: Lite, Full and GLP. You can learn about them in the Comet Assay IV Fact Sheet. The versions are priced according to functionality and, with academic promotions and multi-purchase discounts, we aim to meet your budgeting requirements. Contact us to learn more.  
  
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Mini Case Study 1: A long history of collaboration and a strong future in the application of 3D models for genotoxicity assessment  
Department of Genetic Toxicology and Cancer Biology, National Institute of Biology, Ljubljana, Slovenia   
In 2003, this influential research group released their first comet assay publication incorporating research carried out using Instem’s comet scoring solution. Since then, the comet assay system has been an integral part of their research; they have been using Comet Assay IV on a daily basis, producing high-quality, peer-reviewed, comet-featuring publications every year!  
Recently, their scientists have been working on a 3D in vitro cell model for the assessment of genotoxic activity of xenobiotics. Their 3D hepatic cell model has an increased metabolic competence and, using the comet assay, they demonstrated its high sensitivity for detecting genotoxic activity of different types of indirect acting genotoxic compounds. This novel approach is just one example of how Comet Assay IV is pushing forward the frontiers of genetox testing.  
“In our laboratory Comet Assay IV is used every day often for more than 12 hours a day! Comet assay is an integral part of our research and Comet Assay IV enables gathering reliable data for our genetox publications” Bojana Žegura PhD, Assistant Professor  
Find out more about the National Institute of Biology  
  
Mini Case Study 2: Comet Assay IV: adventures in curriculum, commercialization and clinical trails   
Oxidative Stress Group, Dept. Environmental Health Sciences, Florida International University, Miami, FL USA  
Students in the Post Graduate and PhD programs at FIU can gain valuable laboratory experience, including hands-on use of Comet Assay IV, during their education. This prominent research group are not only conducting valuable research in the formation and repair of oxidatively damaged nuclear and mitochondrial DNA, they also have made several advances to the comet assay method, including a novel method for the high-throughput processing of slides using a vertical gel electrophoresis tank. Another significant advance this group have pioneered using Comet Assay IV, is the whole blood comet assay which, excitingly, is now being used in clinical trials.   
“Comet Assay IV is uncomplicated and straightforward. We’re able to train group members quickly and this leaves more time for us to explore our new research project: DNA inter strand crosslinks” Marcus S. Cooke PhD, Professor and Head of Department  
Find out more about the Oxidative Stress Group  
  
Mini Case Study 3: Comet assay utilized in radiation research to measure DNA repair following alpha-particle exposure  
The Goodarzi Lab for Genome Stability Research, Health Research Innovation Centre, The University of Calgary, Calgary, Alberta, Canada  
At the University of Calgary, pioneering investigations regarding radiation exposure and DNA repair are performed. One particular area of interest is the work of Dan Berger, which focuses on the repair of DNA within cells after damage by alpha particles. Alpha radiation is a destructive form of ionizing radiation and is emitted by radon gas. In the laboratory, brain cells are cultured and then exposed to heavy alpha particles. The comet assay is then performed to monitor how these cells repair DNA damage. Dan strives to better understand the DNA double-strand break repair processes in brain cells, and CAIV helps this exciting research. Conclusions formed in this laboratory have a direct impact on radiation protection procedures.  
“We’ve got a great procedure in place for culturing the brain cells. Initially it was tricky, but we get nice clean cultures, which we’re able to use in the comet assay and analyse easily with Comet Assay IV” Dan Berger, Post Graduate Scientific Investigator  
Read more about using Comet Assay IV in academic environments.  
  
  
  
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Sorcerer Colony Counter  
  
   
GLP and 21 CFR compliant colony counter solution  
Sorcerer Colony Counter is a regulatory compliant system used in laboratories worldwide. Sorcerer Colony Counter combines sophisticated image processing and analysis with innovative hardware to provide fast, accurate counts of bacterial and mammalian colonies for drug development and public health research projects. Sorcerer Colony Counter is widely used in regulatory experiments, such as the Ames test and MLA assay.  
Sorcerer Colony Counter has a global reputation for excellence and many of the world’s top pharmaceutical, contract research and public health organizations are using Sorcerer for their colony counting and image analysis applications.  
Colony counting features:  
  
Automatic separation of overlapping colonies  
Application adaptable (e.g. MLA, Ames, OPA or SBA)  
Detects transparent or opaque colonies on a range of media  
Image Editor for excluding areas (e.g. contamination)   
  
Fast, accurate, automatic plate counting - Sorcerer Colony Counter includes a high-quality industrial-standard camera which relays a live digital video image to your computer screen. At the press of a button, Sorcerer instantly counts all the colonies on your plate and transfers the data to an excel workbook, an Oracle database or Cyto Study Manager.  
Fully configurable - Sorcerer Colony Counter comes with a choice of hardware, viewing stands and camera mounting options, ensuring your sample is optimally illuminated and accurately counted. The software can also be optimized to ensure the most accurate plate count. Areas that can be optimized include:  
  
type of illumination  
detection sensitivity  
object classification  
separate touching colonies  
classify or remove objects by size or shape  
report colony sizes  
   
  
  
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Powerful data processing  
Auditing and user control  
Regulatory compliance with GLP & FDA 21 CFR  
Rapid, accurate and easy to use  
Powerful measurement macro builder  
Data transfer to Excel or Oracle  
Integrates with Cyto Study Manager to ensure seamless study management and data collection   
  
Sorcerer image analysis technology can also be used for other applications such as automatic & interactive measurements, particle sizing & counting, zones & areas analysis. Find out more about using Sorcerer for general image analysis.  
  
  
  
  
  
  
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The leading software platform for the acquisition, display and analysis of physiological signals.  
  
  
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Fast and easy reporting in Microsoft Excel®  
When installing NOTOCORD-hem™, a specific toolbar called Excel wizard is automatically added to your Microsoft Excel® application creating a link between Microsoft Excel® and NOTOCORD-hem™. The Excel wizard provides fast and unique reporting in Excel® with the possibility to create customized data extraction templates saving time for your analysis.  
The Excel wizard include six assistants designed to ease up and fasten data extraction and analysis.  
  
File Info: extracts various information from a data file (filename, acquisition duration, acquisition start time, etc.).  
Formula: extracts experiment information such as values, average, number of points, maximum, etc.  
Event markers: extracts information on markers: number, type, assigned keys, name, etc.  
Edit: redefines the data extraction zone on a signal display.  
Chart: draws a graph representing extracted data.  
Time-matched Extraction: ensures extracted data match appropriate events (eg: extracted data really correspond to a fully detected heartbeat).   
  
   
  
   
With the Maintenance package, you benefit from expertise and consulting on Microsoft Excel®, assistance in optimizing simple extraction models and building complex templates.  
   
  
  
  
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From Acquisition to Reporting: Step-by-Step  
The use of NOTOCORD-hem™ for your studies can be divided in five major steps:   
  
STEP 1 - Build the configuration  
Building a configuration consists in linking modules of interest in order to assemble a system able to perform all acquisition, analysis and display tasks required for the experiment. The modules' parameters can be modified for a truly customized analysis.  
Example configuration  
The configuration below is built to acquire, analyze and display electroencephalogram and video signals.  
  
On the example configuration above:  
  
VSH10a is a video acquisition server connected to CTD60v, a universal chart display with video.  
LAS30a (acquisition) provides EMG and EEG signals, and some additional channels from the implant.  
The EMG signal is processed by a dedicated module NVC31a that removes the offset, rectifies the signal and calculates an activity index. All ouputs are connected to CTD60a, a multigraph continuous display.  
The EEG signal is processed by EEG10a, a spectrum analyzer extracting Delta, Theta, Alpha, and Beta bands on user-defined successive epochs. A filter bank is applied to the input signal and the band powers are measured in real time. Results are displayed on CTD60v, so the EEG signals can be inspected in synchronization with the video.  
  
STEP 2 - Acquire experimental data  
Thanks to dedicated acquisition modules, NOTOCORD-hem™ is compatible with the main hardware on the market: Data Translation® USB A/D cards, DSI™, Hugo Sachs Electronik, Millar, Transonic®, TSE Stellar Telemetry, etc.  
NOTOCORD-hem™ accepts a large number of input channels (upon hardware limitation). The input channels of interest are selected and configured by the user (range, sampling frequency, etc.).  
About acquisition  
  
A file can include several acquisition periods which may last from a few seconds to several days  
Scheduled recording is possible for programmed acquisition periods  
Video recording and synchronization to analogue input channels is ensured thanks to our 4-/8-channel High-Definition video acquisition modules  
Event markers and comments can be inserted during acquisition  
Data review on previous periods is possible without interrupting data acquisition and online analysis   
  
   
STEP 3 - Display signals  
NOTOCORD-hem™ offers several types of display with advanced capabilities: continuous, digital, 2-D, 3-D, video... Signal display (style, color, thickness, etc.) is customizable to meet the user’s preferences.  
  
About display  
  
Graphical superimposition is available for data curves and tendencies comparison  
There are no limitations in the number of displays; each display may show up to 20 individual graphs  
Channels overlay is possible within the same display for flexible visualization of waveforms   
  
STEP 4 - Analyze & review data  
Real time and offline analysis  
NOTOCORD® proposes an extensive library of signal processors and analyzers dedicated to cardiovascular, respiratory and nervous system signals as described in our Solutions and Catalog sections.  
Nearly all analyzers can perform real time analysis. All data are permanently saved in the file and made available for immediate visual inspection and validation.  
  
On the example above, the characteristic points of the EEG signal as well as RR duration and QTc values are computed during acquisition of the signal (top graphs). The same applies for the arterial blood pressure signal with the marking of systolic and diastolic pressure points and the computation of arithmetic mean and rate values.  
Data review  
  
Real time data review is possible, i.e. during acquisition, without inducing interruptions.  
Offline data review, i.e. of files already acquired, is available instantly as large data files open in a few seconds and time-consuming replay is not needed.  
  
Some of our modules modules have been designed specifically for editing and validation. E.g.: our Reference mark editor for arrhythmia RME10a used in association withour Arrhythmia detector ARR30a.  
STEP 5 - Report in Microsoft Excel®  
Thanks to the Excel wizard, a unique reporting system conceived by NOTOCORD®, data are extracted quickly and efficiently in Microsoft Excel®. This function is designed to drastically reduce the time needed to generate reports as users benefit from different time-saving assistants and may create their own extraction templates for further data extraction.  
Traceability is ensured as the origin and location of the extracted data are included in the report.   
Find out more about fast and easy reporting in Microsoft Excel®  
  
  
  
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The leading software platform for the acquisition, display and analysis of physiological signals.  
  
  
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NOTOCORD-hem™, developed by NOTOCORD, and now part the Instem solutions portfolio is the leading software platform for the acquisition, display and analysis of physiological signals, with a focus on the areas of Cardiovascular, Respiratory and Nervous System Research.  
NOTOCORD-hem is used by pharmaceutical companies, contract research laboratories, hospitals and academic research centers around the world.   
Key Features  
  
Over 160 modules for a customized analysis  
In vivo, In vitro and Ex vivo  
Large range of hardware compatibility from analogue to implantable devices   
Simultaneous acquisition from different sources and systems  
Flexible user interfaces offering easy configuration and displays  
Ultra-fast access to data regardless of experiment file size  
Unique Microsoft Excel® Add-in for individualized reporting  
Compliance with GLP & 21 CFR Part 11  
  
NOTOCORD-hem can be installed in a GLP environment, adding access control and audit trail functionalities, restricted access to authorized individuals and use of electronic signatures.   
NOTOCORD-hem is an open software platform compatible with multiple acquisition devices, including implants, and other software.  
  
   
  
From Acquisition to Reporting: Step-by-Step  
Find out more  
  
  
“I would recommend NOTOCORD-hem™ for its intuitive interface, convenient data analysis process, and the excellent customer service provided.” Matt Skinner, Vivonics Preclinical Limited  
“NOTOCORD-hem is the most user-friendly software in the cardiovascular field.” Bernadette Hamon, Sanofi  
“All of our animal models are running with NOTOCORD-hem software.” Frank Cools, Janssen  
“NOTOCORD-hem software is intuitive and logical compared to similar ones.” Nicoletta Garbati, Aptuit  
  
  
  
  
  
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Instem's market leading preclinical software suite for organizations engaged in non-clinical evaluation studies.  
  
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Provantis® is a modern, fully integrated Windows-based system for organizations and universities engaged in non-clinical evaluation studies. From single-user Pathologists to full-function global Toxicology/Pathology laboratories, Provantis streamlines processes and workflows with straightforward, intuitive functionality for simple and complex studies within a GLP or non-GLP environment.  
Instem's customer base consists of the leading pharmaceutical, chemical and contract research organizations, including government and privately funded programs across sites worldwide.  
The integrated Provantis modules operate in the Microsoft Windows environment, either as traditional desktop-client programs (server-based applications) or through our hosted online offering, allowing customers the ultimate freedom to choose the most appropriate platform for their users.  
  
  
  
  
  
On-Demand Education   
Anywhere, Anytime at a Pace that Suits You!Enabling Provantis Users to Excel  
Provantis users can benefit from the Provantis Academy, an intuitive, easy to use, web-based learning solution that is available on-demand whenever a client needs it. Part of the Instem University eLearning platform, the Provantis Academy curriculum provides users with a personalized approach to learning, giving them access to the training they need anywhere, any time.  
Meeting the needs of all users, from super users to staff who only use Provantis infrequently, the Provantis Academy facilitates increased efficiency and effectiveness and fosters a culture of continuous learning.   
Provantis Academy users also have direct, live access to Instem’s team of educational industry experts.  
  
  
Provantis Academy  
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All Provantis clients benefit from unlimited access to live global support to ensure operational effectiveness and success. Additionally, Provantis clients can take advantage of our comprehensive Customer Involvement Program (CIP). The CIP offers customers numerous opportunities to engage with Instem staff and fellow users through a variety of forums including our secure, client-only Customer Center website, Value Visits, client webcasts, online & in-person User Group Meetings and Special Interest Group meetings and more.  
  
  
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General Toxicology  
  
General Toxicology  
  
The Provantis® General Toxicology product is a modern, flexible solution that supports the toxicologist in the management, performance, analysis and reporting of all study types. It fulfils the needs of product safety studies in pharmaceuticals, agro-chemicals and contract research and satisfies all protocols approved by regulatory authorities worldwide.  
  
Data Collection  
The full range of Data Collection types are supported including:  
  
Clinical Observations  
Palpable Masses  
Bodyweights  
Dosing  
Food and Water Consumption  
FOB  
User Defined Measurements  
  
This module also handles the in-life phases of a reproductive study.  
Protocol Management  
The protocol module allows the study director to define the protocol to Provantis, which then manages the duties of the technicians on a day-to-day basis to ensure protocol adherence. The system handles studies on any species and strain, placing no limit on the number and order of parameters measured, or the study design.  
Reporting  
A wide variety of table formats are available, including:  
  
Individual animal data tables   
Group summary tables   
Incidence analysis by animal group, symptom, severity   
Time to response   
Mass location diagrams   
Raw data and audit trail reports   
  
Work Scheduling  
One of the most sophisticated aspects of Provantis is the link between the protocol and data collection modules, which provides the automated scheduling of all animal room activities.  
Labeling  
 Label creation is quick, simple and completely user-definable allowing you to use over 350 standard label formats (including Avery) or customize your own size and layout.  
You may select fields directly from the Provantis database and incorporate objects such as graphics, text, or fields that prompt users for input prior to printing. This may include bar-coded information (25 formats) and the definition can be saved for use by others.  
By using Labeling you can create any label required for the life cycle of your study such as rooms, cages, food bins, dose pots and ECG traces.  
Integration  
Provantis is unique in terms of integration. On any given study, all data collection modules share a single protocol and common glossary management and security structures.  
  
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Pathology  
  
Pathology  
  
Provantis Pathology is a comprehensive, intuitive and flexible software solution that supports the pathologist in the collection, processing and reporting of data for gross and histopathology, including mass tracking and organ weights. The Provantis Pathology solution provides a consistent, familiar look and feel, seamless access to your favorite Microsoft applications and powerful, flexible reporting. Provantis Pathology is used by organizations across the globe, from single user remote Pathologists to multi-site laboratories.  
Data Collection  
Data collection is fast, accurate and flexible. As well as offering a choice of keyboard entry, using user defined codes, or mouse entry picking from lists, there are a wide variety of user preferences to allow you to work in the way you choose – one animal at a time – by tissue - in a matrix of animals and tissues – the choice is yours. Sophisticated completion checking prevents errors and ensures protocol adherence.  
Numerous shortcuts are available to the experienced user and keyboard/mouse activity has been ergonomically reduced to a minimum.  
Integration  
The Pathology module is fully integrated with the rest of the Provantis suite. It shares a common protocol, ensuring all other data such as In-life, necropsy, organ weights and clinical pathology data is available to the pathologist. Provantis Pathology can also be integrated with Spotlighter™, our new Historical Data Management solution.   
Reporting  
A large selection of standard ready-to-publish reports are available. These feature multiple selection criteria, including page headings, animal/group selection and the option to include full or partial observation detail (eg tissues, morphology, modifier):  
Summary reports - Intergroup comparison of gross/histo observations, Intergroup comparison of organ weights and organ weight ratios, Gross/Histopathology observations - animal cross-reference, Tumor summary, Combination incidence of tumors, Chronological listing of tumors, Completed animals, Cause of death summary, Incompleteness check, Major Pathological findings, FDA Biometrics report  
Individual animal reports - Animal data, Gross pathology observations, Correlation of findings, Cause of death, Palpable mass diagnosis and Individual organ weights   
An example of the flexibility can be seen in the intergroup comparison reports, where there is an option to show male/female-only data or combined. One of the reporting format options is to show animals by removal reason and group. Other options include animals with findings only and/or observations split by severity. For histo, the user is able to request neo and non-neoplastic observations separately or combined. Incidences can be shown as percentages or absolute. Syndromes and Merging and Include/Exclude facilities allow manipulation of the presentation of findings.  
A number of animal history reports (including mass tracking from in-life, through gross to histo), raw data and glossary reports are also available.   
Latest Features  
New functionality includes:  
  
Advanced Matrix entry – allowing even faster data entry directly in the matrix  
Direct, automatic inclusion of pathology data into protocol and reports  
Enhanced Completion checking   
Simplified Glossary definition and maintenance   
Automatic production of histology labels from Protocol to Labeling module   
Remote Pathology allows offsite slide reading with full In-Life/Gross information   
  
  
Fact Sheet Download  
  
  
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Clinical Pathology  
  
Clinical Pathology  
  
Instem's Clinical Pathology solution is based on the Provantis® Clinical Pathology product. This product provides bench-level functionality for the collection and processing of Clinical Pathology data, as well as further ‘Supervisor’ review, amend and release options to ensure quality results are released back to the study.  
Quality Control material can be defined, maintained and used throughout the system to check instrument performance prior to and / or during animal data collection.  
The system is driven by the protocol entered in the General Toxicology product, directing sample collection in the animal room and subsequent analysis within the Clinical Pathology laboratory. This level of product integration ensures there is no need to re-enter protocol details. Ad-hoc study samples may also be run as required.  
Clinical Pathology specific reports are held within the ‘Supervisor’ module and provide:  
  
Analytical ‘run’ reports to mimic instrument data print-outs  
Study based animal result and sample raw data reports  
QC based raw data and historical analysis reports  
  
Final study reports are provided from the Provantis Tables & Statistics module and integrate Clinical Pathology data with all other study data  
Key Features  
  
Configurable instrument interfacing software (uni and bi-directional)  
Clear spreadsheet style layout of result data  
Real time display of instrument data capture  
QC collection, validation and export  
Different display modes (results / exceptions) for efficient data review  
Measurement tagging for easy addition of comments and results  
Security controlled data changes  
Full audit trailing  
  
Latest Features  
  
Production of sample labels (including bar-codes) through Provantis Labeling Module  
Electronic signature on review sign-off steps  
Screen lock-out facilities throughout system  
Security enhancements in data transfers  
QC lot maintenance, QC data storage and QC reports  
Randomised / Counter-balanced collection lists  
Dilution factor / audit trailing utility  
Optional additional levels of data review  
  
  
Find Out More  
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Reproductive Tox  
  
Reproductive Toxicology  
  
The Reproductive Toxicology product is a modern, flexible solution that supports the toxicologist and teratologist in the management, performance, analysis and reporting of all reproductive study types, including:  
  
ICH study types (fertility and embryo-foetal development, pre- and post-natal development and embryo-foetal development)   
Multi-generation   
Developmental toxicity   
Behavioral   
Developmental neurotoxicity   
  
Protocol  
The reproductive toxicology module is fully protocol driven. The protocol recognizes the complex, phased nature of many reproductive studies and allows activities to be scheduled relative to study, pairing, mating and littering days, generational phases and observed events or measurements. This allows technicians to easily see what activities are due on which animals. The data entry programs prompt them in accordance with this schedule.  
Data Collection  
The full range of data collection functions are available, including:  
  
Oestrous cycle assessment   
Caesarean section   
Sperm analysis   
Fetal pathology   
Pairing   
Blind reading within fetal pathology   
Evidence of mating   
Supervisor review of fetal findings   
Parturition   
Development signs   
Fate allocation   
Assignment to next generation   
  
In addition the entire general toxicology data collection functions are provided for parental animals, litters and unidentified and identified pups.  
Reporting  
Reproductive toxicology data can be tabulated and analyzed in many formats, including:  
  
Individual animal data tables   
Group summary including various statistical analyses   
Reporting by phase   
Analysis of reproductive end-points   
Calculation of numerous indices (e.g. fertility, survival, reproductive performance, observation indices by litter and foetus)   
Analysis of pup data   
Raw data and audit reports   
  
Latest Features  
  
Blind Reading in Fetal Pathology   
Supervisor Review for Fetal Pathology Findings   
Staggered Delivery Randomization   
Label Creation & Printing, including reproductive toxicology information   
New Reproductive Tables  
   
Intergroup Comparisons:  
   
Pup Mortality   
Pup Bodyweights   
Pup Bodyweights Gains   
Litter Weights   
Litter Weights Gains   
Pup Developmental Markers – By Day Summary   
Pup Developmental Markers – Cumulative Count   
Delivery Data:  
   
General Details   
Mean Pup Counts Changes to Existing Tables   
New Analysis Periods  
   
Weight Gain Tables allow the definition of weight gain intervals   
Pup Tables allow multiple analysis periods   
Better Account of Reproductive Phases   
Descriptive Statistics  
   
Mean   
Standard Deviation   
Maximum Contributory Value   
Minimum Contributory Value   
Standard Error (of Means)   
N – number of contributory values   
  
  
Reproductive Statistics  
   
1 way, 1 way mixed & 2 way ANOVA   
Kruskal Wallis   
Likelihood Ratio Chi-Square   
Generalised Wilcoxon’s test for censored data   
  
  
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Tables & Statistics  
  
Tables & Statistics  
  
The Tables and Statistics product generates tables and, if required, performs statistical analysis on data collected by most other products in the Provantis® family. At any point during a study you can produce tables with a variety of content and formatting options.   
Tables and Statistics with its ease of use, flexibility and coverage of most of standard statistical processing, and its integration with the Protocol & Report Assembly product, can play an important role in meeting the ever increasing demand to produce faster, higher quality, secure reports.  
  
Key Benefits   
  
Common table production framework for all data   
Flexible table generation options  
Standard statistics available to non-specialist users  
Faster reporting via table profiles   
Secure, validated integration with Protocol & Report Assembly   
  
The Open Architecture  
Provantis 8 introduces the new Open Architecture concepts to the Tables and Statistics product. The Open Architecture frees the user from the complexities of the Oracle database, presenting the data in a simple, industry standard, XML file and formatting the data onto the report page using the BusinessObjects Crystal Reports XI reporting tool.  
Features  
  
Open Architecture  
Industry-standard tools - Oracle, Microsoft, SAS, Crystal Reports XI  
Statistics  
  
Descriptive  
Comparative  
User definable by parameter or table  
  
Formatting  
  
Flexible table formats  
Variable fonts, font sizes, paper sizes,margins  
Easily changed or added to  
Output formats Word, PDF, RTF  
Graphical or tabular output  
  
Ease-of-use   
  
One-shot reporting  
User definable table headings  
Comprehensive footnoting  
Table preview  
User chosen table content  
Dispatcher for overnight processing  
Optimised performance  
Integration  
Tables and Statistics is fully integrated with the rest of the Provantis family of products, as well as other commonly used tools such as SAS, Microsoft Office, BusinesssObjects, Crystal Reports XI and Adobe. You can create outputs as XML files for use by other applications, or so that you can apply your own SAS procedures. Integration with the Provantis Protocol and Report Assembly product allows you to combine tables with other contributions, for example text, graphics and spreadsheets, into a secure final report.  
  
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Formulation  
  
Formulation  
  
DISPENSE is a comprehensive computer based system for test item control.  
The DISPENSE system maintains a full record of test item usage right from the initial receipt through formulation/dispensing activities to disposal.  
DISPENSE makes extensive use of bar code identification and on-line electronic data capture from balances to ensure the highest level of data integrity.  
Test Item Receipt  
On receipt, the test item is logged into the DISPENSE system by completing a series of on-screen forms. Some information is mandatory such as name, batch number and expiry date. When all the details have been registered, each container is then assigned a unique barcode by Dispense and labels produced.  
  
All test substance containers carry a unique bar coded label  
The test substance expiry date prevents it from being used in a formulation after expiry  
All receipt amendments are audit trailed  
Gross test substance container weights may be recorded on-line  
  
Formulation Specification  
Formulation instructions are entered into DISPENSE on a per study or project basis and each test substance batch is linked to a study or project. The formulation specification includes details of the test substance to be used, concentration, vehicle and formulated volume (or weight). Following completion of a formulation specification, bar coded labels are printed for all formulation containers.  
Formulation options include:  
  
solutions / suspensions (mg/ml)  
solutions (%)  
capsules (mg)  
dietary formulations (mg/kg)  
  
DISPENSE uses a formulation matrix which covers the requirement for multiple test substances and/or multiple vehicles for some projects.  
Formulation Preparation  
Formulation activities are controlled by DISPENSE. The bar coded labels on all formulation containers and vehicles are used to verify each step in the formulation process. The information on each formulation container label includes the project number and the dose group.  
DISPENSE:  
  
calculates the amount of test substance and vehicle required for each formulation  
ensures that correct weights of test substance and vehicle are used  
records all weights on-line  
  
After entering a study or project number, you are prompted throughout the preparation process to carry out weighing procedures according to the project formulation details. Balance readings are recorded on-line. Only balances that have previously been identified to the system may be used. Identifying the balance includes specifying the balance serial number, a description of the balance, and the number and values of the check weights to be used before any weighing may be carried out on the balance.  
Accountability  
DISPENSE requires the formulator to weigh the bulk test substance container before use on each formulation occasion (Start of Day Accountability). The bulk test substance container is then weighed following completion of formulation work (End of Day Accountability). DISPENSE calculates the theoretical usage of test material and compares this to the actual usage to produce an Accountability Report. Any discrepancy has to be accounted for by the formulator entering an appropriate reason into DISPENSE.  
Reports  
A variety of reports on test substances and projects may be generated. These include Test Substance Receipt, Formulation Specification and Accountability reports. Both standard and custom reports can be produced.  
Security  
Access to all areas of DISPENSE is controlled by a user ID password. Each user is assigned an ID and set of access privileges to the application. This means, for example, access to enter formulation specification details can be assigned to some users and not others.  
  
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Reporting  
  
Reporting  
  
Instem provides a range of reporting products and services to enable our customers to derive the maximum value from their preclinical data.  
The Provantis® family of products provides a comprehensive set of standard tables for raw, individual animal and summary data, for numeric and observational data, and for in-life, clinical pathology, necropsy and pathology data.  
Provantis is integrated with the industry standard SAS statistical analysis tool. Predefined analyses, including a complex decision tree, can be used and summary tables annotated with the results of the analysis. Customers can also use the full power of SAS to define their own analyses.  
Instem also provides a Business Objects Universe that provides simple access to the complex Provantis data structures. The powerful and easy to use Business Objects tools can be used by end users to create their own ad hoc queries or unusual table designs. Instem also provides services to users who wish to create more complex tables.  
The final product of preclinical study is the study report. This draws together a description of the study conduct, summary and individual data tables, statistical, and possibly graphical, analyses, and scientific conclusions. The Provantis Protocol and Report Assembly module allows customers to create study reports as Microsoft Word documents in a secure environment by combining tables and analyses produced by other Provantis modules, and outputs from non-Provantis systems (eg Microsoft Excel). All contributions to a report can be automatically reformatted as required, whilst at the same time protecting the integrity of the data. Users can develop their own formatting macros or use Instem services if they prefer.  
Finally Instem has used its extensive knowledge of preclinical data and data collection systems to help customers create Data Marts for specific purposes such as historical data, and Data Warehouses as more general repositories of preclinical data.  
  
Find Out More  
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Spotlighter™  
  
Introducing Spotligher™ - a new, stand-alone, web-based software solution for historical data management, enabling you to store, retrieve, and evaluate histopathology data across studies in control and treated animals  
It is an easy-to-use, value-added solution for toxicologists, pathologists and study directors, which requires no database or datamining expertise. Spotlighter provides analytical outputs directly interpretable by scientists, which can support their argumentation whilst writing their report.   
Spotlighter uses APIs to extract control and treated data from a wide variety of data sources including SEND datasets and data collected in preclinical data management solutions such as Provantis and Ascentos.   
Key Benefits of Spotlighter  
  
Provides control and reference data requested by regulatory authorities.   
Delivers fast, practical answers on typical questions arising during toxicology & pathology studies.   
Provides summary reports and identifies patterns in your data.   
Supports read-across between studies.   
Uses historical data to gain insight into potential mechanisms.   
Supports pooling of historical data to support statistical analyses.   
Supports virtual control groups.   
  
Find Value in Your Data and Save Time   
Extracting relevant information from historical data can take days of research. With Spotlighter you can get the answers you need in minutes.  
  
Spotlighter combines all reference data into one comprehensive system, removing the need to work from multiple spreadsheets, formats, and data sources. The result is faster turnaround times and fewer manual errors.   
Easily identify patterns in your data and quickly gain insight into potential mechanisms supported by other research.   
Avoid spending time processing background noise by using Spotlighter to quickly highlight which of your results have significant, treatment-related findings.   
  
Spotlighter can be purchased as a standalone solution, or as part of our Provantis preclinical data management solution.   
   
  
Fact Sheet  
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Data Exchanger  
  
Data Exchanger™ is a value-added software solution that enables clients to quickly and securely import data from a wide variety of external sources into Provantis.   
Data Exchanger is the next generation of our Data Import solution, providing enhanced functionality and increased flexibility that enables users to import a wider array of additional, complex data types such as:  
  
SEND and Observational data  
Estrous Cycle and Clin Path data  
Bone Assessment data  
Gross Pathology and Palpable Mass data   
External sample analysis   
& More!  
  
The intuitive Data Exchanger solution imports data through a secure, validated process, complete with comprehensive audit trails and data flagging capabilities.  
Key Features that Deliver Clear Benefits  
  
Allows import from a wide array of file types including Excel, CSV, Access, Text, Binary and Xml, enabling you to import data from all your data sources   
Supports the import of SEND data sets - Using Instem's submit™ solution you can create and exchange SEND data sets between Sponsors, CROs and other collaborators and import the data into Provantis using Data Exchanger  
Supports numeric and textual data - Unlike many other import tools which only support numeric data, Data Exchanger also allows you to import text based, observational data  
Supports animal, cage and study level data entry, enabling you to import data at multiple levels   
Users can review, amend, flag and delete data during import, giving you complete control over which data is imported into Provantis   
Data Exchanger is fully audit trailed, giving you complete visibility of how source data entered Provantis and any changes and selections that were made  
Data Exchanger's flexible, intuitive user interface allow you to quickly and easily configure imports   
Single-click file import enables rapid data entry  
Supports live and retrospective data entry - You control which timestamps are assigned to data, enabling you to indicate whether data was collected live or retrospectively  
Supports the import of multiple files as a single unit, enabling you to import multiple files to describe a single experiment or set of data, such as SEND data sets   
Calculations can be performed on the imported data, enabling you to store values derived from the raw data in Provantis   
  
  
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Products  
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Aspire Cloud Based Clinical Analytics Framework  
BioRails® for Discovery Data Management - New!  
Blur Clinical Anonymization - New!   
Comet Assay IV™  
Cyto Study Manager  
Computational Toxicology Solutions  
Logbook™ ELN  
Morphit™ for Discovery Data Visualization - New!  
NOTOCORD-hem™ Safety Pharmacology Solution  
Provantis® Preclinical  
Submit™ SEND  
  
Services  
Services  
  
Services  
KnowledgeScan Target Safety Assessment  
Predict™ In Silico Toxicology  
SEND Study Services  
Strategic Clinical Trial Transparency Consulting  
Clinical Trial De-Identification Services  
Clinical Trial Analytics Strategic Consulting  
Clinical Trial Analytics Services  
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Instem's market leading preclinical software suite for organizations engaged in non-clinical evaluation studies.  
  
In this section  
  
Preclinical Overview  
  
  
Provantis  
  
  
Logbook  
  
  
NOTOCORD-hem  
  
SEND Solutions  
  
   
Provantis® is a modern, fully integrated Windows-based system for organizations and universities engaged in non-clinical evaluation studies. From single-user Pathologists to full-function global Toxicology/Pathology laboratories, Provantis streamlines processes and workflows with straightforward, intuitive functionality for simple and complex studies within a GLP or non-GLP environment.  
Instem's customer base consists of the leading pharmaceutical, chemical and contract research organizations, including government and privately funded programs across sites worldwide.  
The integrated Provantis modules operate in the Microsoft Windows environment, either as traditional desktop-client programs (server-based applications) or through our hosted online offering, allowing customers the ultimate freedom to choose the most appropriate platform for their users.  
  
  
  
  
  
On-Demand Education   
Anywhere, Anytime at a Pace that Suits You!Enabling Provantis Users to Excel  
Provantis users can benefit from the Provantis Academy, an intuitive, easy to use, web-based learning solution that is available on-demand whenever a client needs it. Part of the Instem University eLearning platform, the Provantis Academy curriculum provides users with a personalized approach to learning, giving them access to the training they need anywhere, any time.  
Meeting the needs of all users, from super users to staff who only use Provantis infrequently, the Provantis Academy facilitates increased efficiency and effectiveness and fosters a culture of continuous learning.   
Provantis Academy users also have direct, live access to Instem’s team of educational industry experts.  
  
  
Provantis Academy  
Download Fact Sheet  
  
All Provantis clients benefit from unlimited access to live global support to ensure operational effectiveness and success. Additionally, Provantis clients can take advantage of our comprehensive Customer Involvement Program (CIP). The CIP offers customers numerous opportunities to engage with Instem staff and fellow users through a variety of forums including our secure, client-only Customer Center website, Value Visits, client webcasts, online & in-person User Group Meetings and Special Interest Group meetings and more.  
  
  
Instem Customer Center  
Support, Forums, Roadmaps & More  
  
  
  
  
  
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Provantis Case Study  
  
  
Provantis Fact Sheet  
  
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Provantis Case Study  
  
   
  
Provantis Modules  
  
General Toxicology  
  
General Toxicology  
  
The Provantis® General Toxicology product is a modern, flexible solution that supports the toxicologist in the management, performance, analysis and reporting of all study types. It fulfils the needs of product safety studies in pharmaceuticals, agro-chemicals and contract research and satisfies all protocols approved by regulatory authorities worldwide.  
  
Data Collection  
The full range of Data Collection types are supported including:  
  
Clinical Observations  
Palpable Masses  
Bodyweights  
Dosing  
Food and Water Consumption  
FOB  
User Defined Measurements  
  
This module also handles the in-life phases of a reproductive study.  
Protocol Management  
The protocol module allows the study director to define the protocol to Provantis, which then manages the duties of the technicians on a day-to-day basis to ensure protocol adherence. The system handles studies on any species and strain, placing no limit on the number and order of parameters measured, or the study design.  
Reporting  
A wide variety of table formats are available, including:  
  
Individual animal data tables   
Group summary tables   
Incidence analysis by animal group, symptom, severity   
Time to response   
Mass location diagrams   
Raw data and audit trail reports   
  
Work Scheduling  
One of the most sophisticated aspects of Provantis is the link between the protocol and data collection modules, which provides the automated scheduling of all animal room activities.  
Labeling  
 Label creation is quick, simple and completely user-definable allowing you to use over 350 standard label formats (including Avery) or customize your own size and layout.  
You may select fields directly from the Provantis database and incorporate objects such as graphics, text, or fields that prompt users for input prior to printing. This may include bar-coded information (25 formats) and the definition can be saved for use by others.  
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Latest Features  
  
Production of sample labels (including bar-codes) through Provantis Labeling Module  
Electronic signature on review sign-off steps  
Screen lock-out facilities throughout system  
Security enhancements in data transfers  
QC lot maintenance, QC data storage and QC reports  
Randomised / Counter-balanced collection lists  
Dilution factor / audit trailing utility  
Optional additional levels of data review  
  
  
Find Out More  
Contact Us  
  
  
  
   
  
Reproductive Tox  
  
Reproductive Toxicology  
  
The Reproductive Toxicology product is a modern, flexible solution that supports the toxicologist and teratologist in the management, performance, analysis and reporting of all reproductive study types, including:  
  
ICH study types (fertility and embryo-foetal development, pre- and post-natal development and embryo-foetal development)   
Multi-generation   
Developmental toxicity   
Behavioral   
Developmental neurotoxicity   
  
Protocol  
The reproductive toxicology module is fully protocol driven. The protocol recognizes the complex, phased nature of many reproductive studies and allows activities to be scheduled relative to study, pairing, mating and littering days, generational phases and observed events or measurements. This allows technicians to easily see what activities are due on which animals. The data entry programs prompt them in accordance with this schedule.  
Data Collection  
The full range of data collection functions are available, including:  
  
Oestrous cycle assessment   
Caesarean section   
Sperm analysis   
Fetal pathology   
Pairing   
Blind reading within fetal pathology   
Evidence of mating   
Supervisor review of fetal findings   
Parturition   
Development signs   
Fate allocation   
Assignment to next generation   
  
In addition the entire general toxicology data collection functions are provided for parental animals, litters and unidentified and identified pups.  
Reporting  
Reproductive toxicology data can be tabulated and analyzed in many formats, including:  
  
Individual animal data tables   
Group summary including various statistical analyses   
Reporting by phase   
Analysis of reproductive end-points   
Calculation of numerous indices (e.g. fertility, survival, reproductive performance, observation indices by litter and foetus)   
Analysis of pup data   
Raw data and audit reports   
  
Latest Features  
  
Blind Reading in Fetal Pathology   
Supervisor Review for Fetal Pathology Findings   
Staggered Delivery Randomization   
Label Creation & Printing, including reproductive toxicology information   
New Reproductive Tables  
   
Intergroup Comparisons:  
   
Pup Mortality   
Pup Bodyweights   
Pup Bodyweights Gains   
Litter Weights   
Litter Weights Gains   
Pup Developmental Markers – By Day Summary   
Pup Developmental Markers – Cumulative Count   
Delivery Data:  
   
General Details   
Mean Pup Counts Changes to Existing Tables   
New Analysis Periods  
   
Weight Gain Tables allow the definition of weight gain intervals   
Pup Tables allow multiple analysis periods   
Better Account of Reproductive Phases   
Descriptive Statistics  
   
Mean   
Standard Deviation   
Maximum Contributory Value   
Minimum Contributory Value   
Standard Error (of Means)   
N – number of contributory values   
  
  
Reproductive Statistics  
   
1 way, 1 way mixed & 2 way ANOVA   
Kruskal Wallis   
Likelihood Ratio Chi-Square   
Generalised Wilcoxon’s test for censored data   
  
  
Find Out More  
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Tables & Statistics  
  
Tables & Statistics  
  
The Tables and Statistics product generates tables and, if required, performs statistical analysis on data collected by most other products in the Provantis® family. At any point during a study you can produce tables with a variety of content and formatting options.   
Tables and Statistics with its ease of use, flexibility and coverage of most of standard statistical processing, and its integration with the Protocol & Report Assembly product, can play an important role in meeting the ever increasing demand to produce faster, higher quality, secure reports.  
  
Key Benefits   
  
Common table production framework for all data   
Flexible table generation options  
Standard statistics available to non-specialist users  
Faster reporting via table profiles   
Secure, validated integration with Protocol & Report Assembly   
  
The Open Architecture  
Provantis 8 introduces the new Open Architecture concepts to the Tables and Statistics product. The Open Architecture frees the user from the complexities of the Oracle database, presenting the data in a simple, industry standard, XML file and formatting the data onto the report page using the BusinessObjects Crystal Reports XI reporting tool.  
Features  
  
Open Architecture  
Industry-standard tools - Oracle, Microsoft, SAS, Crystal Reports XI  
Statistics  
  
Descriptive  
Comparative  
User definable by parameter or table  
  
Formatting  
  
Flexible table formats  
Variable fonts, font sizes, paper sizes,margins  
Easily changed or added to  
Output formats Word, PDF, RTF  
Graphical or tabular output  
  
Ease-of-use   
  
One-shot reporting  
User definable table headings  
Comprehensive footnoting  
Table preview  
User chosen table content  
Dispatcher for overnight processing  
Optimised performance  
Integration  
Tables and Statistics is fully integrated with the rest of the Provantis family of products, as well as other commonly used tools such as SAS, Microsoft Office, BusinesssObjects, Crystal Reports XI and Adobe. You can create outputs as XML files for use by other applications, or so that you can apply your own SAS procedures. Integration with the Provantis Protocol and Report Assembly product allows you to combine tables with other contributions, for example text, graphics and spreadsheets, into a secure final report.  
  
Find Out More  
Contact Us  
  
  
  
  
Formulation  
  
Formulation  
  
DISPENSE is a comprehensive computer based system for test item control.  
The DISPENSE system maintains a full record of test item usage right from the initial receipt through formulation/dispensing activities to disposal.  
DISPENSE makes extensive use of bar code identification and on-line electronic data capture from balances to ensure the highest level of data integrity.  
Test Item Receipt  
On receipt, the test item is logged into the DISPENSE system by completing a series of on-screen forms. Some information is mandatory such as name, batch number and expiry date. When all the details have been registered, each container is then assigned a unique barcode by Dispense and labels produced.  
  
All test substance containers carry a unique bar coded label  
The test substance expiry date prevents it from being used in a formulation after expiry  
All receipt amendments are audit trailed  
Gross test substance container weights may be recorded on-line  
  
Formulation Specification  
Formulation instructions are entered into DISPENSE on a per study or project basis and each test substance batch is linked to a study or project. The formulation specification includes details of the test substance to be used, concentration, vehicle and formulated volume (or weight). Following completion of a formulation specification, bar coded labels are printed for all formulation containers.  
Formulation options include:  
  
solutions / suspensions (mg/ml)  
solutions (%)  
capsules (mg)  
dietary formulations (mg/kg)  
  
DISPENSE uses a formulation matrix which covers the requirement for multiple test substances and/or multiple vehicles for some projects.  
Formulation Preparation  
Formulation activities are controlled by DISPENSE. The bar coded labels on all formulation containers and vehicles are used to verify each step in the formulation process. The information on each formulation container label includes the project number and the dose group.  
DISPENSE:  
  
calculates the amount of test substance and vehicle required for each formulation  
ensures that correct weights of test substance and vehicle are used  
records all weights on-line  
  
After entering a study or project number, you are prompted throughout the preparation process to carry out weighing procedures according to the project formulation details. Balance readings are recorded on-line. Only balances that have previously been identified to the system may be used. Identifying the balance includes specifying the balance serial number, a description of the balance, and the number and values of the check weights to be used before any weighing may be carried out on the balance.  
Accountability  
DISPENSE requires the formulator to weigh the bulk test substance container before use on each formulation occasion (Start of Day Accountability). The bulk test substance container is then weighed following completion of formulation work (End of Day Accountability). DISPENSE calculates the theoretical usage of test material and compares this to the actual usage to produce an Accountability Report. Any discrepancy has to be accounted for by the formulator entering an appropriate reason into DISPENSE.  
Reports  
A variety of reports on test substances and projects may be generated. These include Test Substance Receipt, Formulation Specification and Accountability reports. Both standard and custom reports can be produced.  
Security  
Access to all areas of DISPENSE is controlled by a user ID password. Each user is assigned an ID and set of access privileges to the application. This means, for example, access to enter formulation specification details can be assigned to some users and not others.  
  
Find Out More  
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Reporting  
  
Reporting  
  
Instem provides a range of reporting products and services to enable our customers to derive the maximum value from their preclinical data.  
The Provantis® family of products provides a comprehensive set of standard tables for raw, individual animal and summary data, for numeric and observational data, and for in-life, clinical pathology, necropsy and pathology data.  
Provantis is integrated with the industry standard SAS statistical analysis tool. Predefined analyses, including a complex decision tree, can be used and summary tables annotated with the results of the analysis. Customers can also use the full power of SAS to define their own analyses.  
Instem also provides a Business Objects Universe that provides simple access to the complex Provantis data structures. The powerful and easy to use Business Objects tools can be used by end users to create their own ad hoc queries or unusual table designs. Instem also provides services to users who wish to create more complex tables.  
The final product of preclinical study is the study report. This draws together a description of the study conduct, summary and individual data tables, statistical, and possibly graphical, analyses, and scientific conclusions. The Provantis Protocol and Report Assembly module allows customers to create study reports as Microsoft Word documents in a secure environment by combining tables and analyses produced by other Provantis modules, and outputs from non-Provantis systems (eg Microsoft Excel). All contributions to a report can be automatically reformatted as required, whilst at the same time protecting the integrity of the data. Users can develop their own formatting macros or use Instem services if they prefer.  
Finally Instem has used its extensive knowledge of preclinical data and data collection systems to help customers create Data Marts for specific purposes such as historical data, and Data Warehouses as more general repositories of preclinical data.  
  
Find Out More  
Contact Us  
  
  
  
  
Spotlighter™  
  
Introducing Spotligher™ - a new, stand-alone, web-based software solution for historical data management, enabling you to store, retrieve, and evaluate histopathology data across studies in control and treated animals  
It is an easy-to-use, value-added solution for toxicologists, pathologists and study directors, which requires no database or datamining expertise. Spotlighter provides analytical outputs directly interpretable by scientists, which can support their argumentation whilst writing their report.   
Spotlighter uses APIs to extract control and treated data from a wide variety of data sources including SEND datasets and data collected in preclinical data management solutions such as Provantis and Ascentos.   
Key Benefits of Spotlighter  
  
Provides control and reference data requested by regulatory authorities.   
Delivers fast, practical answers on typical questions arising during toxicology & pathology studies.   
Provides summary reports and identifies patterns in your data.   
Supports read-across between studies.   
Uses historical data to gain insight into potential mechanisms.   
Supports pooling of historical data to support statistical analyses.   
Supports virtual control groups.   
  
Find Value in Your Data and Save Time   
Extracting relevant information from historical data can take days of research. With Spotlighter you can get the answers you need in minutes.  
  
Spotlighter combines all reference data into one comprehensive system, removing the need to work from multiple spreadsheets, formats, and data sources. The result is faster turnaround times and fewer manual errors.   
Easily identify patterns in your data and quickly gain insight into potential mechanisms supported by other research.   
Avoid spending time processing background noise by using Spotlighter to quickly highlight which of your results have significant, treatment-related findings.   
  
Spotlighter can be purchased as a standalone solution, or as part of our Provantis preclinical data management solution.   
   
  
Fact Sheet  
Request PDF  
  
  
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Data Exchanger  
  
Data Exchanger™ is a value-added software solution that enables clients to quickly and securely import data from a wide variety of external sources into Provantis.   
Data Exchanger is the next generation of our Data Import solution, providing enhanced functionality and increased flexibility that enables users to import a wider array of additional, complex data types such as:  
  
SEND and Observational data  
Estrous Cycle and Clin Path data  
Bone Assessment data  
Gross Pathology and Palpable Mass data   
External sample analysis   
& More!  
  
The intuitive Data Exchanger solution imports data through a secure, validated process, complete with comprehensive audit trails and data flagging capabilities.  
Key Features that Deliver Clear Benefits  
  
Allows import from a wide array of file types including Excel, CSV, Access, Text, Binary and Xml, enabling you to import data from all your data sources   
Supports the import of SEND data sets - Using Instem's submit™ solution you can create and exchange SEND data sets between Sponsors, CROs and other collaborators and import the data into Provantis using Data Exchanger  
Supports numeric and textual data - Unlike many other import tools which only support numeric data, Data Exchanger also allows you to import text based, observational data  
Supports animal, cage and study level data entry, enabling you to import data at multiple levels   
Users can review, amend, flag and delete data during import, giving you complete control over which data is imported into Provantis   
Data Exchanger is fully audit trailed, giving you complete visibility of how source data entered Provantis and any changes and selections that were made  
Data Exchanger's flexible, intuitive user interface allow you to quickly and easily configure imports   
Single-click file import enables rapid data entry  
Supports live and retrospective data entry - You control which timestamps are assigned to data, enabling you to indicate whether data was collected live or retrospectively  
Supports the import of multiple files as a single unit, enabling you to import multiple files to describe a single experiment or set of data, such as SEND data sets   
Calculations can be performed on the imported data, enabling you to store values derived from the raw data in Provantis   
  
  
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Submit-SEND  
Clinical Trial Analytics  
  
  
In Silico Solutions  
Genetic Toxicology  
  
  
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Discovery Research Software – BioRails - Instem  
  
  
  
  
  
  
  
  
  
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Products & Services  
  
Products & Services  
  
Products  
Products  
  
Products  
Accel Cloud Based Statistical Computing Environment  
Aspire Cloud Based Clinical Analytics Framework  
BioRails® for Discovery Data Management - New!  
Blur Clinical Anonymization - New!   
Comet Assay IV™  
Cyto Study Manager  
Computational Toxicology Solutions  
Logbook™ ELN  
Morphit™ for Discovery Data Visualization - New!  
NOTOCORD-hem™ Safety Pharmacology Solution  
Provantis® Preclinical  
Submit™ SEND  
  
Services  
Services  
  
Services  
KnowledgeScan Target Safety Assessment  
Predict™ In Silico Toxicology  
SEND Study Services  
Strategic Clinical Trial Transparency Consulting  
Clinical Trial De-Identification Services  
Clinical Trial Analytics Strategic Consulting  
Clinical Trial Analytics Services  
Instem Cloud Services  
  
  
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Improving Discovery Research Workflow: Streamline, Optimize, and Innovate Your Research and Data Management.  
  
In this section  
  
Discovery Overview  
  
  
BioRails  
  
  
BioRails InLife  
  
  
Morphit  
  
   
BioRails® Modules  
BioHub™: Consolidate corporate knowledge into a single, accessible store, ensuring organized and readily available information.  
BioRails PTO™: Enhance project tracking and optimization with tools for streamlined and precise project management.  
BioRails DM™: Simplify data management with tools that ensure consistency and reliability in research data.  
BioRails MT™: Register and manage biospecimens, biologics, and formulations with seamless tracking and utilization of materials.  
BioRails INV™: Optimize inventory control with efficient systems for ordering and tracking resources.  
BioRails InLife™: Boost productivity in the vivarium with tools for streamlined treatment and harvesting tasks.  
  
  
Features for Security and Efficiency: Created by Scientists for Scientists  
Role-based Security Model: Implement a robust security model with differentiated access rights for enhanced protection.  
Authorization and Authentication: Ensure data protection with strong authorization and authentication mechanisms.  
Team and Project Support: Enable seamless project tracking and information sharing with support for teams and real-time collaboration.  
Terms and Terminology Support: Manage pharmaceutical research data with chemically aware terminology support.  
Quantity Model (Unit Handling): Handle various units of measurement with precision and scalability.  
Content Management: Audit-friendly content management that tracks information accurately, consolidates data, and provides rich visualization and integrated tools.  
Streamline Workflows: Automate complex workflows to ensure process consistency and scalability. Handle large data volumes uniformly, maintaining quality and integrity while reducing workload and errors.  
Automate Data Collection: Minimize manual effort and reduce human error in data collection with automation tools. Free up time for critical activities by automating repetitive tasks.  
BioRails® supports both structured experimentation and the integration of unstructured results into a structured environment. It empowers scientists with efficient data exploitation through advanced reporting and analysis tools, reducing the time needed to analyze data and draw conclusions.  
  
BioRails®  
  
BioHub™  
BioHub™ Scalable Data Solution  
  
Data loading and storing all assay results in a single database for ready decision-making.  
Unified Data Repository  
BioHub™ serves as a comprehensive data store, consolidating data from various sources into one centralized location. This eliminates the inefficiencies of fragmented data storage and provides a single point of access for all your data needs.  
Robust Data Loading Mechanisms  
BioHub™ supports diverse data loading methods, enabling seamless integration for both external CROs and internal teams. This ensures efficient data posting and minimizes the risk of data silos.  
Rigorous Data Validation  
All incoming data is meticulously validated against corporate standards and ontologies. BioHub™ ensures only high-quality, compliant data is published to the corporate data warehouse, maintaining data integrity and reliability.  
Versatile Deployment Options  
BioHub™ offers flexible deployment solutions, either in the cloud or on-premise. This adaptability allows organizations to choose the setup that best fits their infrastructure and security requirements.  
Assay Registration and Results Upload  
BioHub™ supports the registration of assays based on formally managed terminology and ontologies. Its user-friendly web interface facilitates the uploading of results from a wide range of assays, from high-throughput screening (HTS) to complex in vitro and in vivo assays.  
Integration with Leading Analytics Tools  
BioHub™ integrates seamlessly with top HTS data analytics software, enabling large datasets to be published directly. This integration reduces the time and errors associated with manual file manipulations.  
Secure Access for CROs  
BioHub™ provides secure access for Contract Research Organizations (CROs) to upload and exchange results. This secure sharing capability enhances collaboration and data exchange efficiency.  
Scalability for Growing Organizations  
Combined with BioRails Warehouse, BioHub™ scales effortlessly to meet the needs of organizations of any size. It can absorb data from numerous sources, creating a robust and scalable resource of results.  
Compatibility with Advanced Informatics Tools  
The data stored in BioHub™ can be easily accessed and utilized by most scientific data informatics tools. This compatibility provides an ideal foundation for data scientists to develop AI algorithms based on corporate knowledge.  
BioHub™ revolutionizes data management by providing a scalable, centralized, and compliant data store. Its robust data loading mechanisms, rigorous validation processes, and flexible deployment options make it the ideal solution for organizations looking to enhance their data consolidation and analysis capabilities. With seamless integration into leading analytics tools and secure access for CROs, BioHub™ ensures that high-quality data is always at your fingertips, empowering data-driven decision-making, and innovation.  
  
Find Out More  
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BioRails PTO™  
BioRails PTO™ Project Tracking and Optimization  
  
A service request and planning tool that enhances discovery research by streamlining assay workflows, improving collaboration, and reducing cycle times.  
Service Definition  
BioRails PTO™ allows you to define a variety of services that can be requested, ensuring all necessary details are captured. These services can represent assays, studies, or general services and are based on item types such as compounds, batches, animals, or instruments. This detailed service definition ensures that requesters have all the information they need to accurately specify their requirements.  
Assay Requesting  
Project teams can easily submit assay requests for published services using BioRails PTO™. This streamlined requesting process ensures that all requests are comprehensive and consistent, reducing errors and facilitating efficient project execution.  
Planning and Scheduling  
Submitted assay requests are consolidated into organized 'Todo lists', allowing planners to allocate items into execution units such as runs, experiments, or studies. BioRails PTO™ provides tools for scheduling start times and allocating personnel, ensuring optimal resource utilization and project timelines.  
Inventory Integration  
When integrated with BioRails INV, planners can evaluate stock levels while requesting assays. This integration allows them to request assay-ready plates from compound management teams, ensuring that all necessary materials are available for seamless execution.  
Cascade  
BioRails PTO™ enables the definition of cascades of assays, organized into multiple tiers. Each tier generates results that can be automatically evaluated using predefined rules to promote compounds to the next level of assays. This feature allows you to track and monitor progress efficiently, reducing cycle times and accelerating the time to market for new treatments.  
BioRails PTO™ offers a comprehensive suite of tools for assay requesting, planning, and cascading. Its intuitive interface and automated features streamline workflows, enhance collaboration, and ensure high-quality results. Whether you're a scientist requesting assays or a service provider managing multiple projects, BioRails PTO™ provides the precision and efficiency needed to drive your discovery research forward, reducing cycle times and bringing innovative treatments to market faster.  
  
Find Out More  
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BioRails DM™  
BioRails DM™ Advanced Data Management Solutions  
  
A data management solution that streamlines data capture, processing, and analysis through a workflow-driven approach, integrating advanced analytics and reporting to transform raw data into actionable insights.  
Structured Data Management  
BioRails DM™ provides an effective platform for comprehensive data management, enabling organizations to implement the highest standards in the field. It supports both structured data capture (results) and unstructured data (observations and interpretations), ensuring all aspects of your data are managed efficiently. Define experimental workflows that combine data capture processes with structured data storage and powerful data analytics templates using Morphit.  
Workflow-Driven Coordination  
BioRails DM™ coordinates activities across multiple departments, internally and with partners and CROs. It enables the definition and execution of high-level workflows addressing various data types captured during scientific experiments. The platform uses analytical templates to drive laboratory workflows, generating plate maps, injection lists for Mass Spectrometers, robotics instruction files, and other experimental artifacts. It reads and analyzes instrument files from fluorescence readers, Mass Spectrometers, and many other types of instruments.  
Knowledge Capture and Protection  
Avoid the need to print data into PDFs and protect your knowledge efficiently. BioRails DM™ includes a 21 CFR Part 11 compliant notebook for writing up experiments, complete with electronic signatures and witnessing. This ensures your data is securely captured and easily retrievable for future reference.  
Advanced Analytics  
Apply statistics, curve fitting, and other analytical techniques to transform raw data into meaningful results. BioRails DM™ allows for the application of advanced quality control criteria within and across experiments to ensure data quality. Search and analyze results across studies to extract valuable knowledge and understanding.  
Documentation and Reporting  
Create documentation templates for study reports, quality reports, certificates of analysis, and various other types of reports. BioRails DM™ allows you to generate high-quality documentation at the press of a button, combining data, results, charts, graphs, and images from within or across experiments. This feature saves hours of time in compiling and formulating documentation.  
Electronic Signatures and Compliance  
BioRails DM™ supports electronic signatures and witnessing as part of its CFR 21P11 compliance effort. This ensures that all data and processes meet regulatory standards, providing peace of mind and reliability.  
Bulk Data Loading  
Load results from CROs and internal teams using bulk loading tools, building extensive databases with hundreds of millions of results. This capability supports the efficient management of large datasets, essential for high-throughput environments.  
Industry Focus  
While BioRails DM™ can address many data capture processes, it is particularly focused on the following areas:  
  
In vitro Drug Metabolism  
In vivo Pharmacokinetics  
Bioanalysis  
In vitro Pharmacology (Screening)  
  
Integration and Compatibility  
BioRails DM™ includes Morphit and is compatible with InLife, ensuring seamless integration with existing systems and enhancing overall functionality.  
BioRails DM™ is a robust data management solution that transforms how organizations handle data capture, processing, and analysis. Its workflow-driven approach ensures data, processes, and insights are secured and managed in one place, promoting efficiency and compliance. By integrating advanced analytics, secure data capture, and comprehensive reporting, BioRails DM™ transforms raw data into actionable insights, driving informed decision-making and accelerating research and development.  
  
Find Out More  
Contact Us  
  
  
  
   
  
BioRails MT™  
BioRails MT™ Comprehensive Material Tracking and Management  
  
A material tracking and management solution supporting the registration of test articles, controls, standards, and assay reagents.   
Material Registration  
BioRails MT™ is designed to support organizations conducting a wide variety of research and development activities. While traditional systems manage specific entities like compounds, lots, proteins, and antibodies, BioRails MT™ extends this capability to a broader range of materials. It integrates with existing compound and biological registration systems, supporting the entire Request-Plan-Test cycle. This includes materials generated during in vivo studies, such as plasma, blood, tissues, and formulation samples, which are often not formally managed by other systems.  
Comprehensive Material Management  
With BioRails MT™, organizations can register and manage various materials, tracking their properties and leveraging the BioRails Request-Plan-Test workflow. This system also keeps track of the quantity and location of samples, ensuring that all materials are accounted for and easily accessible when needed.  
Support for Contract Research Organizations (CROs)  
CROs often receive samples from multiple customers worldwide, typically accompanied by high-level information like IDs and basic properties. BioRails MT™ allows CROs to register these samples, manage the delivery of testing services, and handle both fee-for-service work and integrated projects. CROs can manage the distribution of samples for testing across multiple sites. This transparency improves efficiency, reduces turnaround times, and enables the delivery of more services with the same resources.  
BioRails MT™ offers a robust solution for comprehensive material tracking and management, enhancing operational efficiency and precision in inventory control. The flexibility and integration capability make it an indispensable tool for organizations and CROs looking to optimize their workflows and ensure the accuracy and availability of their materials.  
  
Find Out More  
Contact Us  
  
  
  
   
  
BioRails INV™  
BioRails INV™ Efficient Inventory Control and Supply Management  
  
Comprehensive Inventory Management  
BioRails INV™ offers a comprehensive inventory system designed to support various operations, including in-house, externalized, and hybrid setups. It efficiently manages sample inventory across different locations, including sites, labs, fridges, and freezers. Containers such as microtiter plates, racks, and vials are registered and tracked with precision, ensuring accurate inventory control.  
Flexible Container Support  
The system supports both automated tube stores and traditional stores, catering to diverse storage needs. Whether it's automated storage solutions or conventional storage methods, BioRails INV™ seamlessly manages containers to meet the requirements of different laboratories and research facilities.  
Plate Preparation  
BioRails INV™ facilitates efficient plate preparation processes, including dilutions, stamps, and quad-mapping. This feature streamlines the preparation of assay-ready plates, reducing turnaround time and ensuring that project teams receive results faster. Whether handling solids or liquids, small or large molecules, BioRails INV™ ensures accurate and efficient plate preparation for various experiments.  
Stock Ordering and Receipt Operations  
Users can easily search current inventory stocks for powders or liquid samples and identify samples that fulfill assay needs. BioRails INV™ enables quick and efficient ordering operations, allowing users to place orders for sample delivery seamlessly. The system also supports tracking dispatch and receipt of samples from CROs, ensuring smooth logistics operations.  
Stock Reconciliation  
BioRails INV™ facilitates stock reconciliation operations, helping users reconcile stock differences efficiently. This feature ensures data accuracy and integrity, enabling users to maintain precise inventory records and minimize discrepancies.  
BioRails INV™ offers a powerful solution for managing sample inventory efficiently and effectively. With its comprehensive features for container tracking, plate preparation, stock ordering, and reconciliation, BioRails INV™ streamlines inventory management processes, enhances operational efficiency, and accelerates research workflows. Whether it's managing containers across different locations or preparing assay-ready plates, BioRails INV™ provides the flexibility and precision needed to optimize inventory control and supply management in pharmaceutical and biopharmaceutical companies.  
  
Find Out More  
Contact Us  
  
  
  
  
Workflow Solutions  
BioRails® Workflow Solutions  
  
To meet the dynamic needs of the drug discovery space, our solutions are designed to enhance efficiency, reliability, and flexibility in your research processes. These workflow solutions deliver optimized assay planning and execution within BioRails and Morphit, accelerating deployment and ensuring best practices are adopted.   
Features of BioRails Workflow Solutions  
Clear: Our workflows come fully documented, ensuring that every step is transparent and easy to follow.   
Ease of Use: With instruction-driven designs, our solutions are user-friendly, enabling seamless adoption by your team.   
Reliable: Each workflow is scientifically validated to provide consistent and accurate results.   
Straightforward: Consistent design principles make our workflows intuitive, reducing the learning curve for your team.   
Versatile: Our solutions easily adapt to different instruments and experimental setups, providing unparalleled flexibility.   
Flexible Integration: Whether you need a standalone solution or something that integrates seamlessly with existing systems, our workflows are designed to fit your needs.   
Comprehensive Assay Support:  
 A wide range of assays critical to drug discovery, including but not limited to:   
  
LogD   
Solubility   
BBB (Blood-Brain Barrier)   
Partitioning   
Permeability   
Stability   
Clearance   
Binding   
Enzyme Inhibition and Activation  
  
Advanced Assay Planning:  
 Robust assay planning capabilities, ensuring that your experiments are not only executed efficiently but also strategically planned for optimal outcomes.   
  
Prep Assay & Analysis plates (robotic worklists)   
Pre and post-Assay cassette support   
Generate batch files for MS  
  
BioRails Workflow Solutions  
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In Vitro Pharmacology  
In Vivo PK  
Bioanalysis  
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Improving Discovery Research Workflow: Streamline, Optimize, and Innovate Your Research and Data Management.  
  
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Discovery Overview  
  
  
BioRails  
  
  
BioRails InLife  
  
  
Morphit  
  
   
BioRails® Modules  
BioHub™: Consolidate corporate knowledge into a single, accessible store, ensuring organized and readily available information.  
BioRails PTO™: Enhance project tracking and optimization with tools for streamlined and precise project management.  
BioRails DM™: Simplify data management with tools that ensure consistency and reliability in research data.  
BioRails MT™: Register and manage biospecimens, biologics, and formulations with seamless tracking and utilization of materials.  
BioRails INV™: Optimize inventory control with efficient systems for ordering and tracking resources.  
BioRails InLife™: Boost productivity in the vivarium with tools for streamlined treatment and harvesting tasks.  
  
  
Features for Security and Efficiency: Created by Scientists for Scientists  
Role-based Security Model: Implement a robust security model with differentiated access rights for enhanced protection.  
Authorization and Authentication: Ensure data protection with strong authorization and authentication mechanisms.  
Team and Project Support: Enable seamless project tracking and information sharing with support for teams and real-time collaboration.  
Terms and Terminology Support: Manage pharmaceutical research data with chemically aware terminology support.  
Quantity Model (Unit Handling): Handle various units of measurement with precision and scalability.  
Content Management: Audit-friendly content management that tracks information accurately, consolidates data, and provides rich visualization and integrated tools.  
Streamline Workflows: Automate complex workflows to ensure process consistency and scalability. Handle large data volumes uniformly, maintaining quality and integrity while reducing workload and errors.  
Automate Data Collection: Minimize manual effort and reduce human error in data collection with automation tools. Free up time for critical activities by automating repetitive tasks.  
BioRails® supports both structured experimentation and the integration of unstructured results into a structured environment. It empowers scientists with efficient data exploitation through advanced reporting and analysis tools, reducing the time needed to analyze data and draw conclusions.  
  
BioRails®  
  
BioHub™  
BioHub™ Scalable Data Solution  
  
Data loading and storing all assay results in a single database for ready decision-making.  
Unified Data Repository  
BioHub™ serves as a comprehensive data store, consolidating data from various sources into one centralized location. This eliminates the inefficiencies of fragmented data storage and provides a single point of access for all your data needs.  
Robust Data Loading Mechanisms  
BioHub™ supports diverse data loading methods, enabling seamless integration for both external CROs and internal teams. This ensures efficient data posting and minimizes the risk of data silos.  
Rigorous Data Validation  
All incoming data is meticulously validated against corporate standards and ontologies. BioHub™ ensures only high-quality, compliant data is published to the corporate data warehouse, maintaining data integrity and reliability.  
Versatile Deployment Options  
BioHub™ offers flexible deployment solutions, either in the cloud or on-premise. This adaptability allows organizations to choose the setup that best fits their infrastructure and security requirements.  
Assay Registration and Results Upload  
BioHub™ supports the registration of assays based on formally managed terminology and ontologies. Its user-friendly web interface facilitates the uploading of results from a wide range of assays, from high-throughput screening (HTS) to complex in vitro and in vivo assays.  
Integration with Leading Analytics Tools  
BioHub™ integrates seamlessly with top HTS data analytics software, enabling large datasets to be published directly. This integration reduces the time and errors associated with manual file manipulations.  
Secure Access for CROs  
BioHub™ provides secure access for Contract Research Organizations (CROs) to upload and exchange results. This secure sharing capability enhances collaboration and data exchange efficiency.  
Scalability for Growing Organizations  
Combined with BioRails Warehouse, BioHub™ scales effortlessly to meet the needs of organizations of any size. It can absorb data from numerous sources, creating a robust and scalable resource of results.  
Compatibility with Advanced Informatics Tools  
The data stored in BioHub™ can be easily accessed and utilized by most scientific data informatics tools. This compatibility provides an ideal foundation for data scientists to develop AI algorithms based on corporate knowledge.  
BioHub™ revolutionizes data management by providing a scalable, centralized, and compliant data store. Its robust data loading mechanisms, rigorous validation processes, and flexible deployment options make it the ideal solution for organizations looking to enhance their data consolidation and analysis capabilities. With seamless integration into leading analytics tools and secure access for CROs, BioHub™ ensures that high-quality data is always at your fingertips, empowering data-driven decision-making, and innovation.  
  
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BioRails PTO™  
BioRails PTO™ Project Tracking and Optimization  
  
A service request and planning tool that enhances discovery research by streamlining assay workflows, improving collaboration, and reducing cycle times.  
Service Definition  
BioRails PTO™ allows you to define a variety of services that can be requested, ensuring all necessary details are captured. These services can represent assays, studies, or general services and are based on item types such as compounds, batches, animals, or instruments. This detailed service definition ensures that requesters have all the information they need to accurately specify their requirements.  
Assay Requesting  
Project teams can easily submit assay requests for published services using BioRails PTO™. This streamlined requesting process ensures that all requests are comprehensive and consistent, reducing errors and facilitating efficient project execution.  
Planning and Scheduling  
Submitted assay requests are consolidated into organized 'Todo lists', allowing planners to allocate items into execution units such as runs, experiments, or studies. BioRails PTO™ provides tools for scheduling start times and allocating personnel, ensuring optimal resource utilization and project timelines.  
Inventory Integration  
When integrated with BioRails INV, planners can evaluate stock levels while requesting assays. This integration allows them to request assay-ready plates from compound management teams, ensuring that all necessary materials are available for seamless execution.  
Cascade  
BioRails PTO™ enables the definition of cascades of assays, organized into multiple tiers. Each tier generates results that can be automatically evaluated using predefined rules to promote compounds to the next level of assays. This feature allows you to track and monitor progress efficiently, reducing cycle times and accelerating the time to market for new treatments.  
BioRails PTO™ offers a comprehensive suite of tools for assay requesting, planning, and cascading. Its intuitive interface and automated features streamline workflows, enhance collaboration, and ensure high-quality results. Whether you're a scientist requesting assays or a service provider managing multiple projects, BioRails PTO™ provides the precision and efficiency needed to drive your discovery research forward, reducing cycle times and bringing innovative treatments to market faster.  
  
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BioRails DM™  
BioRails DM™ Advanced Data Management Solutions  
  
A data management solution that streamlines data capture, processing, and analysis through a workflow-driven approach, integrating advanced analytics and reporting to transform raw data into actionable insights.  
Structured Data Management  
BioRails DM™ provides an effective platform for comprehensive data management, enabling organizations to implement the highest standards in the field. It supports both structured data capture (results) and unstructured data (observations and interpretations), ensuring all aspects of your data are managed efficiently. Define experimental workflows that combine data capture processes with structured data storage and powerful data analytics templates using Morphit.  
Workflow-Driven Coordination  
BioRails DM™ coordinates activities across multiple departments, internally and with partners and CROs. It enables the definition and execution of high-level workflows addressing various data types captured during scientific experiments. The platform uses analytical templates to drive laboratory workflows, generating plate maps, injection lists for Mass Spectrometers, robotics instruction files, and other experimental artifacts. It reads and analyzes instrument files from fluorescence readers, Mass Spectrometers, and many other types of instruments.  
Knowledge Capture and Protection  
Avoid the need to print data into PDFs and protect your knowledge efficiently. BioRails DM™ includes a 21 CFR Part 11 compliant notebook for writing up experiments, complete with electronic signatures and witnessing. This ensures your data is securely captured and easily retrievable for future reference.  
Advanced Analytics  
Apply statistics, curve fitting, and other analytical techniques to transform raw data into meaningful results. BioRails DM™ allows for the application of advanced quality control criteria within and across experiments to ensure data quality. Search and analyze results across studies to extract valuable knowledge and understanding.  
Documentation and Reporting  
Create documentation templates for study reports, quality reports, certificates of analysis, and various other types of reports. BioRails DM™ allows you to generate high-quality documentation at the press of a button, combining data, results, charts, graphs, and images from within or across experiments. This feature saves hours of time in compiling and formulating documentation.  
Electronic Signatures and Compliance  
BioRails DM™ supports electronic signatures and witnessing as part of its CFR 21P11 compliance effort. This ensures that all data and processes meet regulatory standards, providing peace of mind and reliability.  
Bulk Data Loading  
Load results from CROs and internal teams using bulk loading tools, building extensive databases with hundreds of millions of results. This capability supports the efficient management of large datasets, essential for high-throughput environments.  
Industry Focus  
While BioRails DM™ can address many data capture processes, it is particularly focused on the following areas:  
  
In vitro Drug Metabolism  
In vivo Pharmacokinetics  
Bioanalysis  
In vitro Pharmacology (Screening)  
  
Integration and Compatibility  
BioRails DM™ includes Morphit and is compatible with InLife, ensuring seamless integration with existing systems and enhancing overall functionality.  
BioRails DM™ is a robust data management solution that transforms how organizations handle data capture, processing, and analysis. Its workflow-driven approach ensures data, processes, and insights are secured and managed in one place, promoting efficiency and compliance. By integrating advanced analytics, secure data capture, and comprehensive reporting, BioRails DM™ transforms raw data into actionable insights, driving informed decision-making and accelerating research and development.  
  
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BioRails MT™  
BioRails MT™ Comprehensive Material Tracking and Management  
  
A material tracking and management solution supporting the registration of test articles, controls, standards, and assay reagents.   
Material Registration  
BioRails MT™ is designed to support organizations conducting a wide variety of research and development activities. While traditional systems manage specific entities like compounds, lots, proteins, and antibodies, BioRails MT™ extends this capability to a broader range of materials. It integrates with existing compound and biological registration systems, supporting the entire Request-Plan-Test cycle. This includes materials generated during in vivo studies, such as plasma, blood, tissues, and formulation samples, which are often not formally managed by other systems.  
Comprehensive Material Management  
With BioRails MT™, organizations can register and manage various materials, tracking their properties and leveraging the BioRails Request-Plan-Test workflow. This system also keeps track of the quantity and location of samples, ensuring that all materials are accounted for and easily accessible when needed.  
Support for Contract Research Organizations (CROs)  
CROs often receive samples from multiple customers worldwide, typically accompanied by high-level information like IDs and basic properties. BioRails MT™ allows CROs to register these samples, manage the delivery of testing services, and handle both fee-for-service work and integrated projects. CROs can manage the distribution of samples for testing across multiple sites. This transparency improves efficiency, reduces turnaround times, and enables the delivery of more services with the same resources.  
BioRails MT™ offers a robust solution for comprehensive material tracking and management, enhancing operational efficiency and precision in inventory control. The flexibility and integration capability make it an indispensable tool for organizations and CROs looking to optimize their workflows and ensure the accuracy and availability of their materials.  
  
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BioRails INV™  
BioRails INV™ Efficient Inventory Control and Supply Management  
  
Comprehensive Inventory Management  
BioRails INV™ offers a comprehensive inventory system designed to support various operations, including in-house, externalized, and hybrid setups. It efficiently manages sample inventory across different locations, including sites, labs, fridges, and freezers. Containers such as microtiter plates, racks, and vials are registered and tracked with precision, ensuring accurate inventory control.  
Flexible Container Support  
The system supports both automated tube stores and traditional stores, catering to diverse storage needs. Whether it's automated storage solutions or conventional storage methods, BioRails INV™ seamlessly manages containers to meet the requirements of different laboratories and research facilities.  
Plate Preparation  
BioRails INV™ facilitates efficient plate preparation processes, including dilutions, stamps, and quad-mapping. This feature streamlines the preparation of assay-ready plates, reducing turnaround time and ensuring that project teams receive results faster. Whether handling solids or liquids, small or large molecules, BioRails INV™ ensures accurate and efficient plate preparation for various experiments.  
Stock Ordering and Receipt Operations  
Users can easily search current inventory stocks for powders or liquid samples and identify samples that fulfill assay needs. BioRails INV™ enables quick and efficient ordering operations, allowing users to place orders for sample delivery seamlessly. The system also supports tracking dispatch and receipt of samples from CROs, ensuring smooth logistics operations.  
Stock Reconciliation  
BioRails INV™ facilitates stock reconciliation operations, helping users reconcile stock differences efficiently. This feature ensures data accuracy and integrity, enabling users to maintain precise inventory records and minimize discrepancies.  
BioRails INV™ offers a powerful solution for managing sample inventory efficiently and effectively. With its comprehensive features for container tracking, plate preparation, stock ordering, and reconciliation, BioRails INV™ streamlines inventory management processes, enhances operational efficiency, and accelerates research workflows. Whether it's managing containers across different locations or preparing assay-ready plates, BioRails INV™ provides the flexibility and precision needed to optimize inventory control and supply management in pharmaceutical and biopharmaceutical companies.  
  
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Workflow Solutions  
BioRails® Workflow Solutions  
  
To meet the dynamic needs of the drug discovery space, our solutions are designed to enhance efficiency, reliability, and flexibility in your research processes. These workflow solutions deliver optimized assay planning and execution within BioRails and Morphit, accelerating deployment and ensuring best practices are adopted.   
Features of BioRails Workflow Solutions  
Clear: Our workflows come fully documented, ensuring that every step is transparent and easy to follow.   
Ease of Use: With instruction-driven designs, our solutions are user-friendly, enabling seamless adoption by your team.   
Reliable: Each workflow is scientifically validated to provide consistent and accurate results.   
Straightforward: Consistent design principles make our workflows intuitive, reducing the learning curve for your team.   
Versatile: Our solutions easily adapt to different instruments and experimental setups, providing unparalleled flexibility.   
Flexible Integration: Whether you need a standalone solution or something that integrates seamlessly with existing systems, our workflows are designed to fit your needs.   
Comprehensive Assay Support:  
 A wide range of assays critical to drug discovery, including but not limited to:   
  
LogD   
Solubility   
BBB (Blood-Brain Barrier)   
Partitioning   
Permeability   
Stability   
Clearance   
Binding   
Enzyme Inhibition and Activation  
  
Advanced Assay Planning:  
 Robust assay planning capabilities, ensuring that your experiments are not only executed efficiently but also strategically planned for optimal outcomes.   
  
Prep Assay & Analysis plates (robotic worklists)   
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In Vitro Pharmacology  
In Vivo PK  
Bioanalysis  
BioRails Workflow Solutions: Bridging Innovation and Application in Drug Discovery  
  
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Enhancing Productivity and Accuracy for the Vivarium  
  
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BioRails  
  
  
BioRails InLife  
  
  
Morphit  
  
   
Experience the future of in vivo studies with BioRails InLife™  
A productivity tool for vivarium scientists that enhances in vivo study execution by providing precise study design, workstation planning, seamless instrument integration, and real-time updates.  
Study Design  
BioRails InLife™ collaborates seamlessly with BioRails DM to assist vivarium staff in accurately preparing, treating, and harvesting samples during in vivo studies. Design single-dose, multi-dose, and other complex in vivo study designs effortlessly, ensuring precision and reliability in study execution.  
Workstation Planning  
Register workstations equipped with connected instruments like balances and RFI scanners to facilitate direct data capture, eliminating the need for transcription and reducing errors. Distribute studies across multiple sites and vivariums efficiently, ensuring optimal resource allocation and timely execution of study activities.  
Instrument Integration  
Utilizing the latest IoT technology, BioRails InLife™ seamlessly integrates with instrumentation to capture measurements such as body weight and syringe weights without manual transcription. This hands-free data capture saves time, increases accuracy, and ensures precise dosing and recording of sample times.  
Real-Time Updates  
Transform study designs into accurate and flexible treatment and harvesting schedules that update in real-time. This feature enables vivarium teams to increase productivity, reduce stress, and enhance the accuracy and quality of in vivo studies by ensuring the right subject receives the right treatment at the right time. InLife is a productivity tool for vivarium scientists that helps them execute in vivo studies accurately.  
From precise study design and workstation planning to seamless instrument integration and real-time updates, BioRails InLife™ enhances efficiency and accuracy throughout the study process. By seamlessly integrating with BioRails DM and BioRails INV, all data is accurately recorded and tracked, ensuring a streamlined workflow from study design to result elaboration. With BioRails InLife™ elevate your in vivo studies to new levels of precision and productivity.  
  
  
  
  
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Empowering Pharma Research with Advanced Data Tools  
  
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BioRails  
  
  
BioRails InLife  
  
  
Morphit  
  
   
Unique Data Application  
Morphit merges the functionality of spreadsheets, databases, and analytical tools into a single, cohesive platform. This unique combination makes Morphit exceptionally powerful and versatile, catering to a wide range of tasks such as assay template definition, planning, plate preparation, reporting, automation, and study design.  
Powerful Data Analytics  
Morphit empowers scientists with robust features for reading, analyzing, and interacting with data. It seamlessly integrates with various data sources, including reader files, mass spectrometer outputs, and fluorescence instruments, using a configurable import definition tool that shields users from instrument changes. With Morphit, users can automatically apply statistics, summarize data, visualize results in interactive charts and graphs, and perform curve fitting with ease.  
Advanced Modelling  
Designed for scientists, Morphit offers advanced tools for curve fitting, statistics, and non-compartmental analysis, particularly useful for pharmacokinetics studies. Scientists can effortlessly calculate key PK parameters such as AUC, half-life and more all within the Morphit platform, removing the need for additional expensive, dedicated software.  
Flexible Reporting  
Create publication-quality report templates and generate standard documentation seamlessly within Morphit. Whether designing management reports like Key Performance Indicators or producing detailed study reports, Morphit streamlines the reporting process, saving time and ensuring consistency in documentation.  
  
  
Versatile Usage  
Morphit is utilized across a broad spectrum of assays, including in vivo pharmacology, in vivo PK, in vitro pharmacology, DMPK/ADME, and inventory and sample preparation. Its adaptability makes it an indispensable tool for various research applications in the pharmaceutical industry.  
Morphit revolutionizes data analysis in pharmaceutical research, offering a comprehensive suite of tools to streamline workflows, drive insights, and accelerate discoveries. From unique application capabilities to powerful data analytics, advanced modelling, and flexible reporting features, Morphit empowers scientists to harness the full potential of their data across a wide range of assays.   
  
  
  
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Applying computational approaches for solving today's biological problems  
  
  
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Life Science organizations continue to face the challenge of developing products that are safe, effective, and financially feasible.  
Biochemists and life scientists have been inundated with data from the Human Genome Project, high throughput screening, protein interactions, expression studies and more. This information is organized in many different databases, some highly structured, others in free text.  
Answers to valuable scientific questions often reside in a range of data sources, in different file and data formats, internal and external to an organization. At Instem Scientific, we have many years’ experience in developing tools for extracting and combining the relevant information from carefully-chosen sources, and distributing it to specialist applications for maximum insight.   
Our highly configurable file and information management platforms provide “big data” scale environments for identifying, capturing and integrating data sources. Fundamental to our philosophy is the idea of data re-modelling, in which data captured for one application is repurposed to serve another. This is made possible through our approach based on NoSQL and SQL technologies combined with experience of structured and graph-based designs.   
  
  
  
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Instem is helping to solve the problem of large-scale bioinformatics and genomics data integration  
  
  
  
Harnessing insight from an extensive collection of public and private sources has allowed researchers at companies like AstraZeneca, Johnson & Johnson, Merck and Abbott to gather information about their targets during program development, find patterns in their research data, and put their own results into a broader scientific context to predict likely outcomes.   
Using our bioinformatics toolset, another Instem client will now be able to access, integrate and query preclinical SEND data being created from their own preclinical data collection system as well as SEND data received from their external study partners. This cross-study search and browsing capability will enable them to identify patterns and trends in their data, generating new knowledge and actionable insight.  
The re-utilization of scientific data has never been more important. Instem Scientific’s solutions have been designed for clients to leverage large volumes of public and proprietary historic data that deliver true Bio-wisdom, enabling them to create additional value from prior research using consolidated healthcare intelligence.  
  
  
  
An informatics-based service for investigating safety concerns in drug development  
Find out more  
  
  
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Bioinformatics  
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Genetic Toxicology  
Image analysis and data management solutions helping users better collect, manage, review and extract data while transitioning information into insight.  
  
  
In this section  
  
Genetic Toxicology Overview  
  
  
Cyto Study Manager  
  
Comet Assay IV  
  
  
Sorcerer Colony Counter  
  
   
Genetic toxicology is the scientific discipline dealing with the effects of chemical, physical and biological agents on the genetic material of living organisms. Genotoxicity assessment, also known as genetox testing, is an essential aspect of product development. Genetox information is used to help R&D organizations make important drug discovery and regulatory decisions and can identify potential biological hazards.  
Global Dominance...  
Our solutions for genetox testing are used by global contract research organizations, and the top 10 pharmaceutical companies worldwide. Our products also serve universities, research institutes, and government programs in over 50 countries, including the National Center for Toxicological Research (NCTR), a Food & Drug Administration (FDA) division.  
  
  
  
Why Choose Us?  
With nearly 30 years industry experience, we know that a well conducted study is vital for robust data that can be accepted by international regulators. Our solutions enable users to conduct their research safe in the knowledge that their results will be accurate and that encoded audit trail files will automatically record all system activity, including settings, measurement data and edits.  
We believe in providing a professional and responsive service based on in depth applications knowledge and expertise. We are committed to building long term mutually beneficial relationships with our clients, which is evidenced by our long track record and customer references.  
  
  
   
What Now?  
Browse our comprehensive suite of Genetic Toxicology solutions that are helping clients around the world make the process of acquiring, managing and reporting genetox assay data as simple and secure as possible and contact us to learn how we can help you deliver results sooner!   
   
  
  
  
  
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Our Products in this area  
  
  
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Data acquisition and reporting for genetic toxicology assays  
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Preclinical  
Powerful software solutions enabling organizations of all sizes to collect, manage, review and submit research data that streamline processes, increase quality and enhance development programs.  
  
  
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Preclinical Overview  
  
  
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The preclinical stage of drug development requires the application of rigorous scientific standards and expertise to effectively advance drug candidates from the laboratory to clinical trials.  
For more than 40 years, Instem’s comprehensive preclinical software solutions have enabled clients to determine the safety of life-changing compounds while assisting them in bringing products to the marketplace as rapidly as possible.  
Keeping Pace ...  
Today, organizations within the Life Sciences are experiencing many challenges including soaring costs, squeezed margins and mounting regulatory pressures. And, the relentless drive for R&D productivity is at an all-time high.  
Instem preclinical solutions keep our clients focused on their science, not their software. From the NIH to GSK - from MD Anderson to SRI International - from WuXi AppTec or Charles River Laboratories to our single-user Pathologist accounts reading slides - Instem technology is on the leading edge to ensure all of our clients keep pace with their scientific demands while delivering intuitive and agile systems designed for today’s research environment. It’s a careful balance, but by working closely with our clients we are successfully delivering powerful solutions scaled perfectly to meet their needs today while remaining adaptable to their requirements tomorrow.  
  
  
  
“This type of innovation, combined with our immediate gains of heightened efficiency, allows us to respond even faster to our clients, with quality results.” Dr. Jean-Francois Le Bigot, President & CEO of CiToxLAB  
  
  
  
Our leadership position within the preclinical segment is built on a solid history of inspired, focused innovation and an unrelenting determination to deliver exceptional value and return to our customers. The unrivalled scale and experience of our team ensures that we deliver not just the leading preclinical products, but it ensures every organization of any size will see immediate and easy-to-measure efficiency gains.  
What Now?  
We invite you to review our wide range of preclinical solutions that clients around the world use to plan, design, execute, analyze and document their research programs and findings throughout all phases of preclinical development. Then, take that next step of contacting us today for a no-pressure practical discussion about how we can come alongside you to help streamline and accelerate your activities.  
  
Our Products in this area  
  
  
Integrated system for organizations engaged in non-clinical evaluations  
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Replace GLP & Non-GLP Paper Data!  
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The leading software platform for the acquisition, display and analysis of physiological signals  
Find out more   
  
  
The most comprehensive and widely deployed set of tools and services supporting SEND  
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Uniquely simplifying the QC review and exploration of SEND datasets all in one place  
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BioRails InLife  
  
  
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Drug discovery involves identifying and characterizing molecules that can safely treat diseases, aiming to develop medicines that improve patients' lives. This process is lengthy, resource-intensive, and requires collaboration across multiple disciplines. Only about 14% of drug candidates entering phase 1 clinical trials gain FDA approval, and successful ones take 10-15 years and around $2.5 billion to develop.   
Despite increased R&D spending, the number of approved drugs has not risen proportionally, requiring higher investment per approved drug each year. Optimizing drug discovery is crucial for the pharmaceutical industry, as efficient identification and selection of drug candidates significantly impact the cost and profitability of new medicines. This can be achieved through a multipronged approach, enhancing modeling technologies for a deeper understanding of disease mechanisms and more accurate identification of potential drug targets.  
  
  
  
  
Our Position...  
Instem’s Discovery Study Management is made up of following functions:  
  
Support - supporting our customers and the consultants working with them  
Product Management - defining the strategy and roadmap for our product line  
Product Delivery - engineering and testing the products  
Project Delivery - bridge the gap between what our customer needs and what we offer. It includes:  
  
Business analysis  
Configure the platform to optimize the benefits  
Prepare and deliver planning and analysis templates  
Training and rollout services  
  
  
BioRails is a platform product suite made up of the following product modules and applications:  
BioRails Modules  
  
PTO - requesting and planning studies  
DM - workflow-driven data management  
INV - inventory of samples consumed and generated  
MT - material registration  
BioHub - tools to load and aggregate data into a warehouse  
  
Applications  
  
InLife - managing vivarium activities  
Morphit - a workflow productivity tool for data capture, analysis, and reporting  
  
Our customers consider BioRails a critical piece of their data infrastructure. With more than 2500 users in 21 organizations, we are on a mission to save one day per week per scientist for our clients.   
  
  
  
Accelerating Drug Discovery  
Find out more  
  
  
Improving Vivarium Productivity  
Find out more  
  
  
Empowering Pharma Research with Advanced Data Tools  
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About Instem  
Powerful Solutions • Unique Perspective • Global Coverage  
Instem provides advanced and best-in-class IT solutions to the global health and life sciences community which improves the productivity of their processes in the discovery and development of new drugs, therapies and products.  
Our Unique Strengths include:  
  
Decades of success supporting the life sciences  
The most experienced business, scientific, regulatory and technology staff  
Commanding market share  
Scalable solutions for clients of all sizes  
Global coverage and regional support  
Client satisfaction rates well beyond the norm  
  
Learn more about what we do  
We help clients collect, analyze, report and submit data to regulatory agencies with confidence while helping them reveal new insights from public and proprietary data  
  
  
  
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Partnering with Instem  
By partnering with Instem you will be gaining access to a community of world-leading universities, research institutes, drug development companies and government research agencies who are constantly turning to Instem to help satisfy unfulfilled scientific and business needs.   
Additionally, our strong sales, marketing and general management support coupled with our leadership position in our core markets can open up significant avenues of new revenue streams for your product or service.  
  
 The objectives of our partner programs are to help us accelerate product adoption and market penetration, streamline vendor relationships and simplify lines of communication, providing clients with a single point of contact and a consistent level of world-class service.  
Track Record of Growth & Success  
We have embarked upon a transformational program to increase our addressable market by expanding our reach into adjacent areas of R&D while further growing within our primary market segments.  
Come join our mission to help and enhance life  
 The type of arrangements and opportunities can vary, but typical options for alliance include:  
  
Distribution of Instem products   
The providing of consultancy  
Instem’s distribution of your products/services  
Integration projects  
New solution development & go-to-market launches  
Co-development projects  
  
Learn more about the power of partnership and how we may align our efforts to generate new opportunities while further helping our collective clients   
Contact us today about becoming an Instem strategic Partner at: partner@instem.com  
   
  
  
  
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Instem Worldwide  
Founded in the United Kingdom over 40 years ago, Instem continues to have deep roots in the region and with the over 60% of Life Sciences R&D undertaken in North America, Instem has maintained a substantial presence there for over 25 years.  
We began formally expanding into the Asia-Pacific life science markets during 2005 and through strong commitment and focus we have become the leading provider of its kind within each region.  
China   
As the first western toxicology/pathology software supplier to enter the Chinese market, Instem officially deployed its first China-based system in one of the largest and most advanced vivariums during 2006. Acknowledging analyst projections that China was on pace to becoming the second largest pharmaceutical market in the world, Instem established a full-service office in Shanghai, recruited local staff and has localized its product suite into Mandarin Chinese. Instem is supporting international organizations and domestic laboratories exclusively serving China using on-site systems as well as our SaaS delivery model from a professionally managed data center based in Shanghai.  
Visit our China site at www.instem-china.cn  
India   
Demand for regulatory toxicology services has grown within India in recent years, fueled by the internal investments of Indian pharmaceutical and chemical companies, the addition of India within the OECD Mutual Acceptance of Data program and the demand from elsewhere in the world for high-quality, cost-effective non-clinical services. Instem entered the early drug development market in India in 2005 with its first customer, Advinus Therapeutics, to help them enhance client services, attract western business and support Good Laboratory Practices. Since that time, organizations within India continued looking for world-class solutions and have turned to Instem to support the automation of critical laboratory processes to further improve productivity while ensuring regulatory compliance in and around drug discovery & development research programs.  
During 2012, Instem further demonstrated its commitment to the region through the establishment of an office in Pune. Since then, the Pune office footprint has doubled in size and resources have tripled. The office employs staff across Product Development, Testing and Customer Support, with an active recruitment program currently in place.  
  
   
  
Japan  
During 2005 when Instem officially entered the Japanese market, the life sciences IT sector had been making investments to modernize, and in many cases to replace their existing systems and processes. This was primarily due to growing regulatory requirements, the need to provide higher levels of efficiencies and for globalization. Organizations in Japan required access to fully proven software solutions that offered intuitive interfaces to help reduce the amount of customization normally associated with Japanese systems. Since that time, Instem has expanded its range of technology offerings and opened an office in Tokyo to help meet demand for its products & services. Today, leading organizations of all sizes throughout Japan rely on Instem solutions to help them plan and execute critical research & development programs.  
Visit our Japan site at jp.instem.com  
Instem technology can also be found hard at work at client sites in:  
  
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Executive Team  
Instem’s international Executive team is a strong, effective and flexible group that understands and is committed to the values and vision of our business. Our team is entrepreneurial in spirit and possesses strong go-to-market skills providing leadership in Product Development, Marketing and Sales along with proven experience in Strategic Partnering and M&A activities.  
  
  
  
Phil Reason\*  
Chief Executive Officer  
Phil has been leading Instem as CEO since 1995, working closely with the Instem Board, investors, management, clients, partners and staff to grow the business from a single product line with fifteen clients to serving hundreds of customers as the global market leader across a wide area of life sciences R&D. Passionate about Instem’s ability to support clients in introducing transformational approaches for life changing therapies, Phil has been a vocal advocate of long-term partnerships, innovative organic growth, geographic expansion and the acquisitive consolidation of the fragmented IT supplier community. Under Phil’s leadership Instem has completed the strategic acquisition of 9 companies, has opened new offices in the US, UK, China, and India and has completed a UK-based IPO in 2010.  
Gordon Baxter BSc, PhD  
 Chief Scientific Officer   
A pharmacologist, Gordon has held several senior discovery positions in major pharmaceutical companies and was a founding entrepreneur of the CRO, Pharmagene plc. and held positions of Chief Scientific Officer and Chief Operating Officer. He was also a founder of the UK-based healthcare intelligence company, BioWisdom Ltd which was acquired by Instem in 2011. He has a track record of innovation in drug discovery and has contributed to the development of several marketed drugs. He is an advocate of Translational Informatics; using data gathered from research, development and medical practice to generate new therapeutic insights. Gordon is on the Board of the R&D information technology group, the Pistoia Alliance.   
Eve Leconte  
Chief People & Culture Officer  
As Chief People & Culture Officer, Eve oversees all strategic and operational people-based activity across Instem’s global locations. Eve is responsible for driving organizational performance and business results by optimizing employee engagement and effectiveness, leadership development, performance management, employee development and talent acquisition.   
 Eve has over 15 years’ Human Resources experience, predominantly in fast growing organizations in a variety of sectors including agrochemical, medical device and IT. She has extensive experience of helping organizations to achieve their corporate goals by delivering the strategic and operational visions of HR both nationally and internationally. Eve is well versed in Trade Union liaison, including successful negotiation of numerous complex agreements. Prior to joining Instem, Eve founded her own HR consultancy, helping start-up companies to create HR departments to support their growth aspirations.   
Mark Poggi PhD, MBA  
Executive Vice President, Global Sales  
Mark joined Instem in 2023 to lead our global sales group and is extensively trained in Solution & Diagnostic selling. Mark is adept at designing and executing sales strategies backed by his strong scientific background. Mark holds a PhD in analytical chemistry, an MBA and has a strong interest in data science and artificial intelligence. Well versed at building high performing teams, Mark is especially passionate about helping other leaders reach their fullest potential. Offering over 15 years of proven experience leading highly technical teams in consultative selling, Mark helps ensure that our solutions are meeting the rapidly expanding needs of our clients for better data-driven decision making.  
\*Board member  
Board of Directors  
John Leveille  
Executive Vice President, Clinical Trial Analytics  
John Leveille was formerly the Co-Founder and CEO of D-wise which was acquired by Instem. He now heads up the Clinical Trial Analytics business unit as Executive Vice President. John has over 20 years of experience in software design and development. As a lead developer at SAS, he was a pioneer in connecting SAS technology with emerging Internet business models, bringing the power of analytics to web applications across a wide variety of businesses. John was awarded two software patents for innovative solutions developed while at SAS. In the early 2000’s he embarked on a consulting career, helping clients to understand and apply technology to their businesses, eventually focusing on the Life Sciences arena.   
Gregor Grant  
 Executive Vice President, Study Management Solutions  
Gregor is an experienced leader with a proven track record of success in developing customer relationships and delivering IT solutions for the Life Sciences Industry. Gregor is passionate about ensuring the exceptional client experience and his team provides development, deployment and support services to Instem’s Preclinical Solutions clients around the world, including products from the acquisition of Perceptive Instruments in 2013. Gregor joined Instem through an acquisition of Apoloco in 1996, a smaller competitor specializing in pathology solutions. For over 20 years Gregor has been instrumental in helping create both a successful software product, and building a reputation for high quality and service within a passionate and demanding user community.   
Mike Harwood   
 Chief Product Officer  
Mike joined Instem in 1999 through the acquisition of Fraser Williams Data Systems where he was a Director overseeing Client Services. While most of Mike’s more recent experience has been in the deployment of regulatory preclinical solutions, since 1977 he has worked on applications across the R&D continuum from early stage chemical databases to late stage clinical trials systems. Mike joined the SEND standard development team back in 2003 providing key input and was pivotal in bringing the first commercial SEND software solution to market in 2005. Mike now leads a team of industry experts supporting the most comprehensive and widely deployed set of tools and services for SEND in today’s global marketplace.  
Joel Hooper  
 Chief Operating Officer  
As Chief Operating Officer, Joel is accountable for the effectiveness of Instem’s core value streams encompassing product and services design, development, delivery and support, and how these come together in delivering exceptional experiences and value for our clients. Joel is a customer- and commercially-oriented COO, who is seasoned in aligning operations processes and practices around innovation in service of customer and business value creation.  
 Joel has held numerous operations leadership roles in the life sciences sector as well as in cross-sector product and services companies. Joel was formerly COO of the regenerative services and software company JET Group, Operations Director at Faculty AI, and worked for 9 years at IQVIA in global operations and services delivery roles. Joel is a founding member of the regenerative collective, North Sea Thriving and holds a PhD in molecular and cellular biology from the University of London.  
   
  
  
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Interested in joining the team?  
Our strength is made possible by the dedication of our staff, a team of highly respected professionals with deep experience in providing ground breaking software solutions to the life sciences. They are the reason that we have become such a significant voice in the Industry. Their levels of commitment and expertise translate directly into a faster return on investment for our customers.  
Are you ready to be challenged?   
Are you ready to take that next step in your career?  
Contact us today at careers@instem.com  
Benefits & Extras  
Instem is proud to offer all of its employees some of the best benefits around.  
 Depending on your location, some of them include:  
  
Life, medical, drug & vision coverage  
Generous retirement plans  
Flexible work hours  
Pro-rated and immediate vacation days  
Discretionary remote work environments (telecommuting)  
Ongoing training and development  
  
Internships  
Looking to gain experience while in school? Contact us today to learn more about how you can join our exciting mission.  
Send an email and your area of interest to: intern@instem.com  
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An Equal Opportunity Employer. All qualified applicants will receive consideration for employment without regard to race, color, religion, sex, sexual orientation, gender identity, national origin, or protected veteran status and will not be discriminated against on the basis of disability.  
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What we do...and why we're the best  
We help our over 700 international clients efficiently access, capture, analyze, report and submit high quality regulatory data, while maintaining compliance for their products around the world. This is combined with our unique ability to generate new knowledge through the extraction and harmonization of public and proprietary sources of actionable scientific information.  
For the more than 700 clients around the world, we are supplying breakthrough technology and services that help them efficiently access, capture, manage and enrich a wide array of data while generating new insight to advance their mission.   
Instem clients experience measurable benefits such as:  
  
Greater confidence in the safety and efficacy of their product portfolio  
Shorter R&D cycles with reduced costs  
Better management controls  
Increased regulatory compliance  
More effective resource utilization with greater staff satisfaction  
Happier and healthier clinical subjects  
Enhanced care and reduction of animal usage  
  
As a result, we enjoy a greater than 98% client retention rate – a statistic that we believe is the true measure of our success. More than just another IT vendor, as a solutions provider we act as a client’s strategic partner helping to optimize their processes, increase the satisfaction of their sponsors and partners while helping them become more competitive in their local, regional and global marketplaces.   
   
We deliver value through a broad yet cohesive spectrum of software products, solution services and scientific consulting organized in the following areas:  
  
View a list of our solutions by area of focus  
  
  
“Instem is so much more than a vendor, they have become a strategic partner and we are excited they are part of the technology-driven transformation we are embarking upon”  
  
   
  
Strategic Growth – Unrivaled Success  
View our Timeline of Success  
  
  
Through the combination of our strong core organic growth and strategic acquisitions and partnerships, Instem has risen above as a true one-stop-shop allowing clients to focus and maximize their investments to help obtain better quality results, more quickly.  
Powerful Solutions • Unique Perspective • Global Coverage  
Our clients are experiencing many challenges including patent expiry, soaring costs, heightened competition, squeezed margins and mounting regulatory pressures amidst an ever-changing corporate landscape. And, the relentless drive for overall R&D productivity is at an all-time high.  
Instem has a strong track record of innovation supported by our exceptional ability to stay close to our customers so as to anticipate and proactively adapt to changes in requirements as they develop.   
Through deep subject matter expertise, Instem is able to see the world from our clients’ perspective, contributing with practical, hands-on assistance to thought leadership that brings a level of service that is quite unique.   
Our staff works hand-in-hand with our clients to ensure that their requirements are converted into solutions that produce clear results to keep them focused on their research, not their software.   
Technology driven insight for today’s R&D environment  
  
  
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In-Silico toxicology protocols  
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Skin sensitization in silico protocol  
   
   
  
  
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January 25, 2024 - Advance™ technology-enabled solution enables R&D organizations to cut study timelines, deliver cost savings and reduce animal experimentation.  
  
Instem Now Part of ARCHIMED to Further Accelerate Growth and Impact  
November 27, 2023 - Healthcare investment specialist ARCHIMED has the expertise, experience, enthusiasm and financial strength to fully back Instem’s ambitions.  
  
Instem Announces New Software Solution to Support Updated Nitrosamines Guidance  
September 28, 2023 - New Software Module Introduced to Support the Latest Regulatory-approved Carcinogenic Potency Categorization Approach (CPCA)  
  
Instem Announces Transfer of ToxHub Platform and launch of Centrus®  
May 15, 2023 - New powerful technology and data sharing suite provides a range of translational science solutions  
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Webinar: Is your team ready for SENDIG-Genetox v1.0?  
August 28, 2024, 3pm-4:30pm BST/10:00am-11:30am EDT  
Virtual Webinar  
Register Now  
Exhibiting at the 5th Cutting Edge Pathology Congress (Joint Congress of ESTP, ESVP & ECVP)  
August 28 - 31, 2024  
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WIL Research Partners with Instem for Global Harmonization Project  
Instem Chosen by International Contract Research Organization to Deploy Multi-site Global Solution  
  
December 12, 2014  
Instem Releases Next Version of Provantis Preclinical Software Suite  
Provantis Version 9.4 Delivering Increased Reporting Capabilities and New Features for Pathology  
  
December 8, 2014  
Alizée Pathology Deploying Provantis Preclinical Software  
Maryland based Pathology Consultancy to Deploy Instem's Provantis Pathology Software Solution to Automate Laboratory Processes  
  
December 1, 2014  
Instem Chief Scientific Officer Conducting Pistoia Alliance Panel Discussion  
Industry Leaders to Discuss Genomics and Impacts to New Modes of Healthcare  
  
November 24, 2014  
Instem Presenting at Chinese National Safety Evaluation Workshop, Shanghai  
Instem to Discuss Comet Assay IV and Systems for Genetic Toxicology  
  
November 19, 2014  
Global Healthcare Leader Becomes SEND-Ready; Completes Purchase of Instem Submit Software Suite  
International Pharma to Standardize Upon Instem's SEND Software Platform  
  
November 12, 2014  
Instem Presenting at British Society of Toxicological Pathology Annual Meeting  
Instem to discuss how public and private literature can provide insight into which preclinical models best represent drug-induced pathology in humans  
  
November 6, 2014  
Leading Chinese Research Institute Purchases Provantis Preclinical Software Solution for Shanghai Headquarters  
Provantis Chosen to Increase Efficiencies at Shanghai-based Research Facility  
  
November 3, 2014  
Leading Contract Research Organization Selects Instem SEND Software Suite  
CRO to Deploy Submit Software Suite for Complete SEND Management  
  
October 28, 2014  
Toxicology Research Laboratory Chooses Instem Software Solutions  
Chicago based Contract Research Organization Selects Instem's Provantis Preclinical Study Management and submit-SEND software   
  
October 27, 2014  
Instem Sponsors Indian Society of Toxicologic Pathology Conference  
Instem Committed to Supporting Growth of R&D Community in India  
  
October 22, 2014  
Center for Predictive Medicine and Emerging Infectious Diseases Expands Biosafety Lab, Purchases Provantis SaaS  
NIH Grant Helps University of Louisville Expand Facilities and Research Program Capabilities  
  
September 30, 2014  
Cyto Study Manager Selected by Roche to Harmonize Genetic Toxicology Assay Processes  
Instem Software Chosen by Roche to Integrate Data Acquisition, Reporting & Management Processes for Genetic Toxicology Investigations  
  
August 21, 2014  
Instem to Present at European Teratology Society Meeting, Hamburg  
Instem Client selects submit™ Solution Suite for Europe and Asia Deployment  
  
July 21, 2014  
Multi-National Organization Purchases Instem's Complete SEND Solution Suite  
Instem Client selects submit™ Solution Suite for Europe and Asia Deployment  
  
July 16, 2014  
NCDSER Purchases Instem's Provantis Preclinical Software Suite  
Leading China CRO Selects Provantis Integrated Software Solution for Shanghai Headquarters  
  
July 2, 2014  
Instem’s SEND Solution Showcasing at Japanese Society of Toxicology Meeting  
Instem and Partner CTCLS to Co-exhibit at the 41st Annual Meeting of the JSOT; Kobe, Japan  
  
June 20, 2014  
Instem to Present at Applied Pharmaceutical Software Conference  
Presentations by Instem Industry Experts Ranging from SEND to Efficient Instrument Interfacing Techniques  
  
June 19, 2014  
Instem to Present at Society of Toxicologic Pathology Annual Symposium, Washington DC  
Instem presenting “Use of Legacy Data to Assess Species Concordance for Liver Injury”  
  
June 5, 2014  
Instem Announces Expanded Global ACIS (Animal Care Information System) Capabilities  
Instem Launches Comprehensive Outreach Program for Animal Management Solution  
  
May 8, 2014  
Ranbaxy Purchases Instem's Preclinical Software Suite  
Provantis Preclinical Software Suite Selected to automate R&D Laboratory Processes in India  
  
April 24, 2014  
Instem Specialist Presenting at Joint FDA and University of Texas Training Course at NIH, Maryland  
Presentation to Compare and Contrast Paper and Electronic Data Collection  
  
April 10, 2014  
Leading CRO Chooses Instem Software Solutions for Global Multi-Site Deployment  
Instem's Provantis Preclinical Study Management and submit-SEND solutions Chosen by International Contract Research Organization  
  
March 31, 2014  
Instem Supports American Cancer Society Key Gala  
Instem Pledges Bronze Sponsorship of the 2014 American Cancer Society Key Gala Boston  
  
March 20, 2014  
Instem Announces SEND Advice Clinic at Society of Toxicology Meeting; Phoenix, Arizona   
Instem SEND Booth Offers Industry Advice, Tools and Latest FDA Timelines  
  
March 19, 2014  
Cyto Study Manager Showcasing at Society of Toxicology Meeting Phoenix, Arizona  
Integrated Data Acquisition, Reporting and Management Software Solution for Comet and Micronucleus Assays Now Available  
  
February 20, 2014  
Leading Pharmaceutical Organization Purchases Instem's Animal Management Software  
Top 10 Pharma Company chooses Instem’s ACIS Software Solution for Multi-Site SaaS Deployment  
  
February 1, 2014  
FDA Issues Draft Guidance, Moves Closer to making SEND a Requirement  
  
  
  
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December 17, 2018  
Instem Reports Increased Market Demand for KnowledgeScan Target Safety Assessment Service  
Pioneering Service Delivers Comprehensive Insight into Biological Target Profiling  
  
October 22, 2018  
Instem Presenting and Exhibiting at the American College of Toxicology Meeting, Florida  
Instem to Present Latest Trends in Target Safety Assessment and Showcase Leading Preclinical Solutions and Outsourced Services   
  
September 26, 2018  
Instem Exhibiting and Presenting at Safety Pharmacology Society Annual Meeting  
Instem showcasing latest release of NOTOCORD-hem™ while also promoting its next generation cloud-based platform for scientific collaboration  
  
August 20, 2018  
Instem Exhibiting at EUROTOX Annual Meeting, Brussels, Belgium   
Instem to Showcase Market Leading Preclinical Solutions and Outsourced Services   
  
July 10, 2018  
Instem Announces Expanded Capabilities and Increased Market Demand for Cyto Study Manager Software   
Instem Welcomes New Clients and Delivers Enhanced Functionality for Leading Genetox Solution  
  
June 06, 2018  
Noble Life Sciences Selects Comprehensive Suite of Preclinical Software Solutions from Instem   
US Contract Research Organization Deploys Provantis Preclinical Software Solution to Automate Study Processes  
  
May 08, 2018  
Instem Exhibiting at Chinese Society of Toxicology Meeting  
Instem to Showcase Preclinical Solutions and Outsourced Services at China’s Leading Toxicology Conference  
  
April 19, 2018  
Instem Exhibiting at Genetic Toxicology Association Meeting, Newark, Delaware  
Instem To Showcase Leading Genetic Toxicology Solutions  
  
March 22, 2018  
Charles River Laboratories Selects Cyto Study Manager Software Solution   
Leading Contract Research Organization Selects Cyto Study Manager to Optimize Genetic Toxicology Operations  
  
March 07, 2018  
Instem Exhibiting and Presenting at Society of Toxicology Meeting  
Instem Showcasing its Preclinical Solutions and Outsourced Services While Holding Educational Presentations Covering SEND and Target Safety Assessment  
  
February 26, 2018  
Instem To Showcase Leading GeneTox Solutions at EEMGS Meeting, Potsdam, Germany  
Instem Exhibiting at Prominent European Genetic Toxicology Conference  
  
January 30, 2018  
Instem Genetox Solution Supports Development of Bioartificial Human Skin Models  
Phenion Scientists Deploy Comet Assay IV To Accurately Measure DNA Damage in Phenion Full Thickness Skin Models  
  
January 08, 2018  
Guangdong Lewwin Pharmaceutical Research Institute Selects Provantis Preclinical Software Solution   
Provantis to Increase Efficiencies and Streamline Preclinical Processes at South China Research Facility  
  
  
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Instem Acquires Leadscope; Prominent Provider of In Silico Safety Assessment Solutions  
Instem’s Acquisition of Leadscope, Inc. is Another Step in its Mission to Help Clients Bring Life Enhancing Products to Market Faster  
  
November 13, 2019  
Instem to Exhibit and Present at the American College of Toxicology Meeting, Arizona  
Instem Continues Powerful Presentation Series Focusing on Their Use of Artificial and Augmented Intelligence Techniques to Improve Drug Development Processes  
  
September 17, 2019  
Instem Announces New Arrhythmia Module Featuring Leading-edge Machine Learning Technology to Aid Earlier Detection of Cardiac Risk  
Instem Showcasing New Software Solution and Presenting Scientific Posters at this Year’s Safety Pharmacology Society Annual Meeting in Barcelona  
  
September 03, 2019  
Instem Kicks-Off Powerful Presentation Series Focusing on Their Use of Artificial and Augmented Intelligence Techniques to Improve Drug Development Processes  
Presentation to Debut at the 55th Annual Eurotox Conference, Helsinki, Finland  
  
July 01, 2019  
Instem Awarded EU Horizon 2020 Research Grant  
Instem Company NOTOCORD Secures Portion of €4m Grant as Member of Exclusive Scientific Consortium Helping to Make Medications Safer  
  
June 04, 2019  
Jiangsu Provincial Institute of Materia Medica Selects Provantis Preclinical SaaS Solution  
Provantis to Increase Efficiencies and Further Improve Study Data Quality at Nanjing Research Facility  
  
March 15, 2019  
FDA SEND 3.1 Mandate Goes Into Effect  
Scope of SEND Widens to Include Support for Cardiovascular and Respiratory Studies   
  
February 07, 2019  
Instem to Showcase Deep RIM Capabilities at DIA’s Upcoming RSIDM Exhibition   
Instem to Present Single-Place-of-Truth™ Approach for Regulatory Affairs Professionals  
  
February 05, 2019  
Instem’s Genetox Software Solution Complements Litron’s State-of-The-Art Genetic Toxicology Testing Methods  
Instem Reports that Leading R&D Organizations are Deploying Cyto Study Manager & Cutting-Edge Flow-Cytometric Regulatory Genetox Testing Techniques   
  
  
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November 27, 2023 - Healthcare investment specialist ARCHIMED has the expertise, experience, enthusiasm and financial strength to fully back Instem’s ambitions.  
  
Instem Announces New Software Solution to Support Updated Nitrosamines Guidance  
September 28, 2023 - New Software Module Introduced to Support the Latest Regulatory-approved Carcinogenic Potency Categorization Approach (CPCA)  
  
Instem Announces Transfer of ToxHub Platform and launch of Centrus®  
May 15, 2023 - New powerful technology and data sharing suite provides a range of translational science solutions  
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Events   
Webinar: Is your team ready for SENDIG-Genetox v1.0?  
August 28, 2024, 3pm-4:30pm BST/10:00am-11:30am EDT  
Virtual Webinar  
Register Now  
Exhibiting at the 5th Cutting Edge Pathology Congress (Joint Congress of ESTP, ESVP & ECVP)  
August 28 - 31, 2024  
San Lorenzo de El Escorial, Madrid, Spain  
Visit Conference Site  
  
Solution Areas: Preclinical Study Management, SEND  
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News from 2015  
December 11, 2015  
Leading Biotechnology Company Selects Instem's submit™ Software Suite  
Company to Deploy submit™ for Complete SEND Management  
  
December 1, 2015  
Pharmaceutical Organization Selects Provantis Preclinical Software Suite for German R&D Center  
International Pharmaceutical Organization Deploying Provantis to Support Growth in GLP Studies  
  
November 16, 2015  
mecklenburg-consulting Automates with Provantis Pathology Module  
Pathology Consultancy Turns to Instem’s SaaS Solution to Manage Preclinical Studies  
  
November 9, 2015  
Instem International Conference Deemed Resounding Success by Delegates  
Instem Reports Successful User Conference, Including Live Streaming to Global Customer Base  
  
November 4, 2015  
Instem Showcasing SEND at Annual Meeting of the American College of Toxicology  
Instem collaborates on SEND Poster Presentation While Promoting Expanded Services   
  
October 30, 2015  
BioReliance Selects Cyto Study Manager to Streamline Genetic Toxicology Services  
Instem Software Chosen to Support Acquisition, Management & Reporting of Genetic Toxicology Data  
  
September 29, 2015  
Instem Leading Sessions at the Society of Quality Assurance Symposium   
Instem to Address Regulatory Compliance in Cloud Computing  
  
September 1, 2015  
SRI International Chooses Instem's SEND Solutions  
SRI International Deploying Submit Software Using SaaS  
  
August 17, 2015  
SENDIG v3.1 Draft B Now on Public Review  
Comments due by September 10, 2015  
  
July 28, 2015  
Instem Announces Details of 2015 International Conference  
Conference Features Presentations, Interactive Breakouts and Workshops; Connecting with Clients from Around the Globe  
  
July 21, 2015  
Shanghai Institute of Materia Medica Selects Instem's Genetic Toxicology and ReproTox Solutions to Support Growth  
Shanghai-Based Drug Development Institute Purchases Expanded Package of Instem Solutions to Support Increasing Demand for Genetic Toxicology and ReproTox Services   
  
July 15, 2015  
SEND Implementation Guide for DART Studies v1.0 - Draft Now Available for Public Review  
Comments due by August 13th 2015  
  
July 1, 2015  
Leading R&D Organizations Deploy Instem SEND Solutions  
Organizations Around the Globe Continue to Become SEND-Enabled with Instem’s Submit Software Platform Following 2014 FDA Mandate  
  
June 23, 2015  
Instem to Present at Teratology Society Annual Meeting, Montreal  
Instem Presenting "SEND for DART: What Is It and When Is It Coming?"  
  
June 17, 2015  
Instem Showcasing Preclinical Software Solutions at Key Industry Events in Korea, Japan and China  
Instem Sponsors Leading Scientific Exhibitions While Further Promoting its Market-Leading Preclinical Study Management and SEND Software Solutions  
  
June 7, 2015  
WuXi AppTec Expands Investment in Instem Software Solutions  
Leading China CRO Purchases New Solutions and Modules, Orders Additional User Licenses and Upgrades to Latest Software Versions  
  
May 8, 2015  
Tripod China Chooses Provantis Preclinical Software Suite for Nanjing Facility  
Chinese CRO Purchases Provantis SaaS to Increase Efficiencies, Further Enhance Quality and Automate Processes at R&D Facility in Nanjing.  
  
April 10, 2015  
Instem to Present at Society of Quality Assurance Annual Meeting in Tampa  
Instem Co-Presenting on Cloud Validation's Impact on the Pharma Industry  
  
March 18, 2015  
Instem to Host SEND Implementation Panel Session at Society of Toxicology Annual Meeting  
Panelists to Discuss Key Factors in Becoming SEND-Ready  
  
March 16, 2015  
CiToxLAB Implements Provantis 9 and submit-SEND Solutions  
International CRO CiToxLAB to Further Improve Reporting Quality and Response Times to Sponsors  
  
March 3, 2015  
Lou Ann Kramer Joins SEND Management Team at Instem  
Instem Appoints Lou Ann Kramer to VP Role as submit-SEND Market Expands  
  
  
  
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Past Events   
Exhibiting at the 51st Annual Meeting of the Japanese Society of Toxicology (JSOT)  
July 3 - 5, 2024  
Fukuoka International Congress Center, Japan, Booth #8 & 9   
Visit Conference Site  
  
Poster Presentation   
 July 4, 5.15-6pm   
 'Embracing Regulatory Compliance: Genetox meets Generation SEND'Charuta Bapat, Senior Product Manager, Instem   
Solution Areas: In Silico, Preclinical Study Management, SEND   
  
Proud to be hosting a Webinar in partnership with the Korea New Drug Development Research Association (KDRA) & Ginapath titled, 'TSA Utilization Strategy Webinar to Accelerate New Drug Development'  
June 24, 2024, 4-5pm (KST)  
Virtual Event  
To attend apply online or email Kim Yeon-seung, Director of Gina Path at yskim@ginapath.com  
  
Presentations  
 'Enhancing Translational Safety Assessment'   
 Dr Brenda Finney, VP Translational Science, Instem  
'Target Safety Assessment for early discovery and/or early phase of New Drug Development'  
 Dr Frances Hall, Scientific Application Director, In Silico and Translational Science Solutions, Instem   
  
Proud to be Sponsoring & Exhibiting at the Society of Toxicologic Pathology Annual Symposium  
June 16 - 19, 2024  
Baltimore Marriott Waterfront hotel, Baltimore, Booth #200  
Visit Conference Site  
  
Solution Areas: Preclinical Study Management, SEND  
  
Proud to be Presenting at the PHUSE/FDA Computational Science Symposium  
June 3 - 5, 2024  
Civic Center, Silver Spring, MD  
Visit Conference Site  
  
Presentation on June 4  
 'Writing Better CSRs to Facilitate Anonymization for CDP/PRCI/CTI'  
 Laura Dodd, Director, Clinical Transparency & Cathal Gallager, Solution Owner, Clinical Transparency, Instem  
Solution Areas: Clinical Trial Transparency  
  
Proud to be Sponsoring & Presenting at Extractables & Leachables USA  
May 21 - 22, 2024  
Bethesda, MD  
Visit Conference Site  
  
Our Senior Research Scientist Candice Johnson PhD, will be participating at the E&L Panel Discussion.  
Poster  
'Development of fit for purpose in silico methods for the toxicological assessments of extractables and leachables'   
Candice Johnson PhD, Senior Research Scientist, Instem  
Solution Areas: In Silico Solutions   
  
Proud to be Presenting at the FDA 2024 Generic Drug Science and Research Initiatives Public Workshop  
May 20 - 21, 2024  
FDA, White Oak Campus, Silver Spring, MD  
Visit Conference Site  
  
Presentation  
'New research in computational toxicology modeling approaches to supplement and expand upon the carcinogenic potency categorization approach to assist generic product development'   
Kevin Cross, PhD, VP Regulatory Science, Instem  
Solution Areas: In Silico Solutions   
  
Webcast Hosted by The SOT Regulatory and Safety Evaluation Specialty Section  
May 13, 2024  
Virtual Event  
Visit Conference Site  
  
Presentation  
 'Nitrosamine Potency Prediction: Reviewing the Carcinogenic Potency Categorization Approach'   
 Kevin Cross, PhD, VP Regulatory Science, Instem  
Solution Areas: In Silico Solutions   
  
Proud to be Sponsoring the British Toxicology Society Annual Congress 2024  
April 15 - 17, 2024  
Spaces at the Spine, Liverpool  
Visit Conference Site  
  
Poster Presentations  
 Technology-enabled Approval Acceleration: Spotlighting the ICH S1B Weight of Evidence  
 Frances Hall, PhD, Scientific Application Director  
Keeping control: Trends in Virtual Control Groups for Ethical Animal Experimentation  
 Marc Ellison, Director, SEND Solutions  
Solution Areas: In Silico, Preclinical Study Management, SEND  
  
Exhibiting at GTA 2024 Annual Meeting 2024  
April 10 - 12, 2024  
Clayton Hall, University of Delaware, Newark  
Visit Conference Site  
  
Presentation 11th April, 1:05pm-1:25pm  
 'Experimental Testing of N-nitrosamines in the MUTAMIND project'   
 Kevin Cross, PhD, VP Regulatory Science, Instem  
Poster Presentations  
 'How structure-activity-relationships of N-nitrosamides and N-nitrosoureas affect carcinogenic potency'  
 Kevin Cross, PhD, VP Regulatory Science, Instem  
'Experimental Testing of N-nitrosamines in the MUTAMIND project'  
 Kevin Cross, PhD, VP Regulatory Science, Instem  
'Direct reactivity predictions as a proxy for small molecule interactions with active biomolecular pharmaceutical ingredient'  
 Candice Johnson, PhD, Senior Research Scientist, Instem   
  
Solution Areas: In Silico, Genetic Toxicology  
  
Proud to be presenting a Spotlight Presentation at the Clinical Data Disclosure, Transparency and Plain Language Summaries Event  
March 19 - 20, 2024  
Hilton Philadelphia at Penn’s Landing, Philadelphia, PA  
Visit Conference Site  
  
Solution Areas: Clinical Trial Analytics & Transparency  
  
Exhibiting at SOT 2024  
March 10 - 14, 2024  
Salt Palace Convention Center, Salt Lake City, Booth #1401   
Visit Conference Site  
SOT Events Page  
  
Solution Areas: In Silico, Preclinical Study Management, SEND  
  
Proud to be Presenting at the 4th Annual Extractables & Leachables Summit 2024  
March 7 - 8, 2024  
Virtual Conference  
  
Visit Conference Site  
  
Presentation 7th March, 2.40pm (CET)  
 'Approaches to the use of in silico methods in the toxicological assessment of extractables and leachables'  
 Dr. Candice Johnson, Senior Research Scientist   
Solution Area: In Silico Solutions   
  
Proud to be hosting a Demo Session at ACDM 2024  
March 3 - 5, 2024  
Radisson Blu hotel, Copenhagen, Denmark  
Visit Conference Site  
  
Solution Areas: Clinical Trial Analytics & Transparency   
  
Exhibiting at PHUSE U.S. Connect 2024  
February 25 - 28, 2024  
Bethesda North Marriott Hotel & Conference Center, Bethesda, Maryland, Booth #27  
Visit Conference Site  
PHUSE U.S. Connect Events Page  
  
Solution Areas: Clinical Trial Analytics & Transparency  
  
Proud to be Exhibiting and Presenting at the 40th Annual Meeting of the Japanese Society of Toxicologic Pathology  
January 23 - 24, 2024  
Curian (Shinagawa General Citizen's Hall), Tokyo, Japan  
Visit Conference Site  
  
Solution Areas: Preclinical Study Management, SEND  
Evening Seminar Presentations: 22nd January  
 18.30-19.10 - 'Unlocking Insights:Revolutionary Pathological Imaging Tool', by Reto Aerni, Senior Executive, Global Business Development  
 19.20-20.00 - 'The Pathologists Guide to Utilizing Translational Safety Data' by Brenda Finney, VP Translational Science  
  
Proud to be Presenting at Extractables & Leachables Summit  
January 17 - 19, 2024  
Virtual Conference  
  
Visit Conference Site  
  
Presentation  
 'Applications of computational methods in the assessment of extractables and leachables'  
 Dr. Candice Johnson, Senior Research Scientist   
Solution Area: In Silico Solutions  
  
Exhibiting at the China SOT 2023  
November 29 - December 2, 2023  
Guangzhou, Guangdong Province, China   
  
Solution Areas: In Silico, Preclinical Study Management, SEND  
  
Exhibiting at ACT 44th Annual Meeting  
November 12 - 15, 2023  
Rosen Shingle Creek® Hotel, Orlando, Florida, Booth 212  
  
Visit Conference Site  
ACT Events Page  
  
Presentation  
 'Factors Influencing the Potency of N-Nitrosamines: Reviewing the Carcinogenic Potency Categorization Approach'  
 Dr. Kevin Cross  
  
Exhibiting at the 38th Annual Meeting of the British Society of Toxicological Pathology (BSTP)  
November 15 - 16, 2023  
Verona, Italy  
Visit Conference Site  
Proud to be presenting at Extractables & Leachables Europe 2023  
November 6 - 7, 2023  
Steinberger Airport Hotel, Schipol, Netherlands  
  
Presentation  
 'Extractables and Leachables (E&L) chemical classification and considerations for class-based thresholds’  
 Dr. Candice Johnson, Senior Research Scientist  
  
Exhibiting at PHUSE EU Connect 2023  
November 5 - 8, 2023  
ICC Birmingham, Booth 20  
Visit Conference Site  
PHUSE EU Connect Events Page  
Exhibiting at the Society of Toxicologic Pathology – India (STP-I)  
October 27 - 29, 2023  
Hotel Narayani Heights, Gandhinagar, Gujarat  
Visit Conference Site  
Proud to be presenting a Poster at ELRIG Drug Discovery 2023  
October 18 - 19, 2023  
ACC Liverpool Exhibition Center, Liverpool  
Visit Conference Site  
  
Poster Presentation  
 'Standardized Target Carcinogenicity Assessment (TCA) Enables ICH S1B-based Regulatory Decisions'  
 Frances Hall PhD, Senior Director, In Silico and Translational Science Solutions  
  
Proud to be Presenting at the Toxicology Round Table  
October 16 - 18, 2023  
Hilton Hotel, South Carolina  
Presentation  
 'Constructing weight-of-evidence arguments for S1B Carcinogenicity Assessment Documents'  
 Dr. Kevin Cross  
  
Proud to be Presenting at NorCal SOT Fall Symposium 2023  
October 10, 2023  
Crowne Plaza, Foster City, CA  
  
Visit Conference Site  
  
Presentation  
 'Technology-enabled Approval Acceleration: Spotlighting The ICH S1B Weight Of Evidence'  
 Logan Laszczyk, Instem Senior Sales  
  
Exhibiting at 20th European Congress of Toxicologic Pathology 2023  
September 26 - 29, 2023  
Basel, Switzerland  
  
Visit Conference Site  
Proud Sponsors of Joint 3R Symposium 2023  
September 19 - 21, 2023  
VUB Health Campus, Brussels, Belgium  
  
Visit Conference Site  
Exhibiting at SPS Annual Meeting  
September 18 - 21, 2023  
SQUARE Meeting Centre, Brussels, Belgium, Booth 805   
  
 Visit Conference Site  
  
Poster #008: "Adding Artificial Arrhythmias During Training Boosts the Performance of Neuronal Networks for Arrhythmia Detection"  
 David Delafontaine, Christophe Bleunven, Anja Wühle, Sylvain Bernasconi  
Poster #086: "Minimal Requirements for Stem-Cells Derived Cardiomyocytes and MEA Usage in View of Field Potential Analysis by Reverse Modelling - A Theoretical Study on the Impact of 3 Variability Factors"  
 Fabien Raphel, Christophe Bleunven, Sylvain Bernasconi  
Poster #089: "Machine Learning approaches used to empower predictivities of hiPSC-CM assays"  
 Haibo Liu, Murielle Boulakia, Damiano Lombardi, Christophe Bleunven, Sylvain Bernasconi  
Exhibiting at Eurotox 2023  
September 10 - 13, 2023  
Ljubljana, Slovenia, Booth 49  
  
Visit Conference Site  
Eurotox 2023 Events Page   
Exhibiting at the 25th North American ISSX Meeting  
September 10 - 13, 2023  
Westin Boston Seaport District, Booth 608  
  
Visit Conference Site  
Proud to be Presenting at the Occupational Toxicology Roundtable 2023  
September 10 - 13, 2023  
Cleveland, Ohio, USA  
  
Visit Conference Site  
  
Presentation  
 ‘Performance improvement of skin sensitization models using proprietary knowledge’  
 Dr. Candice Johnson, Senior Research Scientist  
  
Proud to be Presenting at the 12th World Congress on Alternatives and Animal Use in the Life Sciences  
August 27 - 31, 2023  
Niagara Falls, Canada  
Visit Conference Site  
  
Presentation by Dr Glenn Myatt, Senior Vice President, In Silico & Translational Science Solutions, 'Acute Toxicity In Silico Models and Expert Reviews'. Instem will also be Co-Chairing with the NC3Rs.  
  
Exhibiting at UKEMS Annual Meeting 2023  
July 2 - 5, 2023  
Clontarf Castle Hotel, Dublin, Ireland   
  
Visit Conference Site  
Exhibiting at STP 42nd Annual Meeting 2023  
June 25 - 28, 2023  
Summerlin, Nevada, Booth #211  
  
Visit Conference Site  
  
Proud Sponsors of PHUSE Data Transparency Summer Event  
June 20 - 22, 2023  
Virtual Event  
Exhibiting at JSOT 2023  
June 19 - 21, 2023  
Pacifico Yokohama, Japan, Booth #63  
  
Visit Conference Site  
  
16th European ISSX and DMDG Meeting   
June 11 - 14, 2023  
University of Hertfordshire, De Havilland Campus, Hatfield, UK, Booth 6  
  
Visit Conference Site  
  
CTA Webinar - Accelerating Biometrics Results: Cloud-Based Statistical Computing Solutions for Every Size Pharma, Biotech, or CRO  
June 12, 2023, 2pm (EDT)  
Virtual Webinar  
  
Join us and listen as experts from Instem, Chris Decker and John L. partner with Wayne DellaMaestra from Dermavant Sciences to dive into how users can overcome common obstacles in the biometric area using a statistical computing environment (SCE) which provides a centralized compliance, analysis, and submission solution enabled by the cloud for any size pharmaceutical company and CROs.   
  
PHUSE Summer Data Transparency Event  
June 7 - 9, 2023  
Virtual Conference  
  
Virtual Sponsor  
Visit Conference Site   
  
QSAR 2023  
June 5 - 9, 2023  
Copenhagen, Denmark   
  
Visit Conference Site  
Workshop  
 'Regulatory uses of in silico modelling', Monday 5th June 2023, 10.50am, Kevin Cross, PhD and Glenn Myatt, PhD   
Presentations  
 'A cross-industry collaboration to assess if acute oral toxicity (Q)SAR models are fit-for-purpose for GHS classification and labelling', Glenn Myatt, PhD  
 'Predicting N-nitrosamine carcinogenicity potency in support of regulating acceptable intake levels of drugs', Kevin Cross, PhD  
   
  
EEMGS Meeting & SEMA Annual Meeting   
May 15 - 18, 2023  
Malaga, Spain  
Visit Conference Site  
  
Extractables & Leachables USA 2023  
May 16 - 17, 2023  
Arlington, VA  
Visit Conference Site  
Presentation  
 'Characterizing extractables and leachables chemical space to support in silico toxicological hazard assessments’  
 Dr. Candice Johnson, Senior Research Scientist   
  
Bio Korea 2023  
May 10 - 12, 2023  
COEX International Convention Center, Seoul, South Korea, Booth L21  
Visit Conference Site  
Exhibiting in partnership with Ginapath  
Presentation  
 'Effective Target Safety Assessment - Pioneering tool for drug developers’  
 Dr. Frances Hall, Instem Scientific, In Silico Solutions, Senior Director   
  
Great Lake Drug Metabolism & Disposition Group (GLDMDG) 2023  
May 4 - 5, 2023  
Michigan Union, Ann Harbor  
Visit Conference Site  
  
Annual Genetic Toxicology Association Meeting (GTA)  
May 3 - 5, 2023  
Clayton Hall, University of Delaware, Newark, DE  
Visit Conference Site  
Posters  
 Developing a pragmatic consensus procedure supporting the ICH S1B weight of evidence carcinogenicity assessment (Arianna Bassan)  
 Target Carcinogenicity Assessment (Glenn Myatt, PhD)  
 Data Gap Analysis of N-Nitrosamines Supporting Structure-Activity Relationships (Kevin Cross, PhD)  
Presentations  
 Developing a Pragmatic Consensus Procedure Supporting the ICH S1B WoE Carcinogenicity Assessment (Arianna Bassan)  
 EMA-Mutamind Analysis of Drug Substance Related Nitrosamines (Kevin Cross, PhD)  
  
BTS Annual Congress 2023  
April 17 - 19, 2023  
Park Regis Birmingham  
Visit Conference Site  
Presentation  
 'Pioneering platform enables rapid translational data review’  
 Dr. Brenda Finney  
 With the FDA announcement that it is no longer a requirement to test on animals prior to human trials; there is potential for a paradigm shift in the conduct of regulatory investigations. ToxHub, a translational science tool developed by eTRANSAFE, allows use of integrated databases containing public clinical and legacy preclinical data with visualization and modelling tools that could aid in planning testing programs.  
  
Sensible SEND LIVE!   
April 13, 2023, 10AM EDT   
Webcast   
Join Marc Ellison, Instem’s Director of SEND and author of the Sensible SEND blog, as he discusses and reflects on the most pressing issues, challenges, and opportunities regarding SEND.  
 Summarizing 50+ blog articles from the past two years (not to mention 10+ years of SEND expertise), Marc will navigate the ever-evolving SEND standard so you can gain a deeper understanding of recurring themes and trends coming in 2023  
  
62nd SOT Annual Meeting 2023  
March 19 - 23, 2023  
Music City Center, Nashville, Tennessee, Booth #615  
Visit Conference Site  
SOT 2023 Events Page  
  
Clinical Data Disclosure, Transparency and Plain Language Summaries  
March 21 - 22, 2023  
Hilton Philadelphia, PA, USA & Virtual   
Visit Conference Site  
 Presentation   
 'Beyond Compliance: Transparency's Future Value'   
 Cathal Gallagher, Transparency Solution Owner   
 March 21, 9.20-9.55am EDT  
  
Proud Sponsors of the 7th Global QA Conference  
March 12 - 17, 2023  
National Harbor, Maryland, USA   
Visit Conference Site  
  
3rd Annual Extractables & Leachables Summit 2023  
March 9 - 10, 2023  
Virtual Conference  
Visit Conference Site  
Presentation  
 'The use of computational methods in the assessment of extractables and leachables'  
 Dr. Glenn Myatt, VP Informatics   
  
3rd Annual Genotoxic Impurities in Pharmaceuticals Summit  
March 9 - 10, 2023  
Virtual Conference  
Visit Conference Site  
Presentation  
 'Applications of computational methods in the assessment of extractables and leachables'   
 Dr. Candice Johnson, Senior Research Scientist  
  
PHUSE US Connect 2023  
March 5 - 8, 2023  
Renaissance Orlando at SeaWorld, Orlando, Florida  
Visit Conference Site  
  
RSIDM Management Forum  
February 13 - 15, 2023  
Bethesda North Marriott Hotel & Conference Center  
Visit Conference Site  
 Presentation - February 14  
 'How Regulatory Intelligence empowers Regulatory Information Management'  
 Olaf Schoepke, PhD, Vice President, Regulatory Solutions  
PHUSE Winter Data Transparency Event  
February 7 - 9, 2023  
Virtual Conference  
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Computational Toxicology Release Webcast 2022  
December 7, 2022  
Virtual Webcast  
Register Here  
Presentation  
 Dr. Glenn Myatt, VP of Informatics, will reveal the latest edition of our Computational Toxicology software suite which supports detailed predictions of chemical safety.   
  
2nd Annual Genotoxic Impurities Summit: Nitrosamines & Beyond 2022  
December 1 - 2, 2022  
Virtual Conference  
Visit Conference Site  
Presentation  
 'The use of Structure-Activity Relationships in the Risk Assessment of Nitrosamines'  
 Dr.  
 Kevin Cross   
  
The 51st Annual Meeting of the Japanese Environmental Mutagen and Genome Society (JEMS)  
November 15 - 16, 2022  
JMS Aster Plaza, Hiroshoma, Japan, Booth #1  
Visit Conference Site  
  
PHUSE EU Connect 2022  
November 13 - 16, 2022  
International Convention Centre (ICC), Belfast   
Visit Conference Site  
  
ACT 43rd Annual Meeting 2022  
November 13 - 16, 2022  
Gaylord Rockies Hotel, Aurora, Colorado, Booths #205 & 207  
  
Talking Tox Presentation  
 Tuesday, November 15, 12.00-12.55pm  
 Strategic In Silico: Creating Powerful New Scientific Insights  
Visit Conference Site  
ACT 2022 Events Page  
  
37th Annual Scientific Meeting of the BSTP  
November 10 - 11, 2022  
Harrogate, North Yorkshire, UK   
Visit Conference Site  
  
Extractables & Leachables Europe 2022  
November 7 - 8, 2022  
Crowne Plaza Frankfurt Congress Hotel, Frankfurt, Germany  
  
Presentation:  
 Tuesday, November 8, 9am  
 'Emerging applications of computational methods in the assessment of extractables and leachables'  
 Glenn Myatt, Vice President, Informatics   
  
Visit Conference Site  
  
ELRIG Drug Discovery 2022  
October 4 - 5, 2022  
EXCEL, London, UK  
Visit Conference Site  
Poster Presentation:   
 Polo-like kinase 4 (PLK4) Safety Review – distilling the risks with a rapid augmented intelligence approach   
 Dr. Frances Hall, Senior Director In Silico Solutions, Instem  
DMDG Joint Meeting 2022  
October 3 - 5, 2022  
Hôtel Mövenpick Amsterdam City Centre, Amsterdam  
Visit Conference Site  
  
Norcal SOT 2022 Fall Symposium  
September 27, 2022  
Crowne Plaza Hotel, Foster City, California  
Gold Sponsor  
ETS 2022 50th Annual Meeting  
September 25 - 28, 2022  
Antwerp, Brussels  
Poster Presentation:   
 'Preparation for the regulatory requirement for SEND for development and reproductive toxicology studies'   
 Marc Ellison, Director, SEND Solutions, Instem  
Visit Conference Site  
  
The Extractables and Leachables Safety Information Exchange Consortium (ELSIE) Webinar:  
 Framework for Sensitization Assessment of E&Ls and Practical Application  
  
September 22, 2022  
Virtual   
Presentation by Glenn Myatt, VP Informatics, Instem, 9:30 – 11:00 AM US ET  
Register  
  
ICT 2022 (International Congress of Toxicology)  
September 18 - 21, 2022  
Maastricht Exposition and Conference Centre (MECC), Maastricht, The Netherlands, Booths #18 & 19  
Visit Conference Site  
ICT 2022 Events Page  
  
ESTP Congress  
September 13 - 16, 2022  
Crowne Plaza Hotel, Maastricht, The Netherlands, Booth #4  
Visit Conference Site  
  
SPS Annual Meeting 2022  
September, 11 - 14, 2022  
Palais des congrès de Montréal, Montreal  
Visit Conference Site  
  
RAPS US Convergence 2022  
September, 11 - 13, 2022  
Phoenix Convention Center, Phoenix, Arizona, Booth #823   
Visit Conference Site  
  
10th Annual FDA Scientific Computer Days  
September, 7 - 8, 2022  
Virtual Meeting  
Poster Presentations:  
 'Medical Device Reports Indicate some Devices Associated with Higher Occurrence of Adverse Events in Women', presented jointly with FDA Center for Devices and Radiological Health  
 'Quantitative Structure-Activity Relationship Model to Predict Cardiac Adverse Effects', presented jointly with FDA Center for Drug Evaluation and Research  
Visit Conference Site   
  
ICEM 2022 Annual Meeting  
August 27 - September 1, 2022  
Ottawa, Canada  
  
 Presentation:  
 'ICH M7 expert review procedures and assessment of specific chemical classes', Kevin Cross   
Visit Conference Site  
  
UKEMS Annual Meeting  
July 3 - 6, 2022  
Harrogate, UK   
Proud sponsors of UKEMS 2022  
  
49th JSOT Annual Meeting  
June 30 - July 2, 2022  
Sapporo Convention Center, Japan, Booth #1 Instem Japan K.K.  
  
 Presentation:  
 July 2 - 12:00 - 13:00  
 Leveraging Target Safety Assessment (TSA) and visualization of non-clinical data controlled by CDISC SEND - Instem's solution helps to build the foundation of non-clinical data repository for Digital Transformation  
Visit Conference Site  
  
Medtech Summit 2022  
June 20 - 24, 2022  
Dublin, Ireland, Booth #21  
Visit Conference Site  
  
STP 41st Annual Meeting  
June 19 - 23, 2022  
Austin Marriott Downtown, Austin, Texas, Booth #103  
  
Poster:  
 'Communicate the future proposed Microscopic domain additions or changes to the SEND Implementation Guide'  
 Dan Potenta, SEND Product Specialist  
Visit Conference Site  
  
Informa Clinical Data Disclosure Meeting (CDD)  
June 13 - 14, 2022  
Hybrid Event - Hyatt Regency Coral Gables, Miami  
Visit Conference Site  
  
ICAW & EEMGS meeting  
May 23 - 26, 2022  
Crowne Plaza, Maastricht, The Netherlands  
Visit Conference Site  
  
GTA Annual Meeting  
May 18 - 20, 2022  
Virtual Meeting  
  
Presentation:  
 'Advancing prediction of nitrosamine potency', Kevin Cross  
Visit Conference Site  
  
The (ISB) UK-Local Biocuration Conference  
May 5 - 6, 2022  
Cambridge, UK  
  
Poster:  
 'COSMIC Cancer Gene Census and Hallmarks of Cancer: Identification and functional annotation of genes causally associated with cancer'  
 Lucy Sheppard, In Silico Solutions  
Visit Conference Site  
  
Extractables and Leachables USA  
April 5 - 7, 2022   
The Westin Arlington Gateway, Arlington, Virginia & Online  
  
Virtual Exhibitor  
Presentation  
 ‘In silico assessment of biomolecule reactivity with leachables’, by Candice Johnson   
Visit Conference Site  
  
SOT 61st Annual Meeting  
March 27 - 31, 2022   
San Diego Convention Center, San Diego  
Booths   
 #1625 Preclinical Solutions Hub   
 #1729 In Silico Center of Excellence  
Visit Conference Site  
SOT Events Page  
  
RSIDM Annual Meeting  
February 14 - 16, 2022  
Bethesda North Marriott Hotel, North Bethesda, MD & Online  
  
Presentation  
 Making Digital Transformation Real  
 Speaker: Olaf Schoepke, PhD  
Visit Conference Site  
38th Annual Meeting of the Japanese Society of Toxicologic Pathology (STP)  
January 27 - 28, 2022  
Kobe International Conference Center, Hyogo, Japan   
Visit Conference Site  
  
British Pharmacological Society 90th Anniversary Celebration  
December 1, 2021  
The Royal College of Physicians, London, UK  
Presentation  
Target Safety Assessments: How augmented intelligence is advancing insights for quicker, evidence-based decision making  
 Paul Bradley, Vice President, Data Science Solutions, Instem   
  
Visit Conference Site   
  
Nitrosamine Workshop  
November 23 - 24, 2021  
Virtual Event  
Presentation  
 Nitrosamine SAR/Toxicity predictions  
 Dr Kevin Cross, VP Product Development  
  
ACT Annual Meeting 2021  
November 14 - 17, 2021  
Virtual Conference  
Posters  
Assessing abuse liability using read-across and structural alerts  
 Development of a Structure-Activity Relationship Profiler to Predict Mechanism-Based Inhibition of a Metabolite on CYP Enzymes   
 Using Metabolically Similar Analogs in Read-Across to Establish Dialkyl-N-Nitrosamine Potency  
Visit ACT Events Page  
Visit Conference Site  
  
50th JEMS Annual Meeting  
November 1 - 2, 2021  
Hybrid Event, Yokosuka, Japan  
Visit Conference Site  
  
STP-I 8th Annual Meeting  
October 22 - 24, 2021  
Virtual Conference  
Visit Conference Site  
  
MedTech Summit - Regulatory Conference  
October 18 - 22, 2021  
Virtual Conference  
Presentation  
Kim Young, Director, Global Regulatory Intelligence, Instem  
Using Regulatory Intelligence to Support MDR Compliance  
 October 19, 4.10pm  
Visit Conference Site  
  
10th Annual Meeting of the ASCTT  
October 12 - 14, 2021  
Virtual Conference  
  
Poster  
Incorporating in silico methods in weight of evidence approaches  
  
Visit Conference Site  
  
SPS Annual Meeting   
October 4 - 8, 2021  
Virtual Meeting  
Visit Conference Site  
  
Eurotox 2021  
September 27 - October 1, 2021  
Virtual Conference  
  
Speaker: Dr.Glenn Myatt, VP Informatics, Instem  
 Tuesday 28th September Session 9, 2-4pm 'Acceptance of in silico methods for regulatory purposes'   
Eurotox Event Page  
Visit Conference Site  
  
RAPS U.S. Convergence 2021  
September 12 - 15, 2021  
Virtual Conference   
Visit Conference Site  
  
The Toxicology Forum 2021 Virtual Summer Meeting  
July 27 – August 4, 2021  
Virtual Conference  
August 2nd 12noon – 3pm  
 Predicting N-Nitrosamine Activity from Structure-Activity Relationships   
Dr. Kevin Cross, VP Product Development, Instem  
Visit Conference Site  
48th Annual Meeting of the Japanese Society of Toxicology  
July 7 – 9, 2021  
Hybrid Meeting - Kobe International Conference Center and Virtual  
  
Instem is a virtual exhibitor  
Visit Conference Site  
Proud Sponsors of Extractables and Leachables USA Conference  
June 28 – July 1, 2021  
The Westin Arlington Gateway, Arlington, VA  
  
Poster: A preliminary assessment of biomolecular reactivity in the extractables and leachables chemical space  
Visit Conference Site  
Proud to support the STP Annual Meeting 2021  
June 28 – June 30, 2021   
Virtual Conference  
  
Visit Conference Site  
  
QSAR 2021 - 19th International Workshop on (Q)SAR in Environmental and Health Sciences  
June 7 – 9, 2021  
Virtual Conference  
  
Instem Presentations:  
  
The use of (Q)SAR models for classification and labelling - Dr. Glenn Myatt, VP Informatics, Instem  
Predicting N-Nitrosamine Activity from Structure-Activity Relationships - Dr. Kevin Cross, VP Product Development, Instem  
In silico toxicology protocols - successes and challenges - Dr. Candice Johnson, Research Scientist, Instem  
  
Visit Conference Site  
  
SFPT Scientific Annual Meeting 2021 -"Fighting Cancer with Immuno-Oncology: from Research to Clinic”  
  
May 27 - 28, 2021  
Virtual Conference  
Visit Conference Site  
Annual Meeting of the Chinese Society of Toxicology  
May 21 - 24, 2021  
Zhejiang Province, China  
   
  
Society of Toxicology In Vitro & Alternative Methods Speciality Section and Computational Toxicology Speciality Section Webinar: State of the Science: QSAR Modeling of Skin Sensitization.  
May 19, 2021 at 11:00 AM ET  
Virtual Webinar  
  
Presenter: Glenn Myatt, PhD, VP Informatics, Instem  
 Title: Skin Sensitization In Silico Protocol  
Register  
  
RAPS Euro Convergence 2021  
  
May 10 - 12, 2021  
Virtual Conference  
Visit Conference Site  
GTA Annual Meeting 2021  
May 3 - 6, 2021  
Virtual Conference  
  
Presentation: Predicting N-Nitrosamine Activity from Structure-Activity Relationships  
 Speaker: Kevin Cross, VP, Leadscope (an Instem company)  
Visit Conference Site  
  
Annual Conference of the British Toxicology Society  
April 12 - 14, 2021  
Virtual Conference  
  
Presentation: Establishing standards for in silico toxicity prediction protocols  
 Speaker: Dr. Glenn Myatt, Vice President Informatics, Leadscope (an Instem company)  
Visit Conference Site  
  
SOT Annual Meeting 2021  
March 12 - 26, 2021  
Virtual Conference  
  
Visit one of our three virtual booths:  
 Instem - Study Management Solutions  
 Instem - SEND Solutions  
 Instem - In Silico Toxicology Solutions  
SOT Event Page  
Visit Conference Site  
  
6th German Pharm-Tox-Summit   
March 1 - 3, 2021  
Virtual Conference  
Workshop presentation: In silico toxicology protocols – defining standards and best practices towards mutual acceptance of data  
 Speaker: Dr. Glenn Myatt, Vice President Informatics, Leadscope (an Instem company)  
Visit Conference Site   
  
DIA RSIDM  
February 8 - 10, 2021  
Virtual Event  
  
Proud to support the DIA’s Regulatory Submissions, Information, and Document Management (RSIDM)  
 Listen to Olaf Schoepke, PhD, Instem’s VP of Regulatory Solutions, as he joins a panel of experts to discuss Emerging Technologies including Machine Learning and Artificial Intelligence for the Benefit of Life Science   
Visit Event Page  
  
Nature Research Webinar: The Changing Landscape of Target Safety Assessment  
November 23, 2020 11 AM EST  
Speakers:   
 Dr. Gordon Smith Baxter, Chief Scientific Officer, Instem  
 Dr. Frances Hall, Director of Scientific Solutions  
 Instem  
Watch the webinar  
  
ACT 41st Annual Meeting  
November 15 - 18, 2020  
Virtual Conference  
ACT Event Page  
Visit Conference Site  
  
NorCal SOT Webinar : Overview of In Silico Models for Acute Toxicity Prediction and Study Design   
November 12, 2020, 12:00 Noon–1:30 PM (Pacific Time)  
Speaker: Dr. Glenn Myatt, Vice President Informatics, Leadscope (an Instem company)  
  
Extractables and Leachables USA  
October 26 - 28, 2020  
Virtual Conference  
Poster Presentation: In silico methods to assess the toxicity of extractables, leachables and degradants  
Visit Conference Site  
  
The MedTech Summit 2020  
October 12 - 16, 2020  
Virtual Conference  
Visit Conference Site  
  
TOPRA Webinar: Genesis of Medical Device Regulatory Intelligence  
October 14, 2020, 12:00 BST  
Speaker: Kim Young, Director, Global Regulatory Intelligence, Instem  
Register Now   
  
8th Annual FDA Scientific Computing Days  
September 29 - 30, 2020  
Virtual Event  
Visit Event Site   
  
FDANews Webinar: Global Unique Device Identification (UDI):  
Regulatory Operational Impact and Optimization  
September 30, 2020, 1:30 p.m.-2:30 p.m. EDT  
Speaker: Kim Young, Director, Global Regulatory Intelligence, Instem  
Register Now  
  
RAPS Convergence 2020  
September 12 - 15, 2020  
Virtual Conference  
Visit Conference Site  
  
SPS Annual Meeting  
September 13 - 16, 2020  
Virtual Conference  
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Watch the welcome video  
  
JSOT 2020  
June 29 - July 1, 2020  
Virtual Conference  
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Proud Sponsors of the Annual Scientific Meeting of the SFPT  
May 14 - 15, 2020  
National Veterinary School in Toulouse  
Visit SFPT Site  
  
SOT 59th Annual Meeting  
March 15 - 19, 2020  
Anaheim Convention Center, Anaheim, California   
Canceled - visit conference site for more information  
  
Proud Sponsors of the 34th Annual Scientific Meeting of the BSTP and BTS  
November 19 & 20, 2019  
Hilton Newcastle and Gateshead Hotel, Gateshead, UK  
Visit Conference Site  
  
ACEM/JEMS 2019  
November 18 - 20, 2019  
Tokyo, Japan  
Visit Conference Site  
  
ACT 40th Annual Meeting  
November 17 - 20, 2019  
JW Marriott Desert Ridge, Phoenix, AZ, Booth #113  
Visit Conference Site  
  
SPS Webinar Presentation  
November 14, 2019 - 11am EST  
Title: Mathematical Modeling and Machine Learning for Electrophysiology and Cardiotoxicity  
Visit SPS Site to Regsiter  
  
SPS Annual Meeting  
September 23 - 26, 2019  
Centre de Convencions Internacional de Barcelona, Barcelona, Spain, Booth #905  
Read the news release  
Visit Conference Site  
  
RAPS Regulatory Convergence 2019  
September 21 - 24, 2019  
Pennsylvania Convention Center, Philadelphia, Booth #243  
Visit Conference Site  
  
17th European Congress of Toxicologic Pathology (ESTP)  
September 17 - 20, 2019  
Cologne, Germany  
Visit Conference Site  
  
Eurotox 2019  
September 8 - 11, 2019  
Finlandia Hall, Helsinki, Finland, Booth #30  
Visit Conference Site  
Join our Presentation ‘Leveraging the combined power of technology, expertise & regulatory standards for safer outcomes’  
Tuesday 10 September, 12:30pm - Veranda 1  
  
46th Annual Meeting of the Japanese Society of Toxicology  
June 26 - 28, 2019  
Tokushima City, Tokushima, Booth #99  
Visit Conference Site  
  
STP 38th Annual Meeting  
June 22 - 27, 2019  
Raleigh Convention Center, Booth #206  
Visit Conference Site  
  
Annual Meeting of the Chinese Society of Toxicology  
June 22 - 24, 2019  
Wuhan, Hubei Province  
Visit Conference Site  
  
Proud sponsors of the IGG 33rd Annual Meeting  
June 19 - 20, 2019  
Manchester, UK  
Visit Conference Site  
  
MedTech Summit 2019  
June 17 - 21, 2019  
Crowne Plaza, Brussels, Booth #21  
Visit Conference Site  
  
47th Annual EEMGS Meeting  
May 19 - 23, 2019  
Rennes, France  
Visit Conference Site  
  
GTA Annual Meeting  
May 8 - 10, 2019  
John M. Clayton Hall Conference Center, University of Delaware  
Visit Conference Site  
  
BTS-UKEMS Annual Congress 2019  
April 15 - 17, 2019  
Robinson College, Cambridge, UK  
Visit Conference Site  
  
SOT 58th Annual Meeting & ToxExpo  
March 10 - 14, 2019  
Baltimore Convention Center, Booths #3856, #4234 & #3533  
SOT Event Page  
Watch the video  
  
DIA’s Regulatory Submissions, Information, and Document Management (RSIDM)  
February 11 - 13, 2019  
Bethesda North Marriott Hotel and Conference Center, Booth #104  
Read the News Release  
Visit Conference Site  
  
Safety Pharmacology Society Webinar: Post-Acquisition Analysis Tools  
February 14, 2019 at 11:00 ET, 16:00 GMT  
Join Logan Laszczyk, our NOTOCORD-hem™ Technical Specialist, for a webinar presentation, 'Customized Analysis and the Open Strategy of Notocord-hem'.  
Visit the SPS Site  
  
Proud Sponsors of the 33rd Annual BSTP Meeting  
November 15 - 16, 2018  
Cambridge, UK  
Visit Conference Site  
  
SPS Bay Area Regional Meeting, Filling Translational Gaps in Safety Assessment  
November 14, 2018  
Gilead, Foster City, CA  
Visit Conference Site  
  
SPS Boston Regional Meeting, Emerging Topics on the Cutting Edge of Safety Pharmacology  
November 14, 2018  
Vertex, Boston, MA  
Visit Conference Site  
  
ACT 2018  
November 4 - 7, 2018  
West Palm Beach, Florida  
Visit Conference Site  
  
Japanese Environmental Mutagen Society (JEMS) 47th Annual Meeting  
November 1 - 2, 2018  
Kyoto, Japan  
Visit Conference Site  
  
Seventh Conference of the Society of Toxicologic Pathology - India  
October 26 - 28, 2018  
The Westin Hyderabad Mindspace, India  
Visit Conference Site  
  
RAPS Regulatory Convergence  
October 1 - 4, 2018  
Vancouver, BC  
Visit Conference Site  
  
Safety Pharmacology Society Annual Meeting  
September 29 - October 2, 2018  
Washington, DC  
Visit Conference Site  
Booth 319  
Read the Press Release  
  
EMGS 49th Annual Meeting  
September 22 - 26, 2018  
San Antonio, Texas  
Visit Conference Site  
Booth 5  
  
ACCP Annual Meeting  
September 23 - 25, 2018  
Bethesda, MD  
Visit Conference Site  
  
The MedTech Conference  
September 24 - 26, 2018  
Philadelphia, PA  
Visit Conference Site  
Booth 624  
  
16th European Congress of Toxicologic Pathology  
September 11 - 14, 2018  
Copenhagen, Denmark  
Visit Conference Site  
  
Proud Sponsors of the 46th Annual Meeting of the European Teratology Society  
September 10 - 13, 2018  
Berlin, Germany  
Visit Conference Site  
  
UKEMS 42nd Annual Conference  
September 2 - 5, 2018  
Oxford, UK  
Visit Conference Site  
  
EUROTOX 2018  
September 2 - 5, 2018  
Brussels, Belgium  
Visit Conference Site  
Read the Press Release  
Booths 25 & 26  
  
45th Annual Meeting of the Japanese Society of Toxicology  
July 18 - 20, 2018  
Osaka, Japan  
Visit Conference Site  
  
6th Sino-US Toxicological Pathology International Congress  
July 2 - 4, 2018  
Beijing, China  
   
  
STP Annual Symposium  
June 16 - 21, 2018  
Indianapolis, Indiana  
Visit Conference Site  
Booth 206  
  
Annual Meeting of the Chinese Society of Toxicology  
May 12 - 15, 2018  
Nanjing, Jiangsu Province, China  
Booth B11  
  
Genetic Toxicology Association Meeting  
May 2 - 4, 2018  
Newark, DE  
Visit Conference SiteRead the Press Release  
  
46th European Environmental Mutagenesis & Genomics Society (EEMGS) Meeting  
March 18 - 21, 2018  
Potsdam, Germany  
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Booth 6  
  
Proud Sponsors of the Inauguration Conference of Centro 3R (Interuniversity Center for the Promotion of the Principles of the 3Rs in Teaching and Research)  
March 14, 2018  
Pisa, Italy  
   
  
Society of Toxicology's 57th Annual Meeting and ToxExpo  
March 12 - 14, 2018  
San Antonio, Texas  
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Booths 730 & 1223  
Read the news release | Watch the video  
  
DIA Regulatory Submissions, Information, and Document Management Forum   
February 5 - 7, 2018  
North Bethesda, MD  
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Booth 103  
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Provantis® Preclinical  
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News from 2012  
December 5, 2012  
Leading Global Biopharma Purchases Instem SEND-submit Software Suite  
US-Based International Biopharmaceutical Company Chooses submit™ Software to Convert, Create and Share SEND Data   
  
November 29, 2012  
Instem Releases New Version of OmniViz Data Mining and Visual Analytics Software  
Highly Anticipated Software Release Offers More Processing Power and Speed for Industry and Academic Users  
  
November 14, 2012  
Instem International Conference Series Deemed a Success by Clients  
Delivering Value to Clients at Meetings in US, UK, Japan & China  
  
November 8, 2012  
Government Research Agency Selects Instem Preclinical Software Solution  
Provantis Preclinical Software Chosen to Advance Key NIAID Research Programs  
  
November 5, 2012  
Promising New Tools and Techniques in Search for Alzheimer's Disease Biomarkers  
Researchers at King's College London Undertake Text Mining Exercise with Instem; Research Published in Journal of Translational Medicine  
  
September 11, 2012  
Instem to Present at 17th International German Society for Good Research Practice Meeting, Dresden  
Instem Presenting “Living in the Cloud – New GxP Challenges”  
  
August 30, 2012  
Instem to Present at European Teratology Society Meeting, Linz, Austria  
Instem Presenting on Data Collection and Reporting - System Design Considerations  
  
August 20, 2012  
Instem Software Powers DART Program  
Understanding the Cause and Prevention of Birth Defects: Southern Research’s DART Program Conducts Critical Reproductive Toxicology Work  
  
July 12, 2012  
Instem to Present at 6th Annual AsiaTox Conference, Sendai, Japan  
Instem Presenting on Acceptance Status and Future Deployment Plan of SEND Format by FDA  
  
June 21, 2012  
Japanese Pharmaceutical Organization Selects Instem's Preclinical Software Solution Suite  
Leading Japanese Pharmaceutical Company Chooses Provantis® Preclinical Software Solution for Osaka Facility  
  
June 19, 2012  
Instem Presenting at Society of Toxicologic Pathology Annual Meeting  
Instem Presenting on Extraction and Normalization of Toxicologic Pathology Terminology  
  
May 1, 2012  
Lupin Purchases Instem Preclinical Software for Novel Drug Discovery & Development Program  
Provantis Preclinical Software Selected to Automate Study Processes at Lupin’s Global R&D hub in Pune, India  
  
April 17, 2012  
  
Instem Software Deployed for Translational and Personalized Oncology Programs  
Instem Solutions Being Utilized for Testing Efficacy of Established Oncology Drugs While Increasing Speed of Drug Development for BioPharma  
  
March 29, 2012  
Instem and Apelon Extend Partnership for Patient-Focused Clinical Decision Support  
Instem Solutions Deployed to Help Manage Electronic Medical Data  
  
February 28, 2012  
Instem Recognized for Outstanding Contributions to SEND  
Instem Receives Award for Leadership in its Support of Standard for Exchange of Nonclinical Data (SEND)  
  
January 31, 2012  
Beijing Union Purchases Instem's Preclinical Software Solution  
Chinese Contract Research Organization selects Provantis integrated preclinical software solution to automate study processes  
  
January 27, 2012  
  
Advinus Therapeutics Increases Use of Instem's Preclinical Software Suite to Support Growth  
Advinus Therapeutics increases Provantis user licenses by 40% at Bangalore facility to support growth in India Operations  
  
January 26, 2012  
Multi-National Organization Places $490k Order with Instem for Preclinical Software Suite at Singapore Laboratory  
Instem Continues its Asia-Pacific Expansion  
  
  
  
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December 11, 2013  
Instem Conference Series Delivers Value To Users Across The Globe  
Instem Connects With Clients at Meetings in Europe, North America, China and Japan  
  
November 27, 2013  
Instem to Present at Outsourcing Preclinical Development Conference, Berlin  
Instem Presenting on SEND Status and Industry Deployment Plans  
  
November 22, 2013  
Instem Acquires Perceptive Instruments; Leader in Image Analysis and Data Management Solutions  
Perceptive Products to Increase Study Management Efficiencies within Life Sciences  
  
November 11, 2013  
Instem and AstraZeneca Presenting at the British Society of Toxicological Pathology Annual Meeting  
Instem and AstraZeneca to present “Cardiovascular Drug Toxicities Associated With Pharmacological Activity; Data Harmonization Makes The 'Known' Visible”  
  
October 8, 2013  
Edward Lorenti Appointed as Instem VP Global Sales  
Lorenti Chosen to Lead International Sales Team as Instem Growth Continues  
  
July 24, 2013  
Instem Releases Next Version of SRS Data Integration Platform  
SRS Version 8.4 Provides Advanced Searching Capabilities  
  
July 24, 2013  
Leading China-Based CRO Selects Instem's Provantis Portal for Remote Study Monitoring  
Provantis Portal Remote Study Monitoring Solution Selected to Optimize Client Data Access and Communication  
  
June 4, 2013  
Instem Presenting at the Society of Toxicologic Pathology's Annual Symposium   
Instem Presenting on Use of Legacy Data and Literature Analytics to Understand Digestive Tract Toxicity  
  
May 29, 2013  
Global R&D Organization Places Order for Enhanced SEND Software Solution Suite   
Instem Selected to Provide SEND Solution with Integrated Cross-Study Search and Browsing Capabilities  
  
May 17, 2013  
Instem Receives VOLTAGE Award for Submit-SEND Software Solution Suite  
Submit-SEND Solution Recognized for Innovation & Industry Leadership  
  
May 18, 2013  
Strong Uptake Reported for Provantis 9  
Additional Customer Wins for New Provantis Release  
  
April 10, 2013  
Chinese Government Research Facility Purchases Instem's Preclinical Software Suite  
Beijing-based Government Research Laboratory Selects Version 9 of Provantis Integrated Preclinical Software to Automate Study Processes  
  
March 4, 2013  
Instem Receives Award from National Institute of Environmental Health Sciences  
Provantis Preclinical Software Chosen for National Toxicology Program  
  
March 1, 2013  
Logos Technologies launches PDAQ™ for ePRO data collection  
  
February 28, 2013  
Instem Co-Presenting at 52nd Annual Meeting of the Society of Toxicology  
  
February 7, 2013  
Instem Releases Version 9 of Provantis  
Next Major Version of Instem's World-leading Preclinical Software Solution Suite Offers Rich Features with Clear Benefits  
  
January 29, 2013  
JOINN Laboratories China Purchases Instem's Preclinical Software Suite  
Leading Chinese CRO Selects Version 9 of Provantis Integrated Preclinical Software to Automate Study Processes at Beijing and Suzhou Sites  
  
  
  
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Instem Delivers Centrus Solution to Multi-National Pharmaceutical  
Newly Introduced Centrus Solution to Help Pharma Gain More Insight from Preclinical Data  
  
October 6, 2010  
Shanghai Institute of Materia Medica Chooses Provantis Software Solution  
Provantis Software-as-a-Service Model Chosen by Leading Shanghai-Based Drug Development Institute  
  
September 10, 2010  
Instem Announces Centrus Solution Suite for Early Drug Development  
New Centrus™ Solution Suite to Provide Unique Capabilities for Accessing, Transforming, Viewing and Sharing Scientific Information in Early Drug Development  
  
August 19, 2010  
Instem Announces Global Partnership Agreement with SAS in Life Sciences   
Collaboration Enhances Customer Experience While Increasing Capabilities  
  
August 12, 2010  
National Institute of Environmental Health Sciences Purchases Hosted Provantis Solution  
Provantis Reproductive Toxicology Software Module to be used by National Toxicology Program and Member Organizations  
  
June 3, 2010  
Instem Announces Shanghai-Based Data Center for Asia-Pacific Provantis Clients  
Instem Partners with Datapipe, Global Leader in Remote Systems Management  
  
May 18, 2010  
Eurofins Product Safety Labs Selects Provantis Preclinical Software to Automate NJ Research Facility  
Provantis Chosen to Help Bring New Efficiencies for Collecting, Analyzing & Reporting Study Data  
  
March 5, 2010  
Integrated Laboratory Systems Subscribes to Provantis® Online  
Provantis Preclinical Solution Chosen to Accelerate Study Volume While Reducing Costs  
  
March 5, 2010  
Mitsubishi Chemical Medience Corporation Switches to Provantis®  
Japanese CRO selects Instem's Provantis solution for their Kashima and Kumamoto Facilities  
  
January 5, 2010  
Industry Experts Join Instem; New Jersey Office Opens  
Instem to Accelerate Penetration of New Solutions Throughout Preclinical Market  
  
  
  
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December 8, 2011  
NCSED Chooses Instem's Integrated Software Suite for Preclinical Studies in China  
Provantis® Preclinical Software Solution Chosen for Deployment within China at Government Owned Laboratory  
  
November 30, 2011  
Instem Chosen by SRI International as New Preclinical System Provider  
SRI Purchases Provantis Preclinical SaaS to Meet Needs of Growing Biosciences Operations  
  
October 27, 2011  
Instem Chosen for Global Deployment of Provantis SaaS; Roche Consolidates Preclinical Software Systems  
Provantis Suite to Replace Existing Solutions While Adding New Capabilities for Roche  
  
August 31, 2011  
The Jackson Laboratory Consolidates IT Systems; Selects Instem Preclinical Solutions  
Provantis Preclinical SaaS with Resource Planning Product Selected for Rapid Deployment at Sacramento Facility  
  
July 19, 2011  
Battelle Places Order with Instem for Provantis Preclinical and submit-SEND Software Solutions  
Instem Solutions to Automate Full Range of R&D Processes  
  
June 21, 2011  
Shanghai Medicilon Chooses Provantis Software Solution  
Instem's Software-as-a-Service Model Chosen by one of China's Leading Contract Research Organizations  
  
March 7, 2011  
Instem Acquires Cambridge-Based BioWisdom; Leader in Delivering Healthcare Intelligence Solutions  
Acquisition of Leading Bio-Informatics Solutions Company to Strengthen Instem's Early Drug Development Solution Suite  
  
February 10, 2011  
SNBL USA Purchases Provantis Preclinical Solution Suite; 500 Users to be Deployed  
Provantis to Assist SNBL in Delivering the Exceptional Customer Experience  
  
  
  
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FDA SEND Mandate for Regulatory Submissions Now In Force  
Study Submissions Must Adhere to FDA-Supported Formats  
  
December 06, 2016  
Instem University e-Learning Platform Announced; Provantis Preclinical Academy First to Launch  
On-Demand Education for New and Existing Clients Offers More Effective Ways for Users to Maximize Instem Software Solutions  
  
December 02, 2016  
Leading Japanese Pharmaceutical Organization Becomes SEND-Enabled with Instem's submit™ Software Suite  
Japanese Pharma Company Chooses submit™ and SENDView™ to Address Mandatory FDA Requirements for Nonclinical Data  
  
November 01, 2016  
Instem Exhibiting and Presenting at American College of Toxicology Annual Meeting  
Instem Showcasing its Preclinical Solutions and Hosting a Session on Submission-Ready SEND Packages with Panel of Industry Leaders  
  
October 27, 2016  
vivoPharm Selects Provantis® to Automate GLP Research for Australian Market  
CRO Leverages Provantis to Tap into Australia's Unmet Need for Local GLP Compliant Services   
  
October 21, 2016  
Instem to Host Solutions Seminar in Tokyo to Support Continued Growth in Japan  
Instem Showcasing Solutions for Preclinical Data Collection, Analysis and Regulatory Submissions Management  
  
October 17, 2016  
Instem Sponsors Prominent India Conference and Showcases Preclinical Software Solutions  
Instem Supports the 6th Conference of the Society of Toxicologic Pathology – India  
  
September 20, 2016  
Leading Biopharmaceutical Organization Selects Instem's SEND Software Suite  
New Instem Client Chooses submit™ and SENDView™ SaaS Deployment to Ensure SEND Compliance  
  
September 5, 2016  
Instem Acquires NOTOCORD; Extends Reach and Capabilities While Further Consolidating Preclinical IT  
NOTOCORD Joining Instem Group to Help Drive Growth & Next Stage of Innovation  
  
August 17, 2016  
Instem Appoints Jerry Hacker as SVP Global Sales  
Hacker Selected to Help Further Accelerate Instem's Growth  
  
August 16, 2016  
SEND Implementation Guide for DART Issued by CDISC  
Study Design Coverage Expanding  
  
August 16, 2016  
Pharmaron Selects Instem's Submit™ Software Suite for Complete SEND Management  
Leading Chinese CRO at the Forefront of SEND Compliance in China  
  
July 29, 2016  
Instem Expands SEND Suite with Data Visualization and Analysis Solution  
Instem Signs Agreement with Integrated Nonclinical Development Solutions, Inc.; Becomes Exclusive Global Supplier of SEND Explorer®  
  
July 8, 2016  
SEND Implementation Guide v3.1 Now Available  
Study Design Coverage Expanded  
  
June 21, 2016  
Bio-Safety Laboratory Deploys Provantis Software Solution to Help Streamline Non-Clinical Evaluation Studies  
Provantis Selected to Automate Processes in the Research of Deadly Pathogens, Emerging Diseases and Bioterror Agents  
  
June 15, 2016  
Instem Exhibiting at Leading Industry Conferences in China and Japan  
Instem to Showcase Solutions for Preclinical Study Management, SEND and Genetic Toxicology   
  
June 9, 2016  
Biopharmaceutical Organization Selects Provantis® Pathology to Optimize Histopathology Reviews  
Massachusetts Based Biopharmaceutical Company Automates Histopathology Processes   
  
June 2, 2016  
BoZo Research Center Selects Instem as SEND Outsourcing Partner for Japanese Market  
BoZo Research Responds to Strong Market Demand and Becomes SEND-Enabled   
  
May 31, 2016  
Instem Acquires RIM Solution Provider Samarind  
Samarind Strengthening Global Position as Part of Instem Organization  
  
May 24, 2016  
Shenyang Research Institute Selects Provantis Preclinical Software Solution for Chinese Drug Safety Evaluation Center  
Prestigious Chinese Research Institute Deploying Provantis SaaS to Increase Efficiencies and Further Streamline Preclinical Processes  
  
May 6, 2016  
Instem Showcasing Study Management and Genetic Toxicology Solutions at International Toxicology and Safety Evaluation Workshop  
Instem Sponsors the NCDSER Workshop and Study Director Course in Shanghai  
  
May 3, 2016  
Instem Presenting at SEND Workshop  
Instem, Leading Pharmaceutical Organizations and Regulators to lead discussions on SEND Submission Expectations  
  
May 2, 2016  
Instem Presents at CDISC Europe Interchange  
Instem Discusses Key Differentiators Between Preclinical and Clinical Electronic Study Data Submissions  
  
March 14, 2016  
Instem Participates in SEND Panel Program Sponsored by the Pistoia Alliance  
Pistoia Alliance Debates Webinar Reviewing Key Principles of FDA-Adopted CDISC Preclinical Standard  
  
March 04, 2016  
Instem Exhibiting and Presenting at Society of Toxicology Annual Meeting  
Instem Showcasing its Preclinical Solutions While Leading Sessions on SEND Readiness and Target Safety Assessment  
  
March 03, 2016  
KnowledgeScan Target Safety Assessment Showcasing at Society of Toxicology Annual Meeting  
Instem to Present Novel Approach for Drug Safety Assessment   
  
February 12, 2016  
SEND-Readiness Seminar Being Held in Tokyo as Instem Continues to Expand in Japan  
Life Science Professionals to Discuss the Status of SEND and Options for Becoming SEND-Ready in Japan  
  
  
  
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Upcoming Events   
Webinar: Is your team ready for SENDIG-Genetox v1.0?  
August 28, 2024, 3pm-4:30pm BST/10:00am-11:30am EDT  
Virtual Webinar  
Register Now  
Exhibiting at the 5th Cutting Edge Pathology Congress (Joint Congress of ESTP, ESVP & ECVP)  
August 28 - 31, 2024  
San Lorenzo de El Escorial, Madrid, Spain  
Visit Conference Site  
  
Solution Areas: Preclinical Study Management, SEND  
  
Exhibiting at the China Drug Toxicology Conference 2024  
September 1 - 3, 2024  
Shanghai  
  
Solution Areas: Discovery, Genetox, Preclinical Study Management, In Silico, SEND  
  
Exhibiting at the Drug Metabolism Discussion Group (DMDG) 50th Open Meeting  
September 2 - 4, 2024  
Ron Cooke Hub, University of York, UK, Booth 19  
Visit Conference Site  
  
Solution Areas: Discovery  
  
Exhibiting at EUROTOX 2024 - Gold Sponsor  
September 8 - 11, 2024  
Copenhagen, Denmark, Tivoli Congress Center, Booth 30 & 31  
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Solution Areas: In Silico, Preclinical Study Management, SEND   
  
Webinar: Clinical Data Analysis: Overcoming Obstacles to Success   
September 11, 2024, 2pm EDT, 11am PDT  
Virtual Webinar  
Register  
  
In the world of clinical data analysis, the starting point is deceptively easy: one person and a laptop with a few applications installed. But soon the team grows, your treatment moves toward approval, and your needs have quickly multiplied.  
  
Presenting at the 14th Annual Global Summit Regulatory Science Symposium  
September 18 - 19, 2024  
Little Rock, Arkansas  
Visit Conference Site  
  
Presentation  
 'AI applications in Predictive Toxicology Supporting Drug Safety Assessments'   
 Kevin Cross, PhD, Head of Science, Instem  
Solution Areas: In Silico Solutions  
  
Exhibiting at the Safety Pharmacology Society (SPS) Annual Meeting  
September 22 - 25, 2024  
Town and Country Resort, San Diego, CA, Booth # 508  
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Solution Areas: Preclinical Study Management, SEND  
  
Exhibiting at the 52nd EEMGS & ICAW meeting  
September 23 - 27, 2024  
Hotel Eden, Rovinj, Croatia  
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Solution Areas: Genetic Toxicology  
  
Exhibiting at & Proud Sponsors of PHUSE EU 2024  
November 10 - 13, 2024  
Strasbourg Convention Center, France  
  
Solution Areas: Clinical Trial Analytics & Transparency  
  
Proud to be Sponsoring the 39th Annual Scientific Meeting of the British Society of Toxicological Pathology (BSTP)  
November 14 - 15, 2024  
The Grand Hotel & Spa, York, UK  
Visit Conference Site  
  
Solution Areas: Preclinical Study Management, SEND  
  
Exhibiting at the 44th Annual Meeting of the American College of Toxicolgy (ACT)  
November 17 - 20, 2024  
JW Marriott, Austin, Texas  
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Instem Reporting Strong Start to 2020 for Target Safety Assessment Services  
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June 13, 2024  
Instem to Showcase Enhanced Provantis Pathology Solution at Upcoming STP Symposium  
Powerful study management updates provide cutting-edge digital pathology capabilities.  
  
January 25, 2024  
Instem Enables Clients to Leverage ICH S1B Weight of Evidence Guideline  
Advance™ technology-enabled solution enables R&D organizations to cut study timelines, deliver cost savings and reduce animal experimentation.   
  
November 27, 2023  
Instem Now Part of ARCHIMED to Further Accelerate Growth and Impact  
Healthcare investment specialist ARCHIMED has the expertise, experience, enthusiasm and financial strength to fully back Instem’s ambitions.  
  
September 28, 2023  
Instem Announces New Software Solution to Support Updated Nitrosamines Guidance  
New Software Module Introduced to Support the Latest Regulatory-approved Carcinogenic Potency Categorization Approach (CPCA)   
  
May 15, 2023  
Instem Announces Transfer of ToxHub Platform and launch of Centrus®  
New powerful technology and data sharing suite provides a range of translational science solutions  
  
November 02, 2022  
Instem Unveils New Additions to its Leading Computational Toxicology Software Suite  
New functionality along with Enhanced Models to Deliver More Efficient and Comprehensive Predictions in Chemical Safety  
  
May 10, 2022  
Instem Awarded EMA Research Grant  
Instem Secures Portion of €2.5m Grant as Member of Research Consortium Investigating the Mutagenicity of N-nitrosamines  
  
November 22, 2021  
Instem Expands In Silico Toxicology Service To Meet Growing Demand   
Newly Added Services to Support Latest Regulatory Guidance and Growing Demand for Alternative Testing Methods  
  
September 01, 2021  
  
 Instem Acquires PDS Life Sciences to Help Clients Bring Life Enhancing Products to Market Faster and More Efficiently  
   
Acquisition of PDS Life Sciences Consolidates Non-Clinical Market; Further Extends Instem’s Leadership in Study Management and Regulatory SEND Submission Support   
  
July 29, 2021  
  
 Instem to Release Next Edition of its Leading Computational Toxicology Software Suite  
   
Powerful New In Silico Models and First-to-Market Software Capabilities to Deliver Further Efficiencies and Increased Regulatory Compliance   
  
March 22, 2021  
  
 Instem Acquires Market Leader d-wise to Further Accelerate Life Science Development  
   
Instem’s Acquisition of Leading Clinical Trial Technology and Consulting Provider d-wise Represents Substantial Advancement of its Mission  
  
March 01, 2021  
Instem Announces Acquisition of The Edge; Extends Reach within Discovery R&D  
Instem’s Acquisition of Discovery Technology Solutions Provider, The Edge, Represents Another Advancement of its Mission in the Life Sciences  
  
January 27, 2021  
Instem Reports Another Year of High Growth for In Silico Solutions  
High Demand for Target Safety Assessment Services and Computational Toxicology Solutions Continues Throughout Discovery and Nonclinical  
  
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FDA SEND Mandate for IND Submissions Goes Into Effect  
CDISC SEND Standard Now Applies to all IND Submissions to FDA  
  
December 14, 2017  
Instem Hosts Successful Preclinical Solutions Seminar in Japan  
Seminar Supports an Exciting Year of Continued Growth in the Region  
  
December 12, 2017  
NOTOCORD Celebrates Key Achievements and Milestone Anniversary  
Instem Reports Key Accomplishments for Safety Pharmacology Solutions Business Following First Year as Part of Instem Group  
  
November 14, 2017  
University of Maryland Division of Translational Radiation Sciences Selects Provantis Preclinical Software Solution   
Provantis Selected to Automate and Optimize Study Processes at One of the World’s Largest Medical Countermeasure Programs   
  
October 02, 2017  
Instem Reports Growing Demand for Cyto Study Manager Software Solution   
Leading Organizations Select Cyto Study Manager to Streamline Genetic Toxicology Study Workflows  
  
September 18, 2017  
Instem To Deliver SEND Education Course and Showcase Leading Software Solutions at Safety Pharmacology Society Conference, Berlin  
Instem Exhibiting and Presenting at Annual Safety Pharmacology Meeting  
  
July 10, 2017  
ChemOn Selects Instem to Help Automate Preclinical Processes and Meet Growing Demand for SEND  
South Korean Contract Research Organization to Deploy Provantis® for Preclinical Data Management and Submit™ Software for SEND Management  
  
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USAMRIID Deploys Instem Software to Support Development of Biodefense Solutions  
US Government Laboratory Purchases Expanded Package of NOTOCORD Solutions to Extend Safety Pharmacology Testing Capabilities  
  
June 19, 2017  
Instem Showcasing Leading GeneTox Solutions at UKEMS Meeting, Leuven, Belgium  
Instem's Perceptive Instruments Group to Exhibit at Leading Environmental Mutagenesis Society Meeting  
  
May 08, 2017  
Instem Exhibiting at Genetic Toxicology Association Annual Meeting, Newark, Delaware  
Instem's Perceptive Instruments Group to Showcase Leading GeneTox Solutions  
  
March 28, 2017  
NOTOCORD Releases Latest Version of Leading Data Acquisition Software  
NOTOCORD-hem Version 4.3.0.75 Delivers Improved GLP Compliance and Further Extends Compatibility with Hardware Vendors  
  
March 17, 2017  
Instem Helping to Educate the Quality Assurance Community on SEND  
Instem to co-present at Research Quality Association’s North American Regional Forum   
  
March 13, 2017  
NOTOCORD Sponsors DSI User Group Meeting and Showcases Data Acquisition and Analysis Solutions  
NOTOCORD to Exhibit and Present at DSI User Group Meeting, Reims, France  
  
March 08, 2017  
Instem Showcasing New Solutions and Expanded Offerings to Preclinical Community at Annual Toxicology Meeting  
Instem Exhibiting and Presenting at Society of Toxicology Annual Meeting and ToxExpo Event in Baltimore, Maryland  
  
February 06, 2017  
NOTOCORD User Group Meeting Voted a Great Success by Delegates  
Instem Reports Successful NOTOCORD User Meeting; Featuring 2 Full Days of Presentations, 1:1 Advice Clinics and Networking  
  
January 31, 2017  
Instem Presenting at the DIA Regulatory Submissions, Information, and Document Management Forum  
Instem to present 'Gaining Intelligence from Regulatory Information Management via utilizing Medicinal Product Analytics'  
  
January 17, 2017  
WuXi AppTec Selects Instem's Submit™ Software Suite to Meet Growing Demand for SEND  
Leading China Based CRO Purchases Full Submit Software Suite for Complete SEND Management  
  
January 11, 2017  
Instem Appoints MaryBeth Thompson as Chief Operating Officer   
Thompson Joins Instem to Help Develop and Implement Next Phase of Growth   
  
  
  
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Instem to Release Next Edition of its Leading Computational Toxicology Software Suite  
Powerful New In Silico Models and First-to-Market Software Capabilities to Deliver Further Efficiencies and Increased Regulatory Compliance   
PHILADELPHIA, PA – (BUSINESS WIRE) – July 29, 2021 - Instem, a leading provider of IT solutions and services to the global life sciences market, announced today that the latest edition of its Leadscope Model Applier computational toxicology software solution will be released in September, ahead of a number of key industry meetings. This latest release includes a comprehensive package of new and updated models and alerts to meet the growing market demand for in silico solutions.  
Renowned for their advanced informatics and prediction technology, together with comprehensive database solutions, Instem’s in silico solutions enable organizations around the world to effectively unlock valuable knowledge contained in both public and proprietary sources of research data. Clients can also access well over 500,000 toxicology studies for more than 200,000 chemicals, enabling fast, accurate, defendable and regulatory-accepted predictions.  
Key highlights of the 2021 software release include:  
  
New ICH M7 Protocol Tool - A new out-of-the-box ICH M7 protocol tool that enables faster, more consistent ICH M7 reporting, identification of carcinogenicity and bacterial mutagenicity data, and the ability to assess whether a chemical is in the cohort of concern.  
New Bioactivation Profiler – This brand new, first-to-market Bioactivation Alerts suite includes a series of structural alerts associated with reactive metabolite formation. It replaces existing, labor-intensive manual literature review processes, reducing literature review timescales from days to seconds. The Bioactivation Alerts suite also directly supports recent FDA guidance for industry in relation to in vitro drug interaction studies.   
New Structure Drawing Tool - A new, easy-to-use, integrated structure drawing package that supports chemical structures and substructure queries, eliminating the need for 3rd party structure drawing applications.  
Enhanced Skin Sensitization Models - Updated models and alerts for the assessment of skin sensitization; Includes new models to predict ECETOC categories and supports assessment of chemical products, extractables and leachables, and classification and labelling.  
New Skin Irritation and Corrosion Models – New expert alerts and statistical models to predict Cat. 1 (corrosive), Cat. 2 (irritants), Cat. 3 (mild irritants), and Not Classified, as well as a new, comprehensive skin corrosion/irritation database of approximately 4,000 chemicals.   
New Endocrine Activity Models – New statistical-based models to support the assessment of endocrine activity, including models for estrogen receptor bioactivity and thyroperoxidase inhibition.  
Improved Bacterial Mutagenicity Expert Alerts – Updated alerts based on an analysis of 50,000 public and proprietary chemicals with Ames data, including aromatic amines, nitrosamines, halo pyridines and boronic acids. Clients can expect fewer false positives, false negatives, and out-of-domains, as well as benefiting from additional information to support an expert review.  
Abuse Liability – A new database has been compiled along with structural alerts to profile potential abuse liability.   
  
Dr. Glenn Myatt, VP Informatics, Instem said “We are extremely excited about the 2021 software release, which supports the continued global demand for reliable alternatives to traditional testing methods. Industry and regulators alike are increasingly recognizing the huge benefits of computational toxicology approaches and we are seeing strong and sustained growth in the acceptability and adoption of in silico methods.”   
 Dr. Myatt continued “This latest software release will enable both existing and prospective clients to accelerate their drug discovery and development processes by ensuring fast, accurate, defendable and regulatory accepted predictions for an increasing range of applications.”   
Instem will be conducting a comprehensive program to help raise awareness of this important 2021 software release through on-demand demonstrations and at key industry events.   
To be added to the release alert list and be first to receive a copy of the on-demand presentation, please email insilico@instem.com   
About Instem  
A global provider of leading software solutions and scientific insight services, Instem is helping clients bring their life enhancing products to market faster.  
From Concepts to Cures, we enable organizations in the life sciences to more efficiently collect, report and submit high quality regulatory data, while offering them the unique ability to generate new knowledge through the extraction and harmonization of actionable scientific information.  
Across the entire drug development value chain, every day Instem solutions are meeting the rapidly expanding needs of life science organizations for data-driven decision making, leading to safer, more effective products.  
Instem supports its global roster of clients through offices in the United States, United Kingdom, France, Japan, China, and India.  
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Instem To Showcase Leading GeneTox Solutions at EEMGS Meeting, Potsdam, Germany  
Instem Exhibiting at Prominent European Genetic Toxicology Conference  
CONSHOHOCKEN, PA– February 26, 2018 - - Instem, a leading provider of IT solutions to the global life sciences market, is pleased to announce they will be showcasing their leading genetic toxicology solutions (originally developed by Perceptive Instruments and now part of the Instem solution portfolio) at the 46th European Environmental Mutagenesis and Genomics Society (EEMGS) meeting, to be held in Potsdam, Germany from 18th to 21st March.   
This year’s meeting will be held in conjunction with the 30th GUM (Gesellschaft für Umwelt-Mutationsforschung) Meeting and will cover all aspects relating to DNA damage and mutations caused by environmental agents, with a focus on new technologies and innovative modalities.   
Visitors to Instem’s booth, # 6, will learn how organizations across the globe are using Instem solutions to improve the integration between data acquisition, auditing and reporting for regulatory genetox assays. Solutions on display will include:  
  
Comet Assay IV - the market leading live video imaging system for fast, accurate and reproducible slide comet scoring   
Cyto Study Manager - Data acquisition, integration and reporting for genetic toxicology assays, including modules for the comet assay, micronucleus test and chromosome aberrations  
Sorcerer Colony Counter – instant, automatic plate counting for GLP laboratories  
Ames Study Manager – plate counting, data management and reporting for the Ames test   
  
Booth visitors will also learn the latest FDA SEND (Standard for Exchange of Nonclinical Data) status as it applies to Genetic Toxicology studies.   
About Instem  
Instem is a global provider of leading software solutions and services that are helping over 500 clients bring their life enhancing products to market faster. We enable clients in the life sciences to more efficiently collect, analyze, report and submit high quality regulatory data, while maintaining compliance for their products around the world.   
Instem solutions are in use by customers worldwide, meeting the rapidly expanding needs of life science and healthcare organizations for data-driven decision making, leading to safer, more effective products.  
Instem supports its global roster of clients through offices in the United States, United Kingdom, France, Japan, China and India.   
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FDA SEND Mandate for IND Submissions Goes Into Effect  
CDISC SEND Standard Now Applies to all IND Submissions to FDA  
CONSHOHOCKEN, PA - December 18, 2017 - Instem, a leading provider of IT solutions to the global life sciences market, announced today that the next major milestone in FDA’s adoption of SEND (Standard for Exchange of Nonclinical Data) came into force over the weekend, mandating that IND submissions now fall under the requirement to include SEND datasets. This requirement is for SEND 3.0 and means that the same requirement which has been in place for NDAs, now applies to new INDs that start after December 17, 2017.  
The introduction of SEND for both regulatory submission and the electronic exchange of toxicology data is having a significant impact on the industry. Each organization in the pharmaceutical early development value chain is now touched by the implementation of this standard and will need to make changes to their systems and working practices.  
Failure to comply with the SEND Mandate can result in the FDA’s technical rejection or refusal to file a submission.   
Instem has unparalleled experience in helping companies to prepare for SEND, and its software tools and outsourced SEND services are the most widely adopted in the industry at over 80 client sites across 15 countries. Instem’s team of SEND experts has helped to organize, educate and guide clients to becoming SEND-Ready, identifying specific approaches that maximize the benefits of SEND, while ensuring regulatory compliance.  
For more information about Instem’s submit™-tools & outsourcing services for the creation, management, visualization and pre-submission analysis of SEND datasets click here.  
About Instem  
Instem is a global provider of leading software solutions and services that are helping over 500 clients bring their life enhancing products to market faster. We enable clients in the life sciences to more efficiently collect, analyze, report and submit high quality regulatory data, while maintaining compliance for their products around the world.   
Instem solutions are in use by customers worldwide, meeting the rapidly expanding needs of life science and healthcare organizations for data-driven decision making, leading to safer, more effective products.  
Instem supports its global roster of clients through offices in the United States, United Kingdom, France, Japan, China and India.   
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Guangdong Lewwin Pharmaceutical Research Institute Selects Provantis Preclinical Software Solution  
Provantis to Increase Efficiencies and Streamline Preclinical Processes at South China Research Facility  
CONSHOHOCKEN, PA – Business Wire, Jan 8, 2018 -Instem, a leading provider of IT solutions to the global life sciences market, announced today that Guangdong Lewwin Pharmaceutical Research Institute Co., Ltd. (Guangdong Lewwin Pharmaceutical) has purchased the Provantis® preclinical software solution suite to manage preclinical processes at the Center for Drug Non-clinical Evaluation and Research of Guangdong Institute of Applied Biological Resources in Guangdong, Southern China.  
Established in 2014, Guangdong Lewwin Pharmaceutical is the first institute in South China to gain the full CFDA GLP certificate (9 items) and has also achieved AAALAC international certification in the field of non-clinical safety evaluation pharmacology, toxicology, new drug screening research and cellular biology research.  
Provantis will replace existing manual processes at the Guangdong facility, delivering increased efficiencies in the collection, storage and reporting of preclinical data, as well as ensuring GLP and regulatory compliance.  
Key Facts  
  
Guangdong Lewwin Pharmaceutical to deploy an extensive suite of modules including General Toxicology, Reproductive Toxicology, Pathology, Protocol Report & Assembly, Clinical Pathology, Tables & Statistics, Dispense and Data Import  
Contract awarded following a rigorous competitive evaluation; Provantis recognized as the global market leader and the overwhelming standard within China  
Evaluation included extended onsite visits to two existing Instem clients within China   
Client to harness the power of the Instem University e-learning platform and a range of professional services to facilitate quick implementation and a rapid return on investment   
  
Dr. Wei Yang, Director of the Center said “When evaluating the systems available on the market it was very important for us to hear first-hand experiences from current users and to see the software in action. Members of our team undertook extended visits to two of Instem’s existing clients in the region and we were very impressed with the software functionality, ease of use and the efficiency gains Provantis is delivering within these organizations.”  
Dr. Jianmin Guo, Deputy General Manager of the Center, added “The site visits were not only a great way to evaluate Provantis, we were also able to learn from the experiences of Instem’s current customers to give us a head start on our implementation project which will begin in earnest during the first quarter of this year.”  
 Neil Donaldson, VP Sales Europe & Asia, Instem, commented, “We are delighted to welcome Guangdong Lewwin Pharmaceutical to our growing roster of clients within China and look forward to forging a long and successful relationship with them.”   
Instem’s Provantis solution was the first western toxicology/pathology software to enter into the Chinese market, deploying its initial system in one of the largest and most advanced vivariums during 2006. As the Chinese preclinical market continues to grow, Instem is leading the market, with its Provantis solution deployed at more sites within the region than any competing product.  
Instem has an established full-service office in Shanghai and supports organizations through traditional on-site systems, as well as through its SaaS delivery model from a secure, professionally managed data center based in Shanghai.  
About Guangdong Lewwin Pharmaceutical Research Institute  
Located in Guangzhou, strictly following CFDA GLP regulations and AAALAC animal welfare requirements, Guangdong Lewwin Pharmaceutical is able to provide accurate, reliable and high quality nonclinical research services, including new drug research and development, new drug screening, pharmacology research, drug safety evaluation, non-clinical pharmacokinetics research, new drug registration and application, human disease animal model preparation and research and other professional technical services to support the pharmaceutical industry. The core strength of Guangdong Lewwin Pharmaceutical is its intensively and extensively experienced professionals and management team. Guangdong Lewwin Pharmaceutical aims to become an international non-clinical evaluation center in the future.   
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Instem Exhibiting and Presenting at Society of Toxicology Annual Meeting  
Instem Showcasing its Preclinical Solutions While Leading Sessions on SEND Readiness and Target Safety Assessment   
CONSHOHOCKEN, PA – March 4, 2016 - - Instem, a leading provider of IT solutions to the global early development healthcare market, is pleased to announce it will be exhibiting at the Society of Toxicology Annual Meeting and ToxExpo at The Ernest N. Morial Convention Center in New Orleans March 13-17th. Instem will also be holding two Exhibitor Hosted Sessions and Poster Presentations at the meeting.  
The largest event of its kind, the Society of Toxicology Annual Meeting and ToxExpo will welcome over 6,800 attendees from more than 50 countries around the world and will host over 330 exhibitors. The meeting and exhibition promises stimulating lectures and presentations on scientific breakthroughs, important education and professional training opportunities.  
Visitors to this year’s SOT ToxExpo will learn about:  
  
 Instem stand #737  
  
Submit™ - the most widely deployed set of tools and SEND services, adopted at 35 sites across 12 countries   
Provantis® - the undisputed leading solution for preclinical study management  
KnowledgeScan™ - solution service for enabling optimal Target Safety Assessment  
  
Perceptive Instruments, an Instem Company, stand #1418  
  
Comet Assay IV – the market leading live video imaging system for fast, accurate and reproducible slide comet scoring  
Cyto Study Manager – Data acquisition, integration and reporting for genetic toxicology assays  
  
Instem will also be holding the following Exhibitor Hosted Sessions:  
Making SEND Business as Usual   
Monday, March 14th, Room 212  
4:30pm – 5:30pm  
 At this session an industry panel comprising of Sponsors and CROs will share insights about the steps they have taken in their journeys of becoming SEND-enabled. This program has been designed to better inform, instruct and guide attendees at any stage of SEND Readiness.   
KnowledgeScan™, a New Approach to Target Safety Assessment  
Tuesday, March 15th, Room 213  
4:30pm – 5:30pm  
 Co-presented by special guest, Dr. James Sidaway, Director at Phenotox Ltd., this presentation will introduce attendees to its uniquely effective Target Safety Assessment service. KnowledgeScan is a novel approach which utilizes a combination of manual and automatic data-mining approaches to help users assess the potential safety consequences of targeting specific biological pathways.   
Both sessions will offer complimentary appetizers and drinks.  
KnowledgeScan™ Target Safety Assessment will also be showcased at the following late-breaking poster presentations:  
  
A systematic comparison of genetic intervention and antibody studies for the immune check point inhibitors supports a strategy for predicting novel target-mediated toxicities (Abstract Number/Poster Board number: 3668/P360)   
A systematic assessment of human druggable target genes identifies absent orthologues in mouse and rat (Abstract Number/Poster Board number: 3667/P359)  
Both poster presentations will take place on Thursday, March 17th from 9:30 a.m. 12:45 p.m. in Great Hall A.  
About Instem   
Instem is a leading supplier of IT applications to the early development healthcare market delivering compelling solutions for data collection, management and analysis across the R&D continuum. Instem applications are in use by customers worldwide, meeting the rapidly expanding needs of life science and healthcare organizations for data-driven decision making leading to safer, more effective products.  
Instem’s portfolio of software solutions increases client productivity by automating study-related processes while offering the unique ability to generate new knowledge through the extraction and harmonization of actionable scientific information.  
Instem supports over 400 clients through full service offices in the United States, United Kingdom and China with additional locations in Japan and India.   
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Instem Acquires RIM Solution Provider Samarind  
Samarind Strengthening Global Position as Part of Instem Organization  
CONSHOHOCKEN, PA - (BUSINESS WIRE) – May 31, 2016 - -Instem, a leading provider of IT solutions to the global early development healthcare market, announced today that it has acquired the UK-headquartered Samarind organization to help bring scalability and next generation capabilities to the increasingly complex global regulatory environment.  
Samarind provides Regulatory Information Management (RIM) solutions to the life sciences sector that significantly improve the quality of regulatory information and help achieve and maintain compliance for pharmaceutical, biotech and medical device products.  
Samarind is well known in the marketplace for its commitment to the ongoing development of high quality, sophisticated, user-friendly and well-architected software solutions. Samarind solutions are in use by customers around the world and are supported by a level of customer service that is setting a new benchmark for client satisfaction within the life sciences.  
The Samarind RMS solution suite of software and services gives clients the ability to manage the entire medicinal product life cycle without having to enter information twice. Samarind RMS provides the security, flexibility and ease of use that regulatory affairs teams need to achieve and exceed their regulatory and commercial goals. Samarind RMS is a robust user-friendly software application that precisely manages the key areas of product license acquisition and maintenance, including eCTD, EVMPD, IDMP, Drug Safety and Medical Devices.  
“On behalf of our clients and staff, we couldn’t be happier to be part of the Instem group and the transformation they are leading in health and life sciences,” comments Dr. Olaf Schoepke, Vice President, Regulatory Solution Development at Samarind. “This acquisition by Instem brings core clinical and regulatory capabilities together so we can expand the value and impact that we bring to our client partners.”  
“Our RMS solution provides a single place of truth® for regulatory affairs professionals — in other words, a complete end-to-end system that handles all of the regulatory and pharmacovigilance disciplines in a clear and concise manner,” states Ian Crone, Vice President Global Regulatory Sales at Samarind. “This helps our customers achieve accurate and global control over their data, and is very much suited to providing a fully compliant solution for the adoption of the new upcoming standard known as IDMP.   
We are excited to share this news with our current clients and are looking forward to tapping into the additional capabilities and reach Instem can provide to help us further grow our user community.”  
The European Medicines Agency (EMA) is in the process of implementing the standard developed by the International Organization for Standardization (known as ISO) for the Identification of Medicinal Products (IDMP). These are a set of common global standards for data elements, formats and terminologies for the unique identification and the exchange of information on medicines. Organizations will be required to submit data on medicines and devices in accordance with these formats and terminologies.  
Samarind worked extensively with the EMA on the original standard (EVMPD) in 2005 and were first to market with a fully working EVMPD solution. Samarind’s RMS solution has been designed to adapt to each iteration of the EMA implementation of IDMP, which will evolve into a global standard, as the guidelines are published.   
 Samarind are members of the (European-focused) IRISS IDMP group and the USA’s IDMP External Working Group (IDEX).   
Mike Harwood, Instem’s Executive Vice President of Regulatory Solutions commented, “Samarind aligns perfectly with our strategy of harmonizing IT systems and processes in today’s competitive marketplace. Through our organic and acquisitive growth, we are answering the call of our clients to create a highly functional ecosystem to help them bring life enhancing products to market faster.”   
Harwood also stated, “More specifically, Instem’s experience in developing the Standard for Exchange of Nonclinical Data (SEND) and our commanding leadership position combined with the specialists at Samarind will certainly help during the IDMP implementation and adoption phases. IDMP will be an important change in the market and Samarind is on the forefront of global leadership. Instem’s rapidly growing services capabilities will be especially helpful as the market continues to turn towards Samarind for timely and quality XEVMPD to IDMP data conversion services.”  
Samarind RMS will be aligned with Instem’s eStudy Data and Regulatory Management Solutions group, where they are providing focused software and services for converting, managing, storing, sharing and submitting information to FDA and other agencies.  
Instem is planning to integrate Samarind quickly and will be looking to further increase market penetration in specific functional and geographic sectors. Instem, which is already working directly with many regulatory departments on SEND, will be looking to introduce Samarind RMS so as to deliver more commercial value and regulatory power to the relationship.   
More about Samarind RIM Solution  
Deployed on-site or accessed on-line, Samarind RMS provides a smarter way to manage medicinal product license information, where customers only need to enter data once and reuse it as many times as required. This concept applies to all key data held within the system and is proven to streamline workload and help increase the quality of data. It is a fully integrated software application that has been purpose built to mirror the processes associated with acquiring and maintaining a pharmaceutical product license.  
Components include:  
  
A secure Regulatory Information Management (RIM) system with planning, tracking, automated alerts and comprehensive reporting facilities  
An electronic document management system (EDMS) with version control, template creation and the ability to link to external document management systems such as Documentum™ or SharePoint  
An optional eCTD module for dossier creation and maintenance (NeeS is also supported)  
An optional EVMPD module for automated maintenance of data required by the EMA’s extended medicinal product dictionary, xEVMPD  
A Med Info addition, for quick and easy logging of medical information queries, with links to the associated products elsewhere in the system as necessary  
A Medical Devices module plus UDI add-on to handle any kind of medical devices  
A Drug Safety module, handling Pharmacovigilance requirements  
  
Some of the RMS benefits clients are realizing include:  
  
A ‘single point of truth’ for all product license data, minimizing information inconsistency  
Increased administrative efficiency, allowing timely response to critical deadlines  
Improved global regulatory communications via information sharing through the medicinal product life cycle  
Improved product launch planning  
  
To find out more information about Samarind RMS and a full list of benefits, please visit www.samarindrms.com  
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Instem at SOT 2024  
Empowering Collaboration and Life Enhancing Science  
Stop by Island Booth #1401  
Visit us to learn more about our leading Preclinical Study Management, SEND, In Silico Toxicology and Translational software and services.   
Provantis®  
 the #1 solution for managing preclinical studies. Provantis streamlines processes and workflows with straightforward, intuitive functionality for simple and complex studies within both GLP and non-GLP environments.  
   
SEND Solutions  
 The most comprehensive and widely deployed set of software (Submit™) and services (SEND Advantage™) supporting the creation and management of SEND datasets.   
   
Genetic Toxicology   
 Image analysis and data management solutions helping users better collect, manage, review and extract data while transitioning information into insight, utilizing our Comet Assay IV and Cyto Study Manager tools.   
KnowledgeScan™ Target Safety Assessment (TSA) ServiceDelivering comprehensive TSAs for clients around the world, enabling them to make faster, better-informed decisions on their drug targets.  
Watch the KnowledgeScan Explainer video   
Leadscope Model Applier™ In Silico Toxicology SoftwareAdvanced informatics and prediction technology, together with comprehensive database solutions that are helping organizations effectively unlock valuable knowledge contained in both public and proprietary sources of research data.  
Predict™ In Silico Toxicology ServiceA leading edge, technology-enabled service that delivers a combination of powerful computation models with expert scientific review, to help clients predict chemical safety more quickly, efficiently and comprehensively.  
Advance™ – Weight of Evidence Assessments  
A technology-enabled approach for assessing carcinogenicity based on the recently published ICH S1B Weight of Evidence (WoE) Addendum.   
If you would like to schedule a discussion with us during SOT contact us at info@instem.com indicating your area of interest.   
  
Instem Event Schedule  
Monday March 11  
Exhibitor Hosted Event: Does SEND Pave the Way for Creating Virtual Control Groups?  
Monday, March 11, 3:00 PM - 4:00 PM (Mountain), Room 155 E  
SEND-format data is a required submission standard, but practically, what else can we do with highly formatted and controlled datasets? The industry's universal adoption of standardization and quest for improvement opens the door to exciting, innovative data-reworking applications. This session will discuss the opportunities for data use beyond submissions, specifically in the area of constructing virtual control groups.   
Presented by Marc Ellison, Director of SEND Solutions, Instem & Brenda Finney, PhD, Instem’s VP of Translational Science  
  
Tuesday March 12  
Exhibitor Hosted Event: Future Proofing Drug Safety: Target Carcinogenicity Risk Assessment Meets ICH S1B(R1) Standards  
Tuesday, March 12, 3:00 PM - 4:00 PM (Mountain), Room 155 E  
In the fast-paced and cost-conscious 'drug to market' race, momentum can be gained by implementing a Weight of Evidence (WoE) to negate unnecessary preclinical testing. We will present results from a collaboration to standardize a procedural framework supporting the ICH S1B(R1) integrated assessment. Specifically, target biology (WoE #1) will be presented.  
Presented by Frances Hall, PhD, Scientific Application Director, In Silico and Translational Science Solutions, Instem  
Symposium Session 1208: Nitrosamines: Mechanistic Evidence to Support Subclasses with Varying Mutagenic Potency  
Tuesday, March 12, 4:45 PM - 6:15 PM (Mountain), Grand Ballroom A  
This Symposium will present the findings of the EMA-funded MUTAMIND project and US Food and Drug Administration (US FDA) experimental investigations, as well as discuss the latest regulatory guidelines for SAR-based potency assessment.   
Presenter & Chair- Kevin Cross, PhD, VP, Regulatory Science, Instem  
Symposium Session Panel Discussion: Carcinogenic Potency Assessment and Other Hot Topics for Regulation of N-Nitrosamines  
Tuesday, March 12, 5:50 PM - 6:15 PM (Mountain), Grand Ballroom A  
This panel discussion will present the latest issues regarding the regulatory risk assessment of N-nitrosamines for carcinogenic potency and provide a forum for discussion of issues with the audience.  
Chair: Kevin Cross, PhD, VP, Regulatory Science, Instem  
Co-Chair: Timothy McGovern, US FDA  
Proud Sponsors of the Computational Toxicology Specialty Section (CTSS)   
Instem are proud to be Gold Sponsors of the Computational Toxicology Speciality Section (CTSS) who will be hosting a Reception on Tuesday 12th March at 6:00 PM - 7:30 PM in the Salt Lake Ballroom B at the Hyatt Regency. The event is open to all interested Annual Meeting Attendees  
  
Wednesday March 13  
Exhibitor Hosted Event: Using the Carcinogenicity Potency Categorization Algorithm to Predict N-Nitrosamine Carcinogenicity  
Wednesday, March 13, 12:00 PM - 1:00 PM (Mountain), Room 155 E  
This session will describe the Carcinogenicity Potency Categorization Algorithm (CPCA) that is used by regulators for quickly predicting carcinogenicity potency of N-nitrosamines under ICH M7. It will also present a Health and Environmental Sciences Institute (HESI) nitrosamine QSAR workgroup where Instem is co-leading a collaboration with health authorities, academics, and industry to address current and future nitrosamine regulatory issues.  
Presented by Kevin Cross, PhD, VP, Regulatory Science, Instem & Connie Chen, PhD, Senior Scientific Program Manager, Health and Environmental Sciences Institute  
  
We are also pleased to be involved in the following posters:   
Posters in order of session time:   
Abstract Number/Poster Board number: 3106/P210  
Abstract Title: Mutamind: Benchmark Dose Modelling of N-Nitrosamines based on comet and enhanced Ames assay data   
Presenting Author: Anke Londenberg, Fraunhofer Institute for Toxicology and Experimental Medicine, Co-Author, Kevin Cross, Instem  
Session Title: Genotoxicity/DNA Repair  
Session Time: 11th March 2024 11:45 AM to 1:45 PM   
  
Abstract Number/Poster Board number: 3036/P137  
Abstract Title: Reviewing carcinogenicity potency of N-nitrosamides and N-nitrosoureas in terms of structure-activity-relationship considerations   
Presenting Author: Arianna Bassan (Innovatune), Co-Author, Kevin Cross, Instem  
Session Title: Safety Assessment: Pharmaceutical-Drug Development II  
Session Date and Time: 11th March 2024 2:15 PM to 4:15 PM   
  
Abstract Number/Poster Board number: 3042/P143  
Abstract Title: Emerging applications of computational methods in the reactivity assessment of extractables and leachables  
Presenting Author: Candice Johnson, Instem, Co-Author, Kevin Cross, Instem  
Session Title: Safety Assessment: Pharmaceutical-Drug Development II  
Session Date and Time: 11th March 2024 2:15 PM to 4:15 PM   
  
Abstract Number/Poster Board number: 4671/P558  
Abstract Title: Use of Implantable Wireless Data Loggers to Enhance Cardiovascular Safety Assessment   
Presenting Author: Bob Brockway, TSE Systems, Co-Author, Logan Laszczyk, Instem   
Session Title: Cardiovascular Toxicology/Hemodynamics  
Session Time: 13th March 2024 9:15AM – 11:15AM   
  
Abstract Number/Poster Board number: 4393/P180  
Abstract Title: Application of (Q)SARs for the genotoxicity assessment of flavorings  
Presenting Author: Manuela Pavan, Innovatune SRL, Co-Author, Kevin Cross, Instem  
Session Title: Computational Toxicology II  
Session Time: 13th March 2024 2:15 PM to 4:15 PM   
  
Abstract Number/Poster Board number: 4409/P196  
Abstract Title: Exploring the Carcinogenicity Potency Categorization Algorithm for N-Nitroso Carcinogenicity Predictions - limitations and the future  
Presenting Author: Kevin Cross, Instem  
Session Title: Computational Toxicology II  
Session Date and Time: 13th March 2024 2:15 PM to 4:15 PM  
  
Abstract Number/Poster Board number: 4573/P408  
Abstract Title: Advancement of New Drug Evaluation Process and Required Manufacturer & CRO Responses  
Presenting Author: Takayuki Anzai, Instem  
Session Title: Regulation/Policy  
Session Date and Time: 13th March 2024 2:15 PM to 4:15 PM  
  
Abstract Number/Poster Board number: 5025/P126  
Abstract Title: The Application of Skin Sensitization In Silico Models for the Assessment of Pharmaceuticals and Their Related Compounds  
Presenting Author: Mingzhu Fang, Bristol-Myers Squibb, Co-Author: Candice Johnson, Instem  
Session Title: Late-Breaking 1  
Session Date and Time: 14th March 2024 8:30 AM to 11:30 AM  
   
  
  
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NOTOCORD Sponsors DSI User Group Meeting and Showcases Data Acquisition and Analysis Solutions  
NOTOCORD to Exhibit and Present at DSI User Group Meeting, Reims, France  
CONSHOHOCKEN, PA– March 13, 2017 - - Instem, a leading provider of IT solutions to the global early development healthcare market, is pleased to announce that NOTOCORD, now part of the Instem Group, is exhibiting and presenting at the DSI user group Meeting in Reims, France on March 16th and 17th.  
NOTOCORD will showcase its leading data acquisition and analysis software solutions for cardiovascular, hemodynamic, respiration and neuroscience research. Visitors to NOTOCORD’S booth can view a demonstration of NOTOCORD’S in-vivo telemetry solution, which has direct links with DSI PhysioTel HD and PhysioTel digital implants. Delegates can also see a preview of the upcoming latest release of NOTOCORD-hem, NOTOCORD’S advanced software platform for the acquisition, display and analysis of physiological signals. This latest release, version 4.3.0.75, is compatible with DSI Hardware Configuration 1.8 and offers improved GLP compliance.  
NOTOCORD will also present a brief overview of its solutions at the plenary session on Thursday, March 16th.  
About Instem  
Instem is a leading supplier of IT applications and services to the early development healthcare market delivering compelling solutions for data collection, analysis and regulatory submissions management. Instem solutions are in use by customers worldwide, meeting the rapidly expanding needs of life science and healthcare organizations for data-driven decision making leading to safer, more effective products.  
Instem’s portfolio of software solutions and consulting services increases client productivity by enhancing product development processes while offering the unique ability to generate new knowledge through the extraction and harmonization of actionable scientific information.  
Instem supports over 500 clients through offices in the United States, United Kingdom, France, Japan, China and India.  
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Instem Exhibiting at EUROTOX Annual Meeting, Brussels, Belgium  
Instem to Showcase Market Leading Preclinical Solutions and Outsourced Services   
CONSHOHOCKEN, PA – August 20, 2018 - - Instem, a leading provider of IT solutions to the global life sciences market, is pleased to announce it will be exhibiting at the 54th EUROTOX Annual Meeting from 2nd to 5th September, 2018, in Brussels.  
Visitors to Instem’s booth, #25, will learn more about:   
  
Submit™ for SEND Management- the most widely adopted suite of software and outsourced study services deployed at over 80 client sites in 15 countries. Stop by and learn how to Submit with confidence™. Download a case study now ahead of the event.   
Provantis® - the leading SaaS solution for preclinical study management, serving single users to multi-site clients. Provantis users also have access to the Provantis Academy, an intuitive, online learning solution. Visit us for a demonstration! Learn how clients have reduced preclinical time from hours to minutes, download the case study.  
KnowledgeScan™ - Using a combination of artificial intelligence and human expertise KnowledgeScan is a unique technology that is revolutionizing Target Safety Assessment (TSA). Customers can make faster, better informed decisions on their drug targets as a result of high-quality, unbiased and evidence-based TSA’s. Download the whitepaper.  
  
Visitors to Instem’s booth, #26, will learn more about our Genetic Tox solutions which are used in over 50 countries   
  
Comet Assay IV – the market leading live video imaging system for fast, accurate and reproducible slide comet scoring  
Cyto Study Manager – a comprehensive and configurable solution, which replaces multiple genetox systems and increases data reliability and traceability whilst saving time and resources   
Ames Study Manager – plate counting, data management and reporting for the Ames test  
Sorcerer Colony Counter – instant automatic plate counter for GLP laboratories  
  
The theme at this year’s meeting is “Toxicology Out of the Box” which Instem is pleased and expertly positioned to support. It reflects the willingness and enthusiasm of the organizing committee to offer a very innovative, forward-looking and imaginative scientific programme. There will be lectures and sessions with well-balanced inputs from academia, industry and regulators and over 70 exhibitors.   
About Instem  
Instem is a global provider of leading software solutions and services that are helping over 500 clients bring their life enhancing products to market faster. We enable clients in the life sciences to more efficiently collect, analyze, report and submit high quality regulatory data, while maintaining compliance for their products around the world.   
Instem solutions are in use by customers worldwide, meeting the rapidly expanding needs of life science and healthcare organizations for data-driven decision making, leading to safer, more effective products.  
Instem supports its global roster of clients through offices in the United States, United Kingdom, France, Japan, China and India.   
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Instem at SOT 2019 in Baltimore   
Exhibitor Hosted Sessions  
The Value of SEND Data – Industry Perspectives  
Monday, March 11th  
 4:30pm - 5:30pm  
 Room 337  
Although a standard, there can be differences in the way SEND data can be presented. Some are only concerned about doing what is needed for the FDA to accept their submission, while others are looking beyond to gain maximum value out of their SEND data. Come and join the discussion to shape your strategy and approach to best suit the demands and needs of your organization.  
Watch the video  
Innovation and Industry Trends in Target Safety Assessment  
Tuesday, March 12th  
 4:30pm - 5:30pm  
 Room 337  
Join our session to learn how Instem’s KnowledgeScan TSA service harnesses innovations in technology, workflow and data visualization to enable the expeditious production of comprehensive, consistent and high-quality TSAs.  
Booths at ToxExpo  
Booth 3533  
Leading IT Solutions - Leading IT Results  
 Submit™: The most widely adopted SEND software & outsourced study services. Learn how you can, submit with confidence.   
 Provantis®: The #1 solution for preclinical study management, accessed online (SaaS) or on-premise. KnowledgeScan™ Target Safety Assessment (TSA) Service: Setting new standards in biological target profiling - a pioneering technology-enabled service delivering comprehensive, consistent, high quality TSAs more quickly and efficiently.  
Watch the video  
Booth 3856  
Using Instem’s leading Genetox Solutions, stop by and learn how clients are improving the integration between data acquisition, auditing and reporting for genetox assays. Our flagship solutions include Comet Assay IV, Sorcerer Colony County, Ames Study Manager and Cyto Study Manager. Also be sure to talk to us about SEND! Consolidating, harmonizing and empowering the processes that help bring products to market faster.  
Watch the video   
Booth 4234  
Target Safety Assessment (TSA) Services: Setting new standards in biological target profiling   
 Visit Instem’s TSA Center of Excellence at booth 4234 to learn how organizations are harnessing innovations in technology, workflow, and data visualization to transform TSA processes. Using leading edge augmented intelligence capabilities, our pioneering, technology-enabled KnowledgeScan TSA service enables clients to produce comprehensive, consistent, high quality TSAs more quickly and efficiently.   
Watch the video   
If you would like to talk to us more about anything you saw during your visit to SOT contact us at info@instem.com indicating your area of interest.  
We look forward to seeing you again next year!  
  
  
  
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Instem Exhibiting at Genetic Toxicology Association Meeting, Newark, Delaware  
Instem To Showcase Leading Genetic Toxicology Solutions  
CONSHOHOCKEN, PA– April 19, 2018 - - Instem, a leading provider of IT solutions to the global life sciences market, is pleased to announce they will be showcasing their leading genetic toxicology solutions (originally developed by Perceptive Instruments and now part of the Instem solution portfolio) at the Genetic Toxicology Association (GTA) Annual Scientific meeting, taking place May 3rd – 4th on the campus of the University of Delaware, Newark, DE.   
The meeting offers a comprehensive program focusing on important emerging issues in the field of genetic toxicology and optional workshops will take place on May 2nd preceding the start of this year’s annual meeting.  
Visitors to Instem’s booth will learn how organizations across the globe are using Instem solutions to improve the integration between data acquisition, auditing and reporting for regulatory genetox assays. Solutions on display will include:  
  
Comet Assay IV - the market leading live video imaging system for fast, accurate and reproducible slide comet scoring   
Cyto Study Manager - Data acquisition, integration and reporting for genetic toxicology assays, including modules for the comet assay, micronucleus test and chromosome aberrations  
Sorcerer Colony Counter – instant, automatic plate counting for GLP laboratories  
Ames Study Manager – plate counting, data management and reporting for the Ames test   
  
Booth visitors will also be able to learn more about the latest FDA SEND (Standard for Exchange of Nonclinical Data) status as it applies to Genetic Toxicology studies.   
The Genetic Toxicology Association (GTA) is a tax-exempt educational and scientific organization that was founded in 1975 and incorporated in 1981 under the laws of the state of Delaware. Its primary purpose is to promote the development of the science of genetic toxicology and to foster the exchange and dissemination of information concerning the field.   
About Instem  
Instem is a global provider of leading software solutions and services that are helping over 500 clients bring their life enhancing products to market faster. We enable clients in the life sciences to more efficiently collect, analyze, report and submit high quality regulatory data, while maintaining compliance for their products around the world.   
Instem solutions are in use by customers worldwide, meeting the rapidly expanding needs of life science and healthcare organizations for data-driven decision making, leading to safer, more effective products.  
Instem supports its global roster of clients through offices in the United States, United Kingdom, France, Japan, China and India.   
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Instem to Present at Society of Toxicologic Pathology Annual Symposium, Washington DC  
  
  
  
  
  
  
  
  
  
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Instem to Present at Society of Toxicologic Pathology Annual Symposium, Washington DC  
Instem presenting “Use of Legacy Data to Assess Species Concordance for Liver Injury”  
CONSHOHOCKEN, PA – (Business Wire) - June 19, 2014 - -Instem, a leading provider of IT solutions to the global early development healthcare market, is pleased to announce that Stephanie Berry, Head of Safety Information Management – Data Integration & Bioinformatics, Instem, will be presenting at the 33rd Annual Society of Toxicologic Pathology (STP) Symposium in Washington, DC.   
The poster presentation, “Use of Legacy Data to Assess Species Concordance for Liver Injury”, will discuss how Instem's Safety Intelligence Program (SIP) Tox/Path reference knowledgebase can be used to demonstrate how legacy data from different sources can determine drug effects from early testing through to market, and provide insight into the translational utility of non-human models.  
Ms. Berry said, “This research shows how Instem’s tools can be used to assess the concordance of drug effects in pre-clinical species and man. Our SIP knowledgebase enables a rapid review of what is known in the public domain about drug safety effects, and provides this summary in a format that can be readily analyzed. Instem’s OmniViz analytical platform then allows us to look deeper into this data, to identify key drug classes and pathological effects that correlate well, or poorly, between different species.”   
“Use of Legacy Data to Assess Species Concordance for Liver Injury” will be on display at STP Exhibit Hall C from 3pm Sunday June 22nd until 11:30am Wednesday June 25th.  
Delegates can see the SIP Tox/Path Knowledgebase and OmniViz solutions in action at Instem’s Trade Show Booth #300. At the booth, Instem will also be showcasing their market-leading Provantis® Pathology software solution for the collection, processing and reporting of data for gross and histopathology, as well as the submit™ suite of solutions for creating, managing and reviewing SEND data sets.  
The STP is a non-profit association of pathologists and other scientists whose principal aim is the advancement of pathology as it pertains to changes elicited by pharmacological, chemical, or environmental agents, and factors that modify these responses. STP members are dedicated to the integration of toxicologic pathology into hazard identification, risk assessment, and risk communication regarding human and animal exposure to potentially toxic substances.   
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Instem’s portfolio of software solutions increases client productivity by automating study-related processes while offering the unique ability to generate new knowledge through the extraction and harmonization of actionable scientific information.  
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Instem at Eurotox 2024 - Gold Sponsor  
Instem, Booth 30 & 31  
Discover our innovative Study Management, Regulatory & In Silico Solutions  
Provantis®  
 As the #1 preclinical software suite for organizations engaged in non-clinical evaluation studies, Provantis streamlines processes and workflows with straightforward, intuitive functionality for simple and complex studies within both GLP and non-GLP environments.  
Learn more about the significant updates to our Pathology suite, including enhanced capabilities for digital pathology as well as Spotlighter™, our historical data solution that helps you find the hidden value in your reference data.  
SEND Solutions  
 The most comprehensive and widely deployed set of software (submit™) and services (SEND Advantage™) supporting the creation and management of SEND datasets. Stop by our booth to learn more about our two latest software solutions, DefineNow™ for the creation and editing of define.xml files and GuidePro™, Instem’s Study Data Reviewer’s Guide generator.  
Genetic Toxicology  
 Image analysis and data management solutions helping users better collect, manage, review and extract data while transitioning information into insight, utilizing our Comet Assay IV and Cyto Study Manager tools. Also, don’t miss the opportunity to learn more about our new Transgenic Rodent Assay module!  
Advance™ Weight of Evidence Assessments   
Instem’s latest In Silico service which is re-imagining the way organizations perform carcinogenicity assessments via the 6 Weight of Evidence (WoE) factors under the ICH S1B guideline.  
KnowledgeScan™ Target Safety Assessment (TSA) Service  
Delivering comprehensive TSAs for clients around the world, enabling them to make faster, better-informed decisions on their drug targets.  
Watch the KnowledgeScan Explainer video   
Leadscope Model Applier™  
Advanced informatics and prediction technology, together with comprehensive database solutions that are helping organizations effectively unlock valuable knowledge contained in both public and proprietary sources of research data.   
Predict™ In Silico Toxicology service  
A leading edge, technology-enabled service that delivers a combination of powerful computation models with expert scientific review, to help clients predict chemical safety more quickly, efficiently and comprehensively.  
Centrus®  
An innovative technology platform that delivers a combination of pioneering, well-integrated computing modules, along with a comprehensive catalogue of non-clinical and clinical data.   
  
If you would like to schedule a discussion with us during Eurotox contact us at info@instem.com indicating your area of interest.  
  
Instem Event Schedule  
Tuesday, September 10  
Exhibitor Hosted Event: Information into Insights: How to reuse your SEND data within an S1B submission  
Tuesday, September 10, 12:00 PM - 1:00 PM (CEST)  
This presentation will examine the recent ICH S1B (R1) WoE Addendum – which explains how the two-year rat carcinogenicity test can be removed from the testing program if there is sufficient data already available to discredit (or prove) a cancer risk. If a two-year rat carcinogenicity test will not add value, then it can be negated in lieu of a comprehensive WoE dossier. Using a SEND package, which is already structured, standardized and machine readable, we show how the data can be interrogated to provide evidence for specific factors (e.g. histopathology and genetic toxicology) from the S1B guideline.  
Attendees of this presentation will gain insights into the growing prominence of WoE approaches in safety assessments, learning specifically how SEND datasets can facilitate the incorporation of relevant preclinical data into specific factors. Ultimately, we will provide a deeper understanding of how leveraging existing data can streamline safety assessments and potentially revolutionize regulatory practices.   
Presented by: Frances Hall, PhD, Scientific Application Director, In Silico and Translational Science Solutions, Instem, Marc Ellison, Director, SEND Solutions, Instem and Brenda Finney, PhD, VP Translational Science, Instem  
  
We are also pleased to be involved in the following posters:  
Abstract Number/Poster Board number: #435 /P05-18  
Abstract Title: Chemical classification and predictive models for the assessment of extractables and leachables  
Presenting Author: Kevin Cross, PhD   
Session Title: Computational Toxicology   
Session Date and Time: Monday, September 9, 9:30am  
  
Abstract Number/Poster Board number: #633/P20-19  
Abstract Title: Technology-enabled Approval Acceleration: Spotlighting the ICH S1B Weight of Evidence  
Presenting Author: Frances Hall, PhD   
Session Title: Regulatory Toxicology (REACH)  
Session Date and Time: Tuesday, September 10, 12.00pm  
  
Abstract Number/Poster Board number: #302 /P20-10  
Abstract Title: Embracing Regulatory Compliance: Genetox meets Generation SEND  
Presenting Author: Sofia Salazar Arenas   
Session Title: Regulatory Toxicology (REACH)  
Session Date and Time: Tuesday, September 10, 12:00pm  
  
Abstract Number/Poster Board number: #22 /P20-01  
Abstract Title: FDA SENDIG version 4.0 (the New SENDIG Version): Consideration on Additions and Changes on Histopathology-Related Data  
Presenting Author: Anzai Takayuki, PhD  
Session Title: Regulatory Toxicology (REACH)   
Session Date and Time: Tuesday, September 10, 12:00pm  
   
  
  
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Instem Releases Next Version of SRS Data Integration Platform  
SRS Version 8.4 Provides Advanced Searching Capabilities  
CONSHOHOCKEN, PA - (BUSINESS WIRE) – July 24, 2013 - -Instem, a leading provider of IT solutions to the global early development healthcare market, announced today it has released version 8.4 of its Sequence Retrieval System, also known as “SRS”.  
SRS is a proven and scalable data integration platform that is used at over 300 commercial and academic sites. Designed to ensure flexibility and scalability, SRS provides a multi-layer enterprise scale solution to the problem of large-scale bioinformatics and genomic data integration.  
SRS version 8.4 includes support for indexing data using Apache Lucene technology. This new text indexing technology provides SRS users with access to advanced text-based search capabilities, including improved phrase matching, fuzzy matching of terms and sorting of results based on the relevance of the match to the initial search.   
“Utilizing Lucene indexing on designated databanks, information is more easily and readily found, and does not require complex Boolean logic queries to bring the most relevant search results to the front,” comments Gordon Baxter, Instem’s Chief Scientific Officer. “Our end users can find their information of interest even faster without the need to navigate through pages of results. This is yet another differentiator to alternative technologies in the market and helps ensure our clients see a clear ROI on day one of their deployment.”  
Lucene indexing is configured by the administrator on a per-database level, and SRS administrators have access to a number of configuration options to improve the relevance of results, such as the boosting of individual fields and the specifying of stop-words and synonyms.  
Other Key updates in SRS version 8.4 include:  
  
Updates to platform and operating system support   
Support of latest Linux operating systems, including RedHat Enterprise 6 series and the CentOS 6 equivalents  
Internal stability and functionality changes; such as capabilities to make HTTP web service calls and retrieve remote data from within SRS scripts or parsers, as well as extensions to the SRS query language to support phrase searching  
  
Instem has seen increased interest in its SRS technology, including a recent award from a global healthcare organization to provide an enhanced SEND solution. Using SRS, the client can now identify patterns and trends in their data, generating new knowledge and scientific insight.   
About Instem  
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Chinese Government Research Facility Purchases Instem's Preclinical Software Suite  
Beijing-based Government Research Laboratory Selects Version 9 of Provantis Integrated Preclinical Software to Automate Study Processes  
CONSHOHOCKEN, PA - (BUSINESS WIRE) – April 10, 2013 - - Instem, a leading provider of IT solutions to the global early development healthcare market, announced today that a leading Chinese government research laboratory has purchased its Provantis® preclinical solution suite following a comprehensive competitive evaluation.  
Key Facts  
  
Extensive suite of integrated Provantis modules purchased including In-Life, Reproductive Toxicology, Pathology, Dispense, Clinical Pathology and Data Import  
Beijing research facility to implement Provantis 9; the latest version of Instem’s market leading preclinical software solution   
Contract awarded following a detailed competitive evaluation of Instem and another Western vendor; Instem selected for global market leading position and demonstrable commitment to the China market via a dedicated full service office in Shanghai and localized product suite  
Provantis to replace paper-based systems and in-house developed applications to streamline processes and further improve productivity  
A range of professional services purchased to facilitate rapid implementation and an immediate return on investment  
  
Neil Donaldson, VP European & Asian Operations, Instem said “We are delighted to welcome yet another organization to our growing roster of clients within China. This new contract award demonstrates our continued leadership in the Chinese preclinical market and opens up additional opportunities to expand our footprint within the government sector.”  
This announcement follows a purchase of Provantis by one of China’s largest providers of preclinical services, JOINN Laboratories.  
As the first western toxicology/pathology software supplier to enter the Chinese market, Instem officially deployed its first China-based system in one of the largest and most advanced vivariums during 2006. Acknowledging analyst projections that the People’s Republic of China (PRC) is on pace to becoming the second largest pharmaceutical market in the world, Instem established a full-service office in Shanghai, recruited local staff and has localized the Provantis product suite into Mandarin Chinese. Instem is supporting international organizations and domestic laboratories exclusively serving the PRC using on-site systems as well as their SaaS delivery model from a professionally managed data center based in Shanghai.  
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mecklenburg-consulting Automates with Provantis Pathology Module  
Pathology Consultancy Turns to Instem’s SaaS Solution to Manage Preclinical Studies  
CONSHOHOCKEN, PA – November 16, 2015 - Instem, a leading provider of IT solutions to the global early development healthcare market, announced today that mecklenburg-consulting, based in Hamburg, Germany, has purchased Provantis® Pathology to automate and streamline processes for managing pathology data.   
mecklenburg-consulting specializes in veterinary diagnostic, experimental, and toxicologic pathology, supporting the preclinical development of drugs and medical devices.   
Key Facts  
  
mecklenburg-consulting will use Provantis Pathology to efficiently manage its histopathology data while maintaining GLP compliance  
mecklenburg-consulting will also take advantage of Instem’s expertise through training services and validation support for rapid deployment  
mecklenburg-consulting will use Instem’s hosted, remote delivery model to access Provantis Pathology from anywhere in the world via a standard web browser   
  
Dr. Lars Mecklenburg, founder of mecklenburg-consulting, commented “I have used Provantis at previous companies and was excited to learn that Instem had a scalable SaaS solution that provides the same capabilities to a single user as it does to a multi-site, global organization. Instem’s industry-leading technology and world-class service made my decision process quick and easy.”   
Gary Mitchell, Vice President of Marketing at Instem, added, “It’s always great to welcome a new client to our user community. Dr. Mecklenburg had a positive experience when using our products and services in a large organization and based on this experience he chose Instem to automate his own pathology consultancy. This is a testament to the scalability of our solutions as they grow with a client’s needs, as well as the ongoing expert support that Instem brings to each client relationship.”  
Provantis Pathology is used by drug and chemical development organizations across the globe, from single user remote Pathologists to multi-site laboratories.Every Provantis user has unlimited access to live global support to ensure operational effectiveness and success.   
About mecklenburg-consulting  
mecklenburg-consulting is a Hamburg, Germany based, specialist consultancy concentrating on veterinary diagnostic, experimental, and toxicologic pathology. Dr. Mecklenburg brings 20 years of extensive practical experience in pathology and preclinical development of drugs and medical devices to his consultancy. He serves clients across the globe with expert advice in pathological analyses, molecular investigations as well as interpretation and communication of pathology results.  
About Instem  
Instem is a leading supplier of IT applications to the early development healthcare market delivering compelling solutions for data collection, management and analysis across the R&D continuum. Instem applications are in use by customers worldwide, meeting the rapidly expanding needs of life science and healthcare organizations for data-driven decision making, leading to safer, more effective products.  
Instem’s portfolio of software solutions increases client productivity by automating study-related processes while offering the unique ability to generate new knowledge through the extraction and harmonization of actionable scientific information.  
Instem supports over 400 clients through full service offices in the United States, United Kingdom and China with additional locations in Japan and India.  
Meeting clients at the intersection of investment & return™.  
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Instem to Present at European Teratology Society Meeting, Linz, Austria  
  
  
  
  
  
  
  
  
  
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Instem to Present at European Teratology Society Meeting, Linz, Austria  
Instem Presenting on Data Collection and Reporting - System Design Considerations  
CONSHOHOCKEN, PA – August 30th , 2012 - - Instem, a leading provider of IT solutions to the global early development healthcare market, is pleased to announce that Instem's Reproductive Toxicology Product Manager, John Boycott, has been invited to present at the 40th Annual European Teratology Society (ETS) Meeting, taking place in Linz, Austria from 2nd – 5th September.  
 The European Teratology Society was created in 1971 to bring together European embryologists, reproductive toxicologists, paediatric pathologists, epidemiologists, and clinicians to focus on the causes and prevention of birth defects. Its objectives are to stimulate interest in and promote the exchange of ideas and information about the causes and prevention of adverse effects on reproduction and development.  
The presentation forms part of the annual ETS Education Course which this year is entitled "Right Thinking – Right Answers!!: Study Data Analysis and Interpretation". The Education Course is aimed at both experienced Reproduction Toxicologists and those with an interest in developmental toxicology, and will focus on the variability and impact of data use and interpretation.  
 Instem's presentation, entitled "Data Collection and Reporting – System Design Considerations", will consider how the challenges presented by a range of different scientific Reproductive Toxicology Study Designs impact the need for flexible computerized data collection and reporting systems. It will also consider the need for varying presentation of study data, including numerous different statistical tests.  
The scientific program of the 40th Anniversary ETS Conference reflects the opening of new and interesting fields in Developmental Teratology and Toxicology, and the introduction of new methodologies and applications in modern embryo toxicity studies. The ETS Conference will be held in conjunction with the European Networks of Teratology Information Services (ENTIS) Conference on August 31st-September 2nd. A satellite meeting by the European Society for Alternatives to Animal Testing (EUSAAT) follows from September 6th – 9th.  
  
ETS Education course – "Right Thinking – Right Answers!!" takes place from 2pm – 5.30pm, Sunday 2nd September.  
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Instem at SOT 2023  
Instem, Island Booth #615   
Visit our Preclinical Solutions Center & In Silico Center of Excellence   
Stop by the Preclinical Solutions Center to learn how Instem’s powerful preclinical solutions enable organizations to collect, manage, review and submit research data that streamline processes, increase quality and enhance development programs.  
  
Provantis®  
 As the #1 preclinical software suite for organizations engaged in non-clinical evaluation studies, Provantis streamlines processes and workflows with straightforward, intuitive functionality for simple and complex studies within both GLP and non-GLP environments.   
 Learn more about our new standalone modules within our Pathology suite, including modules for Tissues Processing, Image Management, and SpotlighterTM, our historical data solution that helps you find the hidden value in your reference data.   
  
SEND Solutions  
 The most comprehensive and widely deployed set of software (Submit™) and services (SEND Advantage™) supporting the creation and management of SEND datasets. Stop by our booth to learn more about our two NEW software solutions, DefineNow™ for the creation and editing of define.xml files and GuidePro™, Instem’s Study Data Reviewer’s Guide generator.   
  
Genetic Toxicology   
 Image analysis and data management solutions helping users better collect, manage, review and extract data while transitioning information into insight, utilizing our Comet Assay IV and Cyto Study Manager tools. Also, don’t miss the opportunity to learn more about our new Transgenic Rodent Assay module!   
Visit Instem’s In Silico Center of Excellence and find out how our software and outsourced services enable researchers to generate new scientific insights through the identification, extraction and analysis of data to create actionable information.  
KnowledgeScan™ Target Safety Assessment (TSA) Service: Delivering comprehensive TSAs for clients around the world, enabling them to make faster, better-informed decisions on their drug targets.  
Watch the KnowledgeScan Explainer video   
Leadscope Model Applier: Advanced informatics and prediction technology, together with comprehensive database solutions that are helping organizations effectively unlock valuable knowledge contained in both public and proprietary sources of research data.  
Predict™ In Silico Toxicology service: A leading edge, technology-enabled service that delivers a combination of powerful computation models with expert scientific review, to help clients predict chemical safety more quickly, efficiently and comprehensively.  
If you would like to schedule a discussion with us during SOT contact us at info@instem.com indicating your area of interest.   
  
Instem Event Schedule  
Monday March 20  
Exhibitor Hosted Event: The life of a SEND Dataset  
Monday, March 20, 12:00 PM - 1:00 PM (CT), Room 101C   
The past few years have seen the proliferation of standardized nonclinical data through the implementation of the SEND standard. This session looks at the full lifespan of the study data as they relate to the SEND dataset and address some of the challenges and explore the opportunities they bring.  
Presented by Marc Ellison, Director of SEND Solutions, Instem & Brenda Finney, PhD, Instem’s Director of Translational Solutions  
  
Tuesday March 21  
Exhibitor Hosted Event: Implementation of a Weight of Evidence Carcinogenicity Assessment Aligned with ICH S1B  
Tuesday, March 21, 4:30 PM - 5:30 PM (CT), Room 101B   
This presentation will review the state-of-the-art in assessing carcinogenicity based on the ICH S1B weight of evidence (WoE) addendum, including progress towards developing a transparent and defendable protocol based on the 6 WoE factors.   
Presented by Glenn Myatt, PhD, SVP of In Silico & Translational Science Solutions, Instem, Arianna Bassan, Principal Consultant, Innovatune and Frances Hall, PhD, Senior Director, In Silico Solutions, Instem  
  
Wednesday March 22  
Workshop: Assessing and communicating the developing safety profile of a new product  
 What do we need and how do we find it?   
Wednesday, March 22, 12:00 PM - 1:00 PM (CT)  
Join Brenda Finney, PhD, Instem’s Director of Translational Solutions, for an interactive workshop to discuss best practices and challenges facing project toxicologists in gathering and reviewing study data across a development programme.  
During the workshop, we will discuss the current practices and tools used when working with the data associated with a new therapeutic. These discussions will allow attendees to explore and assess the processes and information needs of toxicologists charged with monitoring and submitting safety assessments throughout the development lifecycle of a new therapeutic.   
Exhibitor Hosted Event: Assessing N-nitrosamine Potency Classes   
Wednesday, March 22, 12:00 PM - 1:00 PM (CT), Room 101D  
This session will review recent regulatory and industry updates in the assessment of N-nitrosamine potency classes based on various collaborations. It will outline new defendable methods, including SAR and read-across approaches, based on a mechanistic understanding of N-nitrosamine carcinogenicity.   
Presented by Kevin Cross, PhD, VP of Product Development, Instem & Arianna Bassan, Principal Consultant, Innovatune  
  
We are also pleased to be involved in the following posters:   
Posters in order of session time:   
Abstract Number/Poster Board number: 3172/P287  
Abstract Title: Challenges in SEND Conversion of Embryo Fetal Development (EFD) Studies in Compliance with the SENDIG DART v1.1 and Practical Examples Addressing the CDISC SEND Conformance Rules v4.0  
Presenting Author: Takayuki Anzai   
Session Title: Regulation/Policy   
Session Time: 20th March 2023 9:00 AM to 10:45 AM (CT)  
  
Abstract Number/Poster Board number: 3176/ P291  
Abstract Title: Application of in Silico Methods for the Definition of Occupational Exposure Banding  
Presenting Author: Manuela Pavan (Innovatune), Co-Author Kevin Cross, Instem  
Session Title: Regulation/Policy  
Session Date and Time: 20th March 2023 9:00 AM to 10:45 AM (CT)  
  
Abstract Number/Poster Board number: 3233/ P350  
Abstract Title: Mechanisms of Nitrosamine Mutagenicity and Their Relationship to Carcinogenicity  
Presenting Author: Graham Smith, Co-Author Kevin Cross, Instem  
Session Title: DNA Damage and Repair  
Session Date and Time: 20th March 2023 10:45 AM to 12:30 PM (CT)  
  
Abstract Number/Poster Board number: 3096/ P202  
Abstract Title: Polo-Like Kinase 4 (PLK4) Safety Review: Distilling the Risks with a Rapid Augmented Intelligence Approach  
Presenting Author: Frances Hall   
Session Title: Safety Assessment: Pharmaceutical - Drug Discovery  
Session Time: 20th March 2023 2:30 PM to 4:15 PM (CT)   
  
Abstract Number/Poster Board number: 3058/ P163  
Abstract Title: In Silico Approaches in Carcinogenicity Hazard Assessment: Case Study of Pregabalin, a Nongenotoxic Mouse Carcinogen  
 Presenting Author: Kevin Cross  
Session Title: Computational Toxicology I  
Session Date and Time: 20th March 2023 2:30 PM to 4:15 PM (CT)  
  
Abstract Number/Poster Board number: 3692/ P177   
Abstract Title: EMA Mutamind: Data Gap Analysis of N-Nitrosamines for Structure-Activity Relationship  
Presenting Author: Anke Londenberg, (Fraunhofer Institute), Co-Author, Kevin Cross, (Instem)  
Session Title: Computational Toxicology II  
Session Date and Time: 21st March 2023 9:00 AM to 10:45 AM (CT)  
  
Abstract Number/Poster Board number: 3671/ P156  
Abstract Title: Predicting the Acute Toxicity 6-Pack to Support Health, Safety, and Environmental Product Stewardship  
Presenting Author: Glenn Myatt  
Session Title: Computational Toxicology II  
Session Date and Time: 21st March 2023 9:00 AM to 10:45 AM (CT)  
  
Abstract Number/Poster Board number: 4477/ P351  
Abstract Title: Risk (Re)Assessment of N-Methyl-N-Nitrosophenethylamine for Use in Computing Acceptable Intake Levels of N-Nitrosamine Drug Substance-Related Impurities  
 Presenting Author: David Woolley (ForthTox Ltd) Co-Author, Kevin Cross, (Instem)  
Session Title: Risk Assessment III  
Session Date and Time: 22nd March 2023 2:30 PM to 4:15 PM (CT)  
  
Abstract Number/Poster Board number: 5152/P253  
Abstract Title: A protocol to support weight-of-evidence assessments in the ICH S1B guideline  
Presenting Author: Arianna Bassan, Co-Authors, Paul Bradley, Jon Chambers, Kevin P. Cross, Brenda Finney, Francis Hall, Candice Johnson, and Glenn J. Myatt  
Session Title: Late-Breaking 5  
Session Date and Time: 23rd March 2023 8:30 AM to 11:30 AM (CT)  
  
   
  
  
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Helping our clients bring their life enhancing products to market faster  
Please stop by one of our booths to learn more about Instem’s powerful software solutions & services  
Preclinical Solutions - Booth #205  
Learn how Instem’s preclinical solutions keep our clients focused on their science, not their software.  
  
Provantis® is the #1 online solution for managing preclinical studies.   
Learn about submit™, the most widely adopted modular software suite for creating, reviewing and managing SEND data or ask our SEND experts about our new SEND Advantage services.   
Our Genetic Tox Solutions are in a class of their own, featuring Comet Assay IV and Cyto Study Manager.  
  
In Silico Solutions - Booth #207  
Learn how our software and outsourced services enable researchers to generate new scientific insights through the identification, extraction and analysis of data to create actionable information.   
  
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Leadscope Model Applier: Easy-to-use software to apply prediction models, perform an expert review, and create reports.  
Genetic Toxicity (Q)SARs: Complete solutions for the computational assessment of genetic toxicity, including statistical-based and expert rule-based models.  
Predict™: A leading edge, technology-enabled service that delivers a combination of powerful computation models with expert scientific review, to help clients predict chemical safety more quickly, efficiently, and comprehensively.  
Industry Workshop & Luncheon  
Assessing and communicating the developing safety profile of a new product – what do we need and how do we find it?   
When? Tuesday November 15th, 1pm-2pm (lunch will be provided)  
Where? Crest 5, Gaylord Rockies Hotel   
Join Brenda Finney, PhD, Instem’s Director of Translational Solutions and our panel of experts from organizations including AstraZeneca, Bristol Myers Squibb, GSK and Novartis, for an interactive workshop to discuss best practices and challenges facing project toxicologists in gathering and reviewing study data across a development programme.  
During the workshop, we will discuss the current practices and tools used when working with the data associated with a new therapeutic. These discussions will allow attendees to explore and assess the processes and information needs of toxicologists charged with monitoring and submitting safety assessments throughout the development lifecycle of a new therapeutic.   
Register Now  
  
Talking Tox Presentations   
Strategic In Silico: Creating Powerful New Scientific Insights. Presented by Gordon Smith Baxter, PhD, Chief Scientific Officer and Glenn Myatt, PhD, Vice President, Informatics.   
Tuesday, November 15th, 12.00-12.55pm (MST) Room: Summit 7  
Sponsored Sessions  
Symposium 1 – ICH S1B(Rq): New Approaches in the Carcinogenicity Assessment of Pharmaceuticals,   
 Monday 14th November 9-12pm (MST)   
Workshop 4 – Addressing the Global Challenge of Nitrosamine Impurities in Pharmaceutical Products  
 Monday 14th November, 2-5pm (MST). Chaired by Dr. Kevin Cross, VP Product Development, Instem   
   
  
  
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SEND Update - Public Comment Period Opens for Developmental and Reproductive Toxicology Studies  
  
  
  
  
  
  
  
  
  
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SEND Update - Public Comment Period Opens for Developmental and Reproductive Toxicology Studies  
Comments due by August 13th 2015  
July 15, 2015 - - The CDISC/SEND Leadership Team has announced that the Public Review period for the CDISC SEND Implementation Guide: Developmental and Reproductive Toxicology (SENDIG-DART) v1.0 is now open, with comments due by August 13th 2015.  
The CDISC SEND Implementation Guide: Developmental and Reproductive Toxicology (SENDIG-DART) v1.0 draft supports study data typically found in embryo-fetal developmental (EFD) toxicity studies and is based on the SEND Implementation Guide Version 3.0. While this release (v1.0) focuses on EFD, other study designs will be covered in future releases.  
To access the document package and provide comments, all interested parties are encouraged to visit the CDISC Public Comment Tracker tool. Reviewers will need to login or register for a CDISC portal account to use the tool. Help is also available on the Public Comment Tracker page Instructions on using the Public Comment Tool  
Instem has been extensively involved in the creation and development of SEND since its inception, working closely with SEND pilot organizations, the FDA and industry to help define the standard and align it with industry practices. Instem is an active participant in the CDISC Reproductive Toxicology Sub Team.   
As a result of this detailed involvement, Instem developed submit™, the first commercially available SEND data management system and is proud to provide the most widely adopted set of SEND tools in the market, with Instem SEND solutions licensed across 11 countries at over 32 sites.   
Instem’s submit platform provides a suite of integrated tools and services for the creation and management of SEND datasets and associated documents for Contract Research Organizations, Sponsors and their study partners. More information about SEND and Instem’s tools can be found here.   
About Instem  
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Instem at SOT 2022  
Preclinical Solutions Hub, Island Booth #1625   
Visit our Preclinical Software Center to discuss all your preclinical needs, or stop by to speak with our SEND experts at The SEND Pavilion.  
Preclinical Software Center  
Learn how Instem’s preclinical solutions keep our clients focused on their science, not their software. Provantis® is the #1 online solution for managing preclinical studies. Come see our new “Insights” feature in our Pathology module. Learn about submit™, the most widely adopted modular software suite for creating, reviewing, and managing SEND data. Our Genetic Tox Solutions are in a class of their own, featuring Comet Assay IV and Cyto Study Manager. Leading IT Solutions - Leading IT Results.  
The SEND Pavilion  
Have all your SEND related questions answered by our SEND experts at The SEND Pavilion. From study conversions to data verifications or consulting, Instem is the leading SEND authority. Our comprehensive services deliver exactly what our clients need, when they need it. Our intuitive submit™ software enables our DIY clients to create, QC review SEND datasets.  
Our unmatched credentials enable organizations around the world to, submit™ with confidence.  
Let us help SEND work for you.  
Expertise. Speed. Quality.  
In Silico Center of Excellence, Booth #1729   
Stop by Instem’s In Silico Center of Excellence and find out how our software and outsourced services enable researchers to generate new scientific insights through the identification, extraction and analysis of data to create actionable information.  
KnowledgeScan™ Target Safety Assessment (TSA) Service: Delivering comprehensive TSAs for clients around the world, enabling them to make faster, better-informed decisions on their drug targets.  
Watch the KnowledgeScan Explainer video   
Leadscope Model Applier: Advanced informatics and prediction technology, together with comprehensive database solutions that are helping organizations effectively unlock valuable knowledge contained in both public and proprietary sources of research data.  
Predict™ In Silico Toxicology service: A leading edge, technology-enabled service that delivers a combination of powerful computation models with expert scientific review, to help clients predict chemical safety more quickly, efficiently and comprehensively.  
If you would like to schedule a discussion with us during SOT contact us at info@instem.com indicating your area of interest.  
Watch the video  
  
Workshop Session  
Join Instem's VP Informatics, Dr. Glenn Myatt, for his presentation titled ‘Assessment of Whether Acute Toxicity In Silico Models Are Fit for Purpose for Classification and Labeling’ as part of the workshop, ‘Use of Computational Methods for Addressing Occupational Safety: Opportunities to Support the 3Rs’  
Wednesday 30th March, 2.00pm - 2.25pm (PST), Room CC 1  
  
Instem Presentations   
Please join us for an Exhibitor Hosted Presentation, no advance registration is required:  
Turn SEND Challenges into Opportunities  
Monday 28th March, 4.30pm - 5.30pm (PST), Room 22  
As an industry service provider, Instem sees studies and SEND from a variety of organizations, giving us a well-rounded viewpoint. In this session, we will share and discuss common challenges and opportunities we see arising from SEND, including its ever-increasing scope and the immanent requirement for DART studies.  
  
Using Leadscope Computational Software to assess N-nitrosamine potency classes – Presented by Instem  
Tuesday 29th March, 3.00pm - 4.00pm (PST), Room 23C  
This session will outline how new in silico models and first-to-market software capabilities from Instem are supporting regulatory submissions, classification and labelling, and various new R&D activities. We will also include a review of recent updates to support the assessment of N-nitrosamine potency classes based on an extensive industry collaboration.  
  
Target Safety Assessment – Accelerating and Optimizing Your Journey to Regulatory Submission  
Wednesday 30th March, 12.00pm - 1.00pm (PST), Room 22  
Instem’s KnowledgeScan™ Target Safety Assessment (TSA) service sets new standards in biological target profiling. After completing hundreds of TSAs, we understand the challenges and opportunities associated with target modulation. Join us to learn how our pioneering, technology-enabled service is transforming the TSA process, driving quality, pace, and insight in R&D.   
  
We are also pleased to be involved in the following posters:   
Abstract Title: The use of Leadscope’s skin sensitization alerts in the OECD 497 Integrated Testing Strategy (ITS) defined approach workflow  
Presenting Author: Candice Johnson   
Session Title: Computational Toxicology II   
Session Time: Wednesday 30 March – 10.45am to 12.30pm (PST)  
  
Abstract Title: Quantitative Structure-Activity Relationship Model to Predict Cardiac Adverse Effects  
Co Author: Kevin Cross (In collaboration with the FDA)  
Session Title: Computational Toxicology II   
Session Time: Wednesday 30 March – 10.45am to 12.30pm (PST)  
  
Abstract Title: A Chemical Landscape Based on In Silico Data Availability Profile across Diverse In Vitro/In Vivo Assays to Support Read-Across Evaluations  
Co Author: Kevin Cross (In collaboration with NIEHS)  
Session Title: Late-Breaking 4  
Presentation Date and Time: Thursday, March 31, 2022; 8.30am to 11.30am  
Presentation Location: Convention Center Sails Pavilion   
  
  
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Instem Announces Global Partnership Agreement with SAS in Life Sciences   
Collaboration Enhances Customer Experience While Increasing Capabilities  
CONSHOHOCKEN, PA - (BUSINESS WIRE) – August 19, 2010 - - Instem, a leading provider of early drug development software solutions, announced today it has signed a global partnership agreement with SAS, the leader in business analytics software and services. The partnering arrangement enables Instem to more cost effectively license its clients directly for SAS® technology embedded within its Provantis® preclinical software suite. This will streamline deployment processes and reduce costs for clients, especially for laboratories with smaller numbers of users.   
Instem’s Provantis solution uses SAS as one of the underlying technologies in its Tables and Statistics module. This market-leading product generates tables and performs statistical analysis on data collected by other products in the Provantis suite. Users can run descriptive or comparative statistics, which are definable by parameter or table, and can be selected at run-time, using easy-to-navigate Provantis functionality.   
SAS technology provides Instem customers a range of techniques and processes for the analysis and interpretation of data to reveal patterns, anomalies, key variables and relationships - ultimately leading to new insights and better answers faster.   
“This is a terrific partnership for Instem and another big win for our clients,” states Gary Mitchell, VP of Global Marketing at Instem. “We have been working with SAS very closely to develop a new and exclusive model for our Provantis clients. This reduces their overall cost of Provantis while streamlining the deployment process for both hosted and traditional on-site installations.”  
Instem, now a SAS Gold Application Partner, additionally has access to ongoing value-added resources in the areas of training, marketing, strategic planning and technical services at SAS offices worldwide.   
Instem help desk personnel will directly support new clients while the technical services team will be empowered to install and maintain all SAS technologies within the Instem delivery framework.  
“Partnering with Instem, leaders in preclinical IT with deep domain expertise, allows SAS to expand and better serve a critical segment of the scientific community,” states Kecia Serwin, SAS General Manager of Health and Life Sciences. “We are looking forward to partnering with Instem as they bring new solutions to market, specifically in the area of knowledge management.”   
In support of new solution development efforts, Mark Wolff, SAS Health and Life Sciences Solutions Architect, presented at Instem’s 2010 international user’s conference in Chicago. Wolff delivered a powerful speech on the challenges facing today’s progressive pharmaceutical R&D community. According to Wolff, “those challenges will be the efficient collection, processing and analysis of vast amounts of disparate research data and the development of facile access points along the R&D process that provide scientists and business decision makers with actionable information. Data-driven insights will serve to manage and direct the future of a compound from discovery to commercialization, and to understand and rationalize post-marketing safety, efficacy and health economics issues.”  
The choice of 100 percent of the FORTUNE Global 500® life sciences companies, SAS is globally recognized as the industry leader in business analytics and the de facto standard for clinical data analysis and reporting. By partnering with Instem, SAS will be able to increase its footprint within the preclinical segment of life sciences through Instem’s integrated Provantis software solution.   
About Provantis®  
Provantis is a modern, fully integrated software system for single users and global organizations engaged in preclinical evaluation studies. Orchestrating every facet of preclinical drug safety assessment, Provantis streamlines processes and workflows with straightforward, intuitive functionality for simple or complex studies within a GLP or non-GLP environment, on-site or over the Web.  
Since the release of Provantis Version 8, Instem introduced a new open architecture concept to the Tables and Statistics product. The open architecture frees the user from the complexities of a database, presenting the data in a simple, industry-standard XML file and easily formatting the data onto the report page.   
About SAS  
SAS is the leader in business analytics software and services, and the largest independent vendor in the business intelligence market. Through innovative solutions delivered within an integrated framework, SAS helps customers at more than 45,000 sites improve performance and deliver value by making better decisions faster. Since 1976 SAS has been giving customers around the world The Power to Know®.  
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JOINN Laboratories China Purchases Instem's Preclinical Software Suite  
Leading Chinese CRO Selects Version 9 of Provantis Integrated Preclinical Software to Automate Study Processes at Beijing and Suzhou Sites  
CONSHOHOCKEN, PA - (BUSINESS WIRE) - January 29, 2013 - -Instem, a leading provider of IT solutions to the global early development healthcare market, announced today that JOINN Laboratories (JOINN), one of China’s largest providers of preclinical services, has purchased the Provantis preclinical solution suite following a comprehensive competitive evaluation of vendors.  
Established in 1995, JOINN provides drug screening, efficacy studies, pharmacokinetics studies, safety evaluations, clinical trials and final drug registration services with a heightened focus on quality. JOINN supports clients from more than 20 provinces across China, Japan and Europe, and within the United States is providing international clients with technical consulting services for FDA drug registration.  
Key Facts  
  
Comprehensive suite of integrated Provantis modules purchased for up to 200 users; including In-Life, Reproductive Toxicology, Pathology, Dispense, Clinical Pathology and Data Import  
JOINN to implement Provantis 9; the latest version of Instem’s market leading preclinical software solution   
Competitive evaluation conducted; Instem selected for established presence within China, combined with global market leadership  
Provantis offers JOINN compliance to national and western standards with dual language operation   
A range of professional services purchased to facilitate quicker, smoother implementation and faster return on investment  
  
Dr. Yuxia Feng, President & CEO, JOINN commented “We were looking for a market leading solution to support our long term growth plans and we are confident that our investment in Provantis will help to deliver demonstrable efficiency improvements within our R&D facilities. We are looking forward to a long and successful partnership with Instem.”  
Phil Reason, President & CEO Instem said “We are delighted to welcome JOINN to the Instem client community. Their order for 200 licensed users adds significantly to the leadership position we already enjoy in the China market and is a further indication of the long term growth potential in what is already the third largest pharmaceutical market in the world.”   
As the first western toxicology/pathology software supplier to enter the Chinese market, Instem officially deployed its first China-based system in one of the largest and most advanced vivariums during 2006. Acknowledging analyst projections that the People’s Republic of China (PRC) is on pace to becoming the second largest pharmaceutical market in the world, Instem established a full-service office in Shanghai, recruited local staff and has localized the Provantis product suite into Mandarin Chinese. Instem is supporting international organizations and domestic laboratories exclusively serving the PRC using on-site systems as well as their SaaS delivery model from a professionally managed data center based in Shanghai.  
About JOINN  
Established in 1995, JOINN provides drug screening, efficacy studies, pharmacokinetics studies, safety evaluations, clinical trials and final drug registration services, supporting clients across China, Europe and Japan.  
JOINN’s R&D operations are located in state-of-the-art facilities in Beijing and Suzhou (Taicang Biomedical Industrial Park). JOINN is China’s first pre-clinical laboratory inspected by the U.S. FDA for GLP compliance and is also AAALAC accredited and SDFA GLP certified.   
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Instem Presenting at SEND Workshop  
Instem, Leading Pharmaceutical Organizations and Regulators to lead discussions on SEND Submission Expectations  
CONSHOHOCKEN, PA – May 3, 2016 - -Instem, a leading provider of IT solutions to the global early development healthcare market, will present at a SEND workshop hosted by the American College of Toxicology (ACT) May 3rd in Reston, Virginia.  
Lou Ann Kramer, Instem Vice President of Regulatory Submissions, will facilitate the sold out workshop, SEND Submissions Demystified. Ms. Kramer will also present along with colleagues from Bristol-Myers Squibb, Eli Lilly and Company, FDA, Genentech, Pfizer and Sanofi.   
This workshop will provide opportunities for participants engaged in, or contemplating SEND implementation to exchange collective experience and to gain a cohesive understanding of FDA SEND Submission expectations. The focus of the workshop will primarily be on SEND business processes with some high-level discussion of the technical aspects of SEND.  
SEND Submissions Demystified will take place Tuesday, May 3 at the Sheraton Reston in Reston, Virginia. For more information, please visit the American College of Toxicology’s website.  
The Instem team has led and participated in the creation of the SEND standard for over 10 years and brings over 30 years of experience in developing, delivering and supporting world-class nonclinical systems and solutions for the scientific community.Instem offers submit™, SEND tools and services at every stage of SEND Readiness and are the most widely adopted in the industry, operating at over 34 sites across 12 countries.  
About Instem   
Instem is a leading supplier of IT applications to the early development healthcare market delivering compelling solutions for data collection, management and analysis across the R&D continuum. Instem applications are in use by customers worldwide, meeting the rapidlyexpanding needs of life science and healthcare organizations for data-driven decision making leading to safer, more effective products.  
Instem’s portfolio of software solutions increases client productivity by automating study-related processes while offering the unique ability to generate new knowledge through the extraction and harmonization of actionable scientific information.  
Instem supports over 450 clients through full service offices in the United States, United Kingdom and China with additional locations in Japan and India.   
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Shanghai Medicilon Chooses Provantis Software Solution  
Instem's Software-as-a-Service Model Chosen by one of China's Leading Contract Research Organizations  
CONSHOHOCKEN, PA - (BUSINESS WIRE) – June 21, 2011 - - Instem, a leading provider of early development software applications, announced today that Shanghai Medicilon Inc. (Medicilon) has purchased an online subscription to the Provantis® preclinical software solution suite. The purchase incorporates a range of Provantis modules across the areas of general toxicology, clinical pathology and pathology.  
Medicilon was founded in 2004 to provide fully integrated services to the global pharmaceutical community. The company’s integrated services across biology, chemistry and preclinical services are specially designed to help their clients develop their research and discovery programs through to IND filings.   
Provantis will be used to support preclinical research studies at their 50,000 square feet AAALAC accredited facility in Chuansha Economic Park in Shanghai. The overwhelming standard in western facilities, Provantis offers Medicilon compliance to national and western standards, dual language operation and proven protocol-driven automation that produces high quality study output in greatly reduced timescales.  
Commenting on the deal, Dr.Chunlin Chen, Medicilon CEO said “We recognize that Instem is the leader in their field and Provantis will be a strategic tool in helping Medicilon achieve its vision of becoming the top CRO in China providing high quality preclinical drug discovery and development services to global pharmaceutical and biotechnology companies.”   
Medicilon will be using Instem’s SaaS (Software-as-a-Service) model offering simpler, more cost effective ways to provide software functionality, maintenance, and support over the Internet. Instem’s Shanghai-based data center meets the highest standards for reliability, security and redundancy and is managed by experienced staff 365 days a year. Strategically located in PuDong, this purpose built data center features a state-of-the-art network, power and environmental infrastructure and is ISO 9001 and SunTone™ certified.  
Neil Donaldson, Instem’s VP of Asian and European Operations commented “We are delighted to welcome Medicilon as our latest client in the Asia Pacific region and are looking forward to working with them to support them in their continued high quality service delivery and business growth.”  
Instem in the People’s Republic of China (PRC)  
As the first western toxicology/pathology software supplier to enter the Chinese market, Instem officially deployed its first China-based system in one of the largest and most advanced vivariums during 2006. Acknowledging analyst projections that by 2014 the PRC would be the second largest pharmaceutical market in the world; Instem established a full-service office in Shanghai, recruited local staff and has localized the Provantis product suite into Mandarin Chinese. Instem is supporting both international organizations and domestic laboratories exclusively serving the PRC.  
About Medicilon  
Medicilon has been recognized as one of the top drug discovery contract research organizations (CROs) in China and is managed by a team of scientists with many years of experience in US-based pharmaceutical and biotechnology companies. As Medicilon’s areas of expertise and service capabilities continue to expand, major pharmaceutical and biotechnology companies from across 4 continents have taken advantage of their integrated drug discovery and development services.   
 Medicilon’s headquarters is located in Zhangjiang High-Tech Park in Shanghai, China, with an additional facility in Chuansha Economic Park, Shanghai, China. They occupy over 200,000 square feet of laboratory space and have over 300 employees cross biology, chemistry and preclinical research. Over 50% of Medicilon’s employees have MS and PhD degrees and over 10% have foreign education and/or working experiences.  
More info about Medicilon can be found at www.mediciloninc.com  
About Provantis®  
Provantis is a modern, fully integrated software system for single users and global organizations engaged in preclinical evaluation studies. Orchestrating every facet of preclinical drug safety assessment, Provantis streamlines processes and workflows with straightforward, intuitive functionality for simple or complex studies within a GLP or non-GLP environment, on-site or over the Web.  
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Instem at PHUSE US Connect 2024  
Stop by Booth #27 to learn more about Instem’s powerful Clinical Trial Analytics and Transparency Solutions as well as our Strategic Consulting Services  
Clinical Trial Analytics   
  
Accel a turnkey cloud based statistical computing environment pre-loaded with all the tools, applications and licenses your biometric team needs to efficiently share data, programs, and analysis. And it’s all validated and ready for use within 1 week, removing any disruption to your teams’ workflow.   
Aspire is a clinical analysis framework that’s flexible clinical components allow data scientists to focus on the managing of the data by automating mundane tasks which also allows a fit-for-purpose workflow and is configured on an extendable cloud architecture.   
  
Clinical Trial Transparency   
  
Blur is the industry leading anonymization and quantifiable risk measurement tool. It was built in collaboration with pharma sponsors and has a user-centric design with Natural Language Processing (NLP) capabilities.   
  
Strategic Consulting Services  
  
Leaders in biometrics and anonymization technology, Instem provides strategic consulting and technology services for modernizing clinical trial analysis environments, validating open-source tools, anonymizing data & documents, and moving to the public cloud.  
  
Instem is proud to Sponsor the Connect Dinner on Monday Evening   
When: Monday 26th February 7:00pm - Close  
Where: Salon D (Plenary Room) Truly a night to remember, this renowned PHUSE social event gathers all attendees for an evening of celebration where they can enjoy a delicious dinner and dance the night away!  
  
Instem Event Schedule  
Instem Presentations and Workshops  
Sunday 25th February  
2:30pm - 4:00pm EST, Salon F/G - Hands-on-Workshop - Step 1 to Becoming Multi-Lingual, Andrew Ratcliffe, Product Manager, Aspire & Alastair Scarlett, Senior Consultant   
 Our stats programming future is multi-lingual, using the most appropriate tool for each task, in an environment that contains a rich set of tools. Are you a confident SAS programmer who worries at your lack of knowledge of R? Are you looking for a shortcut into R and other languages?  
 Experience the future in this workshop as we jump between SAS, R, Python and other tools, broadening and enhancing your skills in R, Pharmaverse, Git and more. Understand the benefits of each language and which language to choose for which purpose. Understand how this can improve productivity and enable novel new activities and insights. In this workshop we will leverage a cloud-based environment to work on hands-on exercises that move across different clinical programming languages.   
 Learn new skills, understand new terms and concepts, and return to your office to contribute to and influence your enterprise’s adoption of the future. Help define the future!  
Monday 26th February  
12:00pm - 12:30pm EST, Salon A - Presentation DS03: Digital Protocol Vision … How Digital Information Can Transform and Automate Our Processes, Bill Qubeck, VP, Consulting & Enterprise Hosting   
2:30pm - 3:00pm EST, Salon B - Presentation DS06: Standards Library: Getting Started – A Medical Device Case Study, Veramed & Instem, Thierry Philippe, Principal Consultant  
Wednesday 28th February   
2:00pm - 2:30pm EST, Salon B - Presentation ET05: What Role Does ChatGPT Have in Your Clinical Programming? Andrew Ratcliffe, Product Manager, Aspire  
   
We look forward to seeing you in Bethesda!  
  
   
  
  
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Advinus Therapeutics Increases Use of Instem's Preclinical Software Suite to Support Growth  
Advinus Therapeutics increases Provantis user licenses by 40% at Bangalore facility to support growth in India Operations  
CONSHOHOCKEN, PA - (BUSINESS WIRE) – January 27, 2012 - - Instem, a leading provider of early development software applications, announced today that Advinus Therapeutics (Advinus) has purchased additional Provantis® preclinical software user licenses for their 220,000 square foot facility in Bangalore.  
   
Advinus is a research-based Pharmaceutical company offering end-to-end development services to the global Pharmaceutical, Agrochemical and Biotech industries, while at the same time creating long-term value through internal and collaborative innovative Drug Discovery.  
Instem has been proud to support Advinus since 2005 when they selected Instem’s integrated Provantis solution suite following a comprehensive competitive evaluation of preclinical systems on the market.   
Key Facts  
  
New users to access integrated General Toxicology, Clinical Pathology, Pathology and Protocol & Report Assembly (P&RA) modules deploying at Bangalore facility   
Unique P&RA module provides Advinus faster, more efficient production of study protocols and final reports  
Order represents 40% Increase in User Licenses   
  
Dr. R. S. Rao, Head, Safety Assessment at Advinus comments, “We have been extremely impressed with Instem’s products and services as well as the knowledge, commitment and experience of the Instem team. The deployment of Instem solutions at our Bangalore site has been instrumental in helping us to attract more Western business, as well as further enhancing our client services and ensuring GLP compliance.”   
Demand for regulatory toxicology services has grown within India in recent years, fueled by the internal investments of Indian pharmaceutical and chemical companies, the recent addition of India within the OECD Mutual Acceptance of Data program and the demand from elsewhere in the world for high-quality, cost-effective non-clinical services.  
“Our partnership with Advinus has successfully developed over the years and we are delighted that they have committed to further roll out Provantis across their organization,” comments Neil Donaldson, Instem’s VP of Asian and European Operations. “Given our presence in the region and our commitment to the Indian R&D community, we believe that Instem is ideally poised to support the important role that Indian organizations play in this increasingly competitive global market”.  
  
About Advinus Therapeutics  
Advinus Therapeutics is a research-based Pharmaceutical Company founded by leading global pharmaceutical executives and promoted by the TATA Group. The company is the first of its kind in India to offer end-to-end development services to the global Pharmaceutical, Agrochemical and Biotech industries and at the same time creating long-term value through internal and collaborative innovative Drug Discovery.   
  
 Advinus has three operational sites; Advinus Drug Discovery, which is located in a state of the art facility in Pune (near Mumbai) and the Advinus Pharmaceutical and Agrochemical development centers based in Bangalore.   
Advinus’ vision is to emerge as the leading and most admired life sciences R&D company from India, creating value for its customers and stakeholders.  
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WuXi AppTec Expands Investment in Instem Software Solutions   
Leading China CRO Purchases New Solutions and Modules, Orders Additional User Licenses and Upgrades to Latest Software Versions  
CONSHOHOCKEN, PA - (BUSINESS WIRE) – June 3, 2015 - -Instem, a leading provider of IT solutions to the global early development healthcare market, announced today that WuXi AppTec (WuXi) has committed to a further, major investment in Instem solutions to support its ongoing growth plans.  
WuXi is a leading global pharmaceutical, biopharmaceutical, and medical device open-access capability and technology platform with operations in China and the United States. In 2009, WuXi selected Instem’s integrated Provantis preclinical solution suite to automate study processes at its newly constructed 314,000 square feet toxicology facility in Suzhou. WuXi invested in Provantis to support its ongoing commitment to helping worldwide customers shorten drug discovery and development time and lower the cost of drug and medical device R&D.   
This latest contract from WuXi includes a comprehensive set of services to facilitate WuXi’s upgrade to Provantis 9, the addition of the Provantis Reproductive Toxicology module and a 50% increase in user licenses.   
Importantly the contract also includes the purchase of the Ames Study Manager (ASM) software from Perceptive Instruments (now part of Instem), which has recently been launched in the China market. WuXi has also purchased the Sorcerer Colony Counter and associated implementation services.   
Key Facts  
  
WuXi to implement the Provantis Reproductive Toxicology module to support the management, performance, analysis and reporting of all reproductive study types  
WuXi to implement the Ames Study Manager (ASM) software, an integrated suite of software for conducting the Bacterial Reverse Mutation Test, together with a Sorcerer Colony Counter and associated implementation services  
Wuxi to upgrade to Provantis 9, the latest version of Instem’s world-leading preclinical software solution, adding further user licenses  
Comprehensive package of services purchased to facilitate quick implementation and a rapid return on investment   
  
Dr. Yi Jin, Vice President of Toxicology, WuXi said “ The deployment of Instem solutions at our Suzhou facility has been instrumental in helping us to achieve our ambitious growth plans and has enabled us to deliver even higher levels of customer service to our global client base. We look forward to further strengthening our partnership with Instem through our expanded investment in Instem solutions.”  
Mr. Neil Donaldson, VP Sales Europe & Asia, Instem, commented “Our partnership with WuXi has successfully developed over the years and we are delighted that they have chosen to increase and expand the use of Instem solutions across their facility.”   
  
About WuXi AppTec  
Established in December 2000, WuXi AppTec (NYSE: WX) is a leading global pharmaceutical, biopharmaceutical, and medical device open-access capability and technology platform with operations in China and the United States. As an innovation-driven and customer-focused company, WuXi AppTec provides a broad and integrated portfolio of services throughout the drug R&D process. WuXi AppTec’s services are designed to help its worldwide customers shorten the discovery and development time and lower the cost of drug and medical device R&D through cost-effective and efficient solutions.  
WuXi AppTec has developed from four founders and a single laboratory in December 2000 to 9,000 employees and 5 million square feet of laboratory and manufacturing space, including facilities under construction. The company is actively improving its capabilities and capacity through new expansions in its global business. Capitalizing on the great advantage of conducting R&D services both in China and in the United States, WuXi AppTec is building an alternative R&D engine to serve the global life-science industry.  
To learn more about WuXi AppTec please visit https://www.wuxiapptec.com/  
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Leading Pharmaceutical Organization Purchases Instem's Animal Management Software  
  
  
  
  
  
  
  
  
  
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Leading Pharmaceutical Organization Purchases Instem's Animal Management Software  
Top 10 Pharma Company chooses Instem’s ACIS Software Solution for Multi-Site SaaS Deployment  
CONSHOHOCKEN, PA – February 20, 2014 - - Instem, a leading provider of IT solutions to the global early development healthcare market, is pleased to announce that one of the world’s leading Pharmaceutical organizations has selected Instem’s ACIS software solution (animal care information system) to manage its animal facilities and provide regulatory reporting across Europe and North America.  
The client sought to standardize its software across a number of global locations and following a comprehensive competitive review of solutions on the market, Instem’s ACIS solution was selected due to its flexibility, regulatory reporting capabilities for Home Office Returns, USDA, AAALAC and Experiment Register and for its functionality supporting their IACUC workflow.   
The client will be deploying ACIS using Instem’s SaaS (Software-as-a-Service) model offering simpler, more cost effective ways to provide software functionality, maintenance and support.   
 Based in a centralized professional data center, ACIS will be accessible by users from any location that offers connectivity to the Internet.   
ACIS is the complete solution for managing animal facilities; efficiently managing the requisition, procurement and reporting of animal usage within research establishments. ACIS has all the capabilities and functionality necessary to address the changes recently introduced by the new European Directive 2010/63/EU and boosts client efficiencies by automating laboratory processes enabling real-time data to be visible across various user groups.   
Key Facts  
  
ACIS being deployed across multiple sites in Europe and North America by one of the top ten global pharmaceutical organizations  
Competitive review undertaken; ACIS selected for its flexibility, comprehensive functionality, regulatory reporting capabilities and IACUC functionality  
SaaS delivery model selected to support flexible deployment and easy global access  
ACIS to replace several legacy 3rd party and in-house solutions, consolidating systems across the organization   
ACIS supports IACUC protocols and latest EU regulations - 2010/63/EU and 2012/707/EU   
  
Neil Donaldson, VP Global Sales Europe & Asia said “We are extremely excited about this contract award and are delighted that our client has chosen to extend the use of the ACIS across their organization at sites in the United States and in Europe.”  
About Instem  
Instem is a leading supplier of IT applications to the early development healthcare market, delivering compelling solutions for data collection, management and analysis across the R&D continuum. Instem applications are in use by customers worldwide, meeting the rapidly expanding needs of life science and healthcare organizations for data-driven decision making leading to safer, more effective products.  
Instem’s portfolio of software solutions increases client productivity by automating study-related processes while offering the unique ability to generate new knowledge through the extraction and harmonization of actionable scientific information.  
Instem supports over 400 clients through full service offices in the United States, United Kingdom and China with additional locations in India and a full service distributor based in Japan.  
Meeting clients at the intersection of investment & return™.  
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Instem Presenting at the DIA Regulatory Submissions, Information, and Document Management Forum  
  
  
  
  
  
  
  
  
  
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Instem Presenting at the DIA Regulatory Submissions, Information, and Document Management Forum  
Instem to present 'Gaining Intelligence from Regulatory Information Management via utilizing Medicinal Product Analytics'  
CONSHOHOCKEN, PA - (BUSINESS WIRE) – January 31, 2017 - -Instem, a leading provider of IT solutions to the global early development healthcare market, is pleased to announce that Dr. Olaf Schoepke, Vice President, Regulatory Strategy, will present at the DIA Regulatory Submissions, Information, and Document Management Forum which will take place from February 6-8, 2017 in Bethesda, Maryland.  
Attendees of the session will learn how to:  
  
Increase the effectiveness of Regulatory Information Management (RIM) beyond the traditional medicinal product life cycle to gain business advantages from existing information via Analytics  
Use RIM to help to consolidate applications, share information across the enterprise and provide a real-time view on any data required for successful medicinal product management   
Address the challenges in determining the “golden truth”, the piece of data the entire enterprise can rely on  
Utilize the ‘single place of truth’ to analyze information, enabling companies to make strategic decisions based on existing data.  
  
“This presentation takes RIM to the next level, utilizing information beyond the pure medicinal product life cycle,” said Dr. Schoepke. Gaining Intelligence from Regulatory Information Management via utilizing Medicinal Product Analytics will be presented during Track 2: RIM Technology on Tuesday, February 7th.  
For more information about this session, contact info@instem.com or visit DIA Regulatory Submissions, Information, and Document Management Forum.  
About Samarind RIM Solution  
Deployed on-site or accessed on-line, Samarind RMS provides a smarter way to manage medicinal product license information, where customers only need to enter data once and reuse it as many times as required. This concept applies to all key data held within the system and is proven to streamline workload and help increase the quality of data. It is a fully integrated software application that has been purpose built to mirror the processes associated with acquiring and maintaining a pharmaceutical product license.  
Components include:  
  
A secure Regulatory Information Management (RIM) system with planning, tracking, automated alerts and comprehensive reporting facilities  
An electronic document management system (EDMS) with version control, template creation and the ability to link to external document management systems such as Documentum™ or SharePoint  
An optional eCTD module for dossier creation and maintenance (NeeS is also supported)  
An optional EVMPD module for automated maintenance of data required by the EMA’s extended medicinal product dictionary, xEVMPD with a clear path to IDMP   
A Med Info addition, for quick and easy logging of medical information queries, with links to the associated products elsewhere in the system as necessary  
A Medical Devices module plus UDI add-on to handle any kind of medical devices  
A Drug Safety module, handling Pharmacovigilance requirements  
An Analytics module, allowing users to visualize large amounts of data in graphical format, supporting critical business decisions in real time  
  
Some of the RMS benefits clients are realizing include:  
  
A ‘single place of truth’ for all product license data, minimizing information inconsistency  
Increased administrative efficiency, allowing timely response to critical deadlines  
Improved global regulatory communications via information sharing through the medicinal product life cycle  
Improved product launch planning  
  
Samarind was acquired by Instem in 2016 to help bring scalability and next generation capabilities to the increasingly complex global regulatory environment. To find out more information about Samarind RMS and a full list of benefits, please visit www.samarindrms.com  
About Instem  
Instem is a leading supplier of IT applications and services to the early development healthcare market delivering compelling solutions for data collection, analysis and regulatory submissions management. Instem solutions are in use by customers worldwide, meeting the rapidly expanding needs of life science and healthcare organizations for data-driven decision making leading to safer, more effective products.  
Instem’s portfolio of software solutions and consulting services increases client productivity by enhancing product development processes while offering the unique ability to generate new knowledge through the extraction and harmonization of actionable scientific information.  
Instem supports over 500 clients through offices in the United States, United Kingdom, France, Japan, China and India.  
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Instem Posters  
Assessing abuse liability using read-across and structural alerts  
 Glenn J. Myatt, Dave Bower, Kevin P. Cross, Lidiya Stavitskaya, Scott Miller  
   
Development of a Structure-Activity Relationship Profiler to Predict Mechanism-Based Inhibition of a Metabolite on CYP Enzymes  
 Arianna Bassan, Rajamani Selvam, David Bower, Kevin Cross, Glenn Myatt, Xinning Yang, Donna A. Volpe, Lidiya Stavitskaya  
  
Using Metabolically Similar Analogs in Read-Across to Establish Dialkyl-N-Nitrosamine Potency  
 Kevin P. Cross, Glenn J. Myatt  
  
Instem Talking Tox Webinars  
Today’s SEND Challenges: How to Overcome Them and Realize Tomorrow’s R&D Opportunities  
 Marc Ellison - Instem, Director, SEND Solutions  
 Date: Tuesday, November 9, 2021  
 Time: 12:00 Noon - 1:00 PM  
Development of N-Nitrosamine Potency Classes to Support Regulatory Submissions  
 Dr. Glenn Myatt - VP Informatics  
 Dr. Kevin Cross - VP Product Development  
 Date: Thursday, November 11, 2021  
 Time: 1:30 PM - 2:30 PM  
   
Target Safety Assessments: How Augmented Intelligence Is Advancing Insights for Quicker, Evidence-Based Decision-Making  
 Dr. Frances Hall - Director, Scientific Solutions  
 Paul Bradley - VP, Data Science Solutions  
 Date: Thursday, November 11, 2021  
 Time: 12:00 Noon - 1:00 PM   
   
  
  
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SENDIG v3.1 Draft B Now on Public Review   
Comments due by September 10, 2015  
August 17, 2015 – The CDISC/SEND Leadership Team has announced that the second draft of the CDISC/SEND Implementation Guide, v3.1, is now available for public comment. This draft addresses issues identified by the first public comment period in December 2014, and also resolves ambiguity in some of the timing variables.  
To access the document package and provide comments, interested parties are encouraged to visit the CDISC announcement www.cdisc.org/send.  
Instem has been extensively involved in the creation and development of SEND since its inception, working closely with SEND pilot organizations, the FDA and industry to help define the standard and align it with industry practices.  
As a result of this detailed involvement, Instem developed submit™, the first commercially available SEND data management system and is proud to provide the most widely adopted set of SEND tools in the market, with Instem SEND solutions licensed across 12 countries at 35 sites.   
Instem’s submit platform provides a suite of integrated tools and services for the creation and management of SEND datasets and associated documents for Contract Research Organizations, Sponsors and their study partners. More information about SEND and Instem’s tools.   
About Instem  
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KnowledgeScan Target Safety Assessment Showcasing at Society of Toxicology Annual Meeting  
Instem to Present Novel Approach for Drug Safety Assessment  
CONSHOHOCKEN, PA – March 3, 2016 - -Instem, a leading provider of IT solutions to the global early development healthcare market, announced today that it will showcasing its KnowledgeScan™ Target Safety Assessment Service at this year’s Society of Toxicology’s 55th Annual Meeting taking place in New Orleans.  
Developed and optimized by experienced toxicologists and bioinformaticians, Instem’s KnowledgeScan™ Target Safety Assessment Service ensures optimal toxicological interpretation of target genetics and biology using powerful information technology and transparent, systematic and comprehensive analytical workflows.   
Showcase Events  
Monday March 14th – 16th  
 Members of the international team will be at booth #737 to talk more about the benefits of deploying KnowledgeScan™ as an effective alternative, or supplement, to your in-house target safety assessment capabilities.   
Tuesday, March 15th 4:30pm – 5:30pm  
Room 213, 2nd floor  
 Join Instem and our special guest, Dr. James Sidaway, Director at Phenotox Ltd., for an interactive and informative group session that will review how KnowledgeScan™ provides an optimal assessment of toxicity risks relating to target or therapeutic modality using automated data mining and expert review.”  
 Appetizers and drinks will be served (free entry).   
Thursday, March 17th 9:30am – 12:45pm  
Great Hall A – Late Breaking Poster Session 2  
 Please stop by to review and discuss the following poster presentations. Instem staff and a client co-author will be on-hand:  
A systematic comparison of genetic intervention and antibody studies for the immune check point inhibitors supports a strategy for predicting novel target-mediated toxicities - Poster board #3668/P360  
A systematic assessment of human druggable target genes identifies absent orthologues in mouse   
and rat - Poster board #3667/P359  
“Following years of investment and development, we are very encouraged by the attention that KnowledgeScan™ is receiving,” comments Gordon Baxter, Chief Scientific Officer at Instem. “The response to this unique technology-driven approach and feedback from our clients has been excellent. We see this as a real research accelerator and something that will help reveal new insight beyond what clients can do manually much more quickly and efficiently.”   
For more than a decade Instem has helped its pharmaceutical customers develop safer, more effective drugs with its blend of specialist software, knowledge bases and vocabulary products, backed up by a team of experienced scientific and IT professionals. Known for supplying fast, practical and cost-effective solutions, Instem has enhanced its data mining and analysis platforms making KnowledgeScan™ one of the most powerful solutions available today.   
About Instem   
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Japanese Pharmaceutical Organization Selects Instem’s Preclinical Software Solution Suite  
  
  
  
  
  
  
  
  
  
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Japanese Pharmaceutical Organization Selects Instem's Preclinical Software Solution Suite  
Leading Japanese Pharmaceutical Company Chooses Provantis® Preclinical Software Solution for Osaka Facility  
CONSHOHOCKEN, PA - (BUSINESS WIRE) - June 21, 2012 - - Instem, a leading provider of IT solutions to the global early development healthcare market, announced today that one of Japan’s leading research-oriented global pharmaceutical companies has purchased the Provantis preclinical software solution for their Osaka R&D facility, following a competitive evaluation.  
   
Headquartered in Tokyo, this global organization focuses its development efforts in the fields of urology, immunology and infectious diseases, oncology, neuroscience, and DM complications and metabolic diseases.  
Key Facts  
  
Comprehensive suite of modules purchased to support the areas of General Toxicology, Reproductive Toxicology, Pathology and Pharmacy   
Competitive evaluation conducted; Instem selected for best product fit combined with global market leadership  
Replacing an ageing legacy solution, the project also includes a systems integration component, leveraging the client’s investment in existing software systems and demonstrating a commitment to an “open” systems approach  
  
Instem will be working in close co-operation with their Japanese distributor, CTCLS, to ensure a smooth and successful deployment. CTCLS is one of Japan’s leading providers of integrated R&D support systems for the life sciences, supporting Instem’s solutions through their full service offices in Tokyo and Osaka.  
Neil Donaldson, VP of European & Asian Operations, Instem said “This is excellent news for both CTCLS and Instem, and demonstrates the winning combination of global technology leadership and local support that we offer to organizations throughout Japan.”  
  
 As a member of Itochu Techno-Solutions Corporation, CTCLS has evolved into one of Japan's leading solution providers, specializing in the integration of R&D support systems for life science companies.  
With incomparable end-to-end solution capability, CTCLS deals with pharmaceutical, chemical and food manufacturers, as well as universities and public offices, and offers a wide-range of products and services that cover every stage of R&D activities.   
About Instem  
Instem is a leading supplier of IT applications to the early development healthcare market, delivering compelling solutions for data collection, management and analysis across the R&D continuum. Instem applications are in use by customers worldwide, meeting the rapidly expanding needs of life science and healthcare organizations for data-driven decision making leading to safer, more effective products.  
Instem’s portfolio of software solutions increases client productivity by automating study-related processes while offering the unique ability to generate new knowledge through the extraction and harmonization of actionable scientific information.  
Instem supports over 400 clients through full service offices in the United States, United Kingdom and China with additional locations in India and a full service distributor based in Japan.  
Meeting clients at the intersection of investment & return™.  
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Edward Lorenti Appointed as Instem VP Global Sales  
Lorenti Chosen to Lead International Sales Team as Instem Growth Continues  
CONSHOHOCKEN, PA - (BUSINESS WIRE) – October 8, 2013 - -Instem, a leading provider of IT solutions to the global early development healthcare market, announced today it has named Edward Lorenti as its Vice President of Global Sales.  
Lorenti has held a number of leadership positions within the Life Sciences industry and brings an extensive background in business and market development to Instem’s management team.  
Prior to joining Instem, Lorenti was sales director at Accenture (formerly Octagon Research Solutions, which they acquired in 2012) where he was responsible for their enterprise content management and submission software platform serving pharmaceutical and biotechnology organizations worldwide.  
Lorenti’s proven track record to build and manage high performing sales operations spans nearly 25 years and in this role will help Instem further shape, define and execute their strategic growth plans. Lorenti will be based out of Instem’s US Headquarters but will be traveling extensively, and along with the experienced sales team he will be supporting current and prospective clients throughout North America, Europe and Asia-Pacific.  
“We are delighted to bring Ed on board into this important role at this stage of our company’s evolution,” comments Phil Reason, CEO at Instem. “Ed has the comprehensive credentials to help us convert our dynamic product portfolio into software solutions that will further increase our growth across the R&D continuum. Our global sales team will certainly benefit from his day-to-day experience as a sales leader along with his demonstrated strategic abilities.”  
“I’m very excited about joining Instem – a great company with a seasoned, first class team – and look forward to the challenge of leading the global sales group to the next level of coverage and performance,” comments Lorenti. “Listening to clients and staff will be a very high priority as we aim to increase market share in existing segments while opening up new areas with Instem’s growing set of powerful technology solutions. Instem has built an excellent reputation for its innovation and client satisfaction, and I am very pleased to continue the efforts to deliver value to each and every user.”   
Instem has been developing, releasing and introducing a steady stream of technology solutions to the market in its mission to deliver data-driven insights. Capitalizing on its leadership within preclinical, Instem entered the early phase clinical market earlier this year with the ALPHADAS® EDC and automation software suite, a solution which organizations across four continents are using to accelerate and streamline clinical trial operations and service.   
Instem plans to remain active in expanding the reach of its product portfolio into related scientific domains significantly reducing costs and cycle times while improving clients’ quality of data.  
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Leading Biopharmaceutical Organization Selects Instem’s SEND Software Suite  
New Instem Client Chooses submit™ and SENDView™ SaaS Deployment to Ensure SEND Compliance  
CONSHOHOCKEN, PA – September 20, 2016 - Instem, a leading provider of IT solutions to the global early development healthcare market, announced today that a specialty-focused, research-based biopharmaceutical company headquartered in the United States has purchased Instem’s submit™ software solution suite. The company has selected submit to generate and manage SEND (The Standard for Exchange of Nonclinical Data) compliant data and documents.   
The new client evaluated a range of SEND management tools on the market, including those provided by their existing preclinical IT vendor. Instem was selected because of their SEND leadership position and submit product functionality, especially the ability to extract data from the organization’s 3rd party preclinical data management system and create SEND datasets   
Key Facts  
  
Client has purchased the full submit software platform, a suite of integrated tools for the creation and management of SEND datasets and associated documents   
The purchase includes Instem’s SENDView™ application for simplified QC review   
Client to access submit and SENDView using Instem’s SaaS delivery model   
The organization has signed a multi-year subscription agreement with Instem.   
  
In December 2014, the US Food and Drug Administration issued a binding guidance implementing the electronic submission requirements for study data in new drug applications (NDAs), abbreviated new drug applications (ANDAs), and certain biologic licensing applications (BLAs) and investigational new drug applications (INDs). The guidance points to standards specified in the Data Standards Catalog, including SEND for non-clinical data, with an implementation date of December 17, 2016. This new client will be fully SEND enabled and well prepared for this year’s FDA SEND deadline.   
Gary Mitchell, Vice President of Marketing at Instem, said, “We are delighted to welcome another client to our SEND-submit client roster; they will be joining the largest and fastest growing SEND-enabled community in the world. Their use of submit and SENDView will help them to meet the impending FDA SEND deadline and solidify their SEND capabilities moving forward.”   
The submit platform provides a suite of integrated tools and services for the creation and management of SEND datasets and associated documents. Instem developed submit, the first commercially available SEND software solution in 2005 and it is now the most widely adopted in the market, supporting over 45 client sites across 15 countries. The submit platform is meeting the very wide range of demands that span the needs of the largest multi-national pharmaceutical organizations and CROs to the smallest organizations and their advisors.   
About Instem   
Instem is a leading supplier of IT applications and services to the early development healthcare market delivering compelling solutions for data collection, analysis and regulatory submissions management. Instem solutions are in use by customers worldwide, meeting the rapidly expanding needs of life science and healthcare organizations for data-driven decision making leading to safer, more effective products.  
Instem’s portfolio of software solutions and consulting services increases client productivity by enhancing product development processes while offering the unique ability to generate new knowledge through the extraction and harmonization of actionable scientific information.  
Instem supports over 500 clients through offices in the United States, United Kingdom, France, Japan, China and India.  
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Instem Acquires Leadscope; Prominent Provider of In Silico Safety Assessment Solutions   
Instem’s Acquisition of Leadscope, Inc. is Another Step in its Mission to Help Clients Bring Life Enhancing Products to Market Faster  
CONSHOHOCKEN, PA – (BUSINESS WIRE) - November 15, 2019 - Instem, a leading provider of IT solutions to the global life sciences market, announced today that it has acquired Leadscope, Inc. as part of its mission to further consolidate and harmonize key application areas that are helping customers streamline and accelerate their research and development processes.   
Founded in 1997 and based in Columbus, Ohio, Leadscope is a well-respected name within the scientific community. Leadscope is known for its advanced informatics and prediction technology, along with database solutions, that help organizations effectively unlock valuable knowledge contained in both public and proprietary sources of research data.  
Leadscope accelerates the drug discovery and development process through intuitive tools that are used by their international clients to predict toxicity and perform expert reviews for genetic toxicity, skin sensitization, carcinogenicity, acute toxicity, reproductive and developmental toxicity, organ toxicity and environmental toxicity.  
“On behalf of our clients and staff, we couldn’t be happier to be part of the Instem group and the transformation they are leading in health and life sciences,” comments Dr. Glenn Myatt, CEO at Leadscope. “The Instem brand is synonymous with innovation and market leadership, and they have managed to balance their growth while maintaining excellent service to their clients – something that is highly important for us here at Leadscope. As a leading provider of in silico safety assessment solutions, having the resources and global reach of Instem will help us further meet the growing need of industry and regulators for adaptable and flexible workflows that embed comprehensive and ethically acceptable safety assessments.”  
Leadscope are renowned leaders in computational toxicology and their clients include pharmaceutical, chemical and consumer products organizations, as well as international regulatory agencies. Leadscope’s innovative solutions allow researchers to combine their own proprietary data with publicly-curated toxicity databases. Clients searching Leadscope’s toxicity databases can access well over 500,000 toxicology studies for more than 200,000 chemicals, enabling fast, accurate, defendable and regulatory accepted predictions.   
“This acquisition is a great fit for us, and the synergies created will further help us enable clients to make better informed decisions,” states Phil Reason, CEO at Instem. “We have been in regular dialogue with Glenn and the Leadscope team for over 10 years, and with the increasing needs of the market for in silico tools, both in regulatory submissions and in safety profile screening, the timing is perfect. They have built a deep relationship with the regulatory authorities, a fantastic client base and have an excellent reputation in the market as true collaborators.”   
  
 Leadscope provides scientific leadership in computational toxicology enabled through several Research Collaboration Agreements with the FDA and through the management of consortia to develop protocols and position papers to help further drive market adoption. This includes an in silico toxicology protocol project funded by an NIH grant where Leadscope is managing a consortium of over 60 members, including international regulatory agencies, pharmaceutical, chemical and consumer products organizations, academics and toxicity consultants.   
Increased Demand for Model Based Drug Development  
The acceptability and use of alternative approaches, and more specifically in silico methods, are being driven by the need to maximize the relevance and credibility of safety assessments. The industry continues to evaluate the practicality of high-cost animal testing combined with the need to assess the safety of substances in a limited timeframe amidst a competitive environment; including the need to innovate new chemicals and products that satisfy ever-changing market demands.  
Leadscope has a long-standing relationship with the FDA through their Research Collaboration Agreements to develop in silico solutions to support regulatory needs. Leadscope’s solutions help reduce, refine and ultimately replace animal experiments, while addressing the need to reduce the amount of time spent by scientists in referencing disparate sources of data to aid decision making related to toxicity assessment.  
Computational toxicology covers a wide range of endpoints, one of which is now driven by ICH M7, the first international regulatory guideline to include computational toxicology models. The ICH M7 guideline describes a consistent approach, that can be utilized from preclinical through to final submissions, to identify, categorize, and control DNA reactive (mutagenic) impurities in pharmaceutical products to limit potential carcinogenic risk. Leadscope has actively supported the adoptions of ICH M7 and offers a complete solution to support this guideline.  
Enhanced Capabilities  
The Leadscope team will be part of Instem’s Scientific division, which currently is providing Target Safety Assessment (TSA) services through its KnowledgeScan™ offering. Through this acquisition, Instem is poised to offer the market better starting points by combining a wider array of key data to help clients gain a clearer picture of candidates from early biology to early chemistry.  
Going forward, combining Instem and Leadscope’s technologies will provide unique and more seamless solutions for the integration of public data and proprietary information to support the discovery and development of pharmaceuticals and other chemical products.   
Teams from both Instem and Leadscope will be exhibiting and presenting at next week’s American College of Toxicology 2019 Annual Meeting in Phoenix, Arizona.  
Leadscope Solutions  
Provided on a subscription or pay-per-use basis, Leadscope’s solutions employ sophisticated artificial intelligence and machine-learning algorithms to help researchers better predict potential safety outcomes. Accessed on-line as a SaaS solution or deployed on-site, Leadscope’s software is used to easily extract knowledge from both public data and proprietary sources enabling scientists to perform expert reviews.  
About Instem  
Instem is a global provider of leading software solutions and services that are helping over 500 clients bring their life enhancing products to market faster. We enable clients in the life sciences to more efficiently collect, analyze, report and submit high quality regulatory data, while maintaining compliance for their products around the world.   
Instem solutions are in use by customers worldwide, meeting the rapidly expanding needs of life science and healthcare organizations for data-driven decision making, leading to safer, more effective products.  
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Leading China-Based CRO Selects Instem’s Provantis Portal for Remote Study Monitoring   
Provantis Portal Remote Study Monitoring Solution Selected to Optimize Client Data Access and Communication  
CONSHOHOCKEN, PA - (BUSINESS WIRE) – July 16, 2013 - -Instem, a leading provider of IT solutions to the global early development healthcare market, announced today that WuXi AppTec (WuXi), a leading supplier of R&D services to the pharmaceutical, biotechnology, and medical device industries with operations in China and the United States, has purchased the Provantis Portal™ Remote Study Monitoring solution.   
 In 2009, WuXi selected Instem’s integrated Provantis preclinical solution suite to automate study processes at their newly constructed 314,000 square-feet toxicology facility in Suzhou. The Provantis Portal, launched in 2012, now allows WuXi’s toxicology clients to log into a secure Web site using any standard browser to view data from their on-going studies on-demand. This makes it easy for clients, particularly international organizations, to monitor their studies remotely while being able to more effectively communicate internally and with WuXi.  
“WuXi’s mission is to create a broad, integrated platform of R&D services that will allow anyone and any company to develop new medicines efficiently and cost effectively,” said Stephen Mason, Vice President of Operations for Preclinical Services at WuXi. “The speed and quality of communications made possible by the Provantis Portal supports our commitment to better serve our customers globally through high-quality services.”  
Neil Donaldson, Vice President of Asian and European Operations at Instem, commented, “We are delighted that WuXi continues to take advantage of solutions from within our Study Workflow and Automation suite, and I’m encouraged to hear that their use of the Provantis Portal is bringing immediate value to them and their clients. It is also fantastic to see WuXi expand the number of users and modules of Provantis as they increase capacity at their Suzhou facility.”  
  
 As the first western toxicology/pathology software supplier to enter the Chinese market, Instem officially deployed its first China-based system in one of the largest and most advanced vivariums during 2006. Acknowledging analyst projections that the People’s Republic of China (PRC) is on pace to becoming the second largest pharmaceutical market in the world, Instem established a full-service office in Shanghai, recruited local staff and has localized the Provantis product suite into Mandarin Chinese. Instem is supporting international organizations and domestic laboratories exclusively serving the PRC using on-site systems as well as their SaaS delivery model from a professionally managed data center based in Shanghai.  
Instem will be demonstrating its Provantis preclinical software suite and the Provantis Portal Remote Study Monitoring Solution at the 3rd China Annual Meeting of Drug Toxicology, Suzhou, China, July 16-19th.   
About Instem  
Instem is a leading supplier of IT applications to the early development healthcare market, delivering compelling solutions for data collection, management and analysis across the R&D continuum. Instem applications are in use by customers worldwide, meeting the rapidly expanding needs of life science and healthcare organizations for data-driven decision making leading to safer, more effective products.  
Instem’s portfolio of software solutions increases client productivity by automating study-related processes while offering the unique ability to generate new knowledge through the extraction and harmonization of actionable scientific information.  
Instem supports over 400 clients through full service offices in the United States, United Kingdom and China with additional locations in India and a full service distributor based in Japan.  
Meeting clients at the intersection of investment & return™.  
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Instem Chosen for Global Deployment of Provantis SaaS; Roche Consolidates Preclinical Software Systems  
Provantis Suite to Replace Existing Solutions While Adding New Capabilities for Roche  
CONSHOHOCKEN, PA - (BUSINESS WIRE) – October 27, 2011 - - Instem, a leading provider of early development software applications, announced today that Roche has purchased Instem's Provantis Preclinical solution suite using its SaaS delivery model. This purchase will consolidate several key application areas and harmonize Roche sites worldwide.  
Key Facts  
  
Roche will access the integrated General Toxicology, Pathology, Clinical Pathology and Protocol & Report Assembly (P&RA) modules using SaaS delivery model from US-based data center  
Data Import solution being deployed allowing Roche to import data from external sources  
Competitive evaluation conducted, Instem chosen for product coverage and SaaS capabilities  
Roche originally using traditional on-site software from multiple suppliers; consolidation includes new automated capabilities from Instem in their Clinical Pathology Laboratories  
Use of SaaS model to lower Roche infrastructure and support costs while enabling more frequent upgrades for access to latest features and functions  
4-year agreement with on-line deployment starting in 2011  
  
"To help with the rising cost of research and development, we are again encouraged to see that organizations such as Roche are consolidating the number of IT systems and vendors, allowing them to further focus on their science," adds Phil Reason, CEO at Instem. "Instem is well poised to support organizations such as Roche and we'll continue to proactively work with clients as they look to meet the demand for growth while increasing efficiencies."  
"This decision will allow us to harmonize our system landscape for the non-clinical safety departments and help our scientists to further optimize laboratory processes with one fully integrated solution", comments Alain Nanzer, Head of Non-Clinical Safety Informatics at Roche.  
About Instem  
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Instem Unveils New Additions to its Leading Computational Toxicology Software Suite  
New functionality along with Enhanced Models to Deliver More Efficient and Comprehensive Predictions in Chemical Safety   
PHILADELPHIA, PA – (BUSINESS WIRE) – November 2, 2022 - Instem, a leading provider of IT solutions and services to the global life sciences market, announced today that the latest edition of its powerful Leadscope Model Applier Computational Toxicology software solution has been released.   
This latest update includes new functionality to provide a more seamless experience when performing a Read-Across, as well as new and updated predictive models to support the increasing market need for in silico solutions. The new release will also be used as part of the recently introduced Predict™ technology-enabled service for nitrosamine carcinogenicity risk assessment.  
Renowned for their advanced informatics and prediction technology, together with comprehensive database solutions, Instem’s in silico solutions enable organizations around the world to effectively unlock valuable knowledge contained in both public and proprietary sources of research data. Clients can also access well over 600,000 toxicology studies for more than 200,000 chemicals, enabling fast, accurate, defendable and regulatory-accepted predictions.  
Core features of the 2022 software release include:  
  
NEW Read-Across Tool – a single and easy-to-use tool for searching analogs and performing read-across, while providing direct access to an extensive toxicology database.   
Leadscope Advanced™ Edition – includes advanced functionality and now available online, eliminating the need to invest in computer hardware and enabling quicker, easier access to new software updates.  
UPDATED Genetox Expert Alerts – The Leadscope Expert Alerts suite for bacterial mutagenicity, widely used for ICH M7 regulatory submissions, has been updated to enhance predictivity and interpretation.   
UPDATED Sensitization Models and Alerts - Updated models and alerts for the assessment of skin sensitization; including models to predict strong or extreme sensitizers formed on a growing database.  
NEW Acute Toxicity Predictive Models – New expert predictive models to predict acute lethality in dermal, oral and inhalation studies, based on research of over 175,000 chemicals with acute toxicity data.   
NEW Statistical Models and Expert Alerts to support the prediction of eye irritation and corrosion.   
NEW and UPDATED Statistical-Based Models to support the assessment of endocrine activity, drug permeability across the blood-brain barrier\* (supporting abuse liability), and cardiac toxicity\* (\*developed by the US FDA under the Research Collaboration Agreement).  
  
Dr. Glenn Myatt, VP Informatics, Instem said “We are delighted to introduce the 2022 Computational Toxicology software release, which will further strengthen the ongoing demand for reliable alternatives to traditional testing methods.”   
Dr. Myatt continued “This latest release is highly anticipated and will give both existing and prospective clients expanded support for regulatory guidelines, drug discovery, classification and labeling as well as occupational toxicology. Throughout the lifecycle of the release, we have been working in close collaboration with our clients, and feedback has been extremely positive.”   
Instem has developed a comprehensive program to help raise awareness of this important 2022 software release through on-demand demonstrations and presentations at key industry events including the ACT 43rd Annual Meeting, November 13th – 16th, Denver, Colorado.   
To be added to the release alert list and be one of the first to receive a copy of the on-demand presentation, please email insilico@instem.com   
About Instem  
A global provider of leading software solutions and scientific insight services, Instem is helping clients bring their life enhancing products to market faster.  
We enable organizations in the life sciences to more efficiently collect, report and submit high quality regulatory data, while offering them the unique ability to generate new knowledge through the extraction and harmonization of actionable scientific information.  
Across the entire drug development value chain, every day Instem solutions are meeting the rapidly expanding needs of life science organizations for data-driven decision making, leading to safer, more effective products.  
Instem supports its global roster of clients through offices in the United States, United Kingdom, France, Switzerland, Japan, China, and India.  
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Leading Global Biopharma Purchases Instem SEND-submit Software Suite  
US-Based International Biopharmaceutical Company Chooses submit™ Software to Convert, Create and Share SEND Data  
CONSHOHOCKEN, PA - (BUSINESS WIRE) - December 5, 2012 - - Instem, a leading provider of IT solutions to the global early development healthcare market, announced today one of the world’s largest biopharmaceutical organizations has purchased their submit™ solution suite to support CDISC’s Standard for Exchange of Nonclinical Data (SEND).  
SEND defines the organization, structure, and format of standard nonclinical tabulation datasets for interchange between organizations such as sponsors and contract research organizations and for submission to the US Food and Drug Administration (FDA).  
Key Facts  
  
Biopharma client purchases Instem’s complete submit software solution suite to create and manage SEND datasets throughout their lifecycle  
Instem software to reduce client time and effort by translating study data to controlled terminology and automatically checking against SEND guidelines to ensure compliance  
Instem’s newly announced SENDView™ solution for simplified data review part of submit delivery package  
Purchase additionally includes capability for management, secure storage and sharing of SEND datasets with external partners  
Fully integrated validation solution being utilized for rapid and comprehensive deployment  
  
“As a member of the CDISC SEND committee, I’m encouraged to see a top 10 biopharma moving aggressively to leverage the value of standardized nonclinical data in advance of the FDA requirements,” comments Jennifer Feldmann, VP Business Development at Instem. “They have clearly seen the benefits of submit as a fully-integrated solution for SEND file preparation, review, management and exchange, and we are looking forward to working with yet another Fortune 500 company as industry responds to this critical standard.”  
Enhancing the submit solution suite, Instem recently introduced SENDView, a new tool for simplifying the review of SEND datasets; enabling users to overcome hard-to-understand SEND concepts, view the data and its relationships in meaningful combinations while easily keeping track of their dataset review progress. SENDView is available as part of the submit suite or as an independent solution which can be used with any SEND dataset regardless of how it was produced.  
The US-headquartered client generates over $20 billion in net sales annually with $3 billion being spent in research & development as they advance their mission to discover, develop and deliver innovative medicine to cure the most serious of diseases.   
About Instem  
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Charles River Laboratories Selects Cyto Study Manager Software Solution   
Leading Contract Research Organization Selects Cyto Study Manager to Optimize Genetic Toxicology Operations  
CONSHOHOCKEN, PA – March 22, 2018 - -Instem, a leading provider of IT solutions to the global life sciences market, is pleased to announce that Charles River Laboratories (Charles River) has purchased the Cyto Study Manager genetic toxicology software solution.  
Charles River selected Cyto Study Manager to streamline their genetic toxicology study workflows into one comprehensive web-based system that can be securely accessed from anywhere. Cyto Study Manager’s powerful features will enable Charles River to increase efficiencies to better serve their clients.  
Read the full story on the Charles River website   
About Cyto Study Manager  
Cyto Study Manager, originally developed by Perceptive Instruments and now part of the Instem solution portfolio, integrates genetox data acquisition, auditing, reporting and study management into a single system. This GLP compliant solution is revolutionizing genetox study workflows, and leading R&D organizations across the globe are deploying Cyto Study Manager to help them streamline genetic toxicology operations, reduce costs, increase efficiencies and improve regulatory compliance.  
Download The Case Study – Leading EU Pharma Company Revolutionizes Genetox Study Workflow with Cyto Study Manager   
About Instem  
Instem is a global provider of leading software solutions and services that are helping over 500 clients bring their life enhancing products to market faster. We enable clients in the life sciences to more efficiently collect, analyze, report and submit high quality regulatory data, while maintaining compliance for their products around the world.   
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Instem to Host SEND Implementation Panel Session at Society of Toxicology Annual Meeting  
Panelists to Discuss Key Factors in Becoming SEND-Ready  
CONSHOHOCKEN, PA – March 18, 2015 - - Instem, a leading provider of IT solutions to the global early development healthcare market, is pleased to announce it will be moderating a panel discussion on the preparation and implementation of CDISC’s Standard for the Exchange of Nonclinical Data (SEND) at the Society of Toxicology Annual Meeting in San Diego, March 23rd. Joining the panel are contacts from Allergan, Bristol-Myers Squibb and MPI Research.   
The session, “Practical SEND Planning and Implementation: Key Learnings from a Dedicated Community of Experience and Expertise” will review the experiences of twenty-one sponsors and CROs across eleven countries that have completed or are implementing new processes for SEND. The panel discussion will allow attendees to hear from both CRO and sponsor organizations that are implementing solutions for SEND compliance. The presentation will also include a review of Final Guidance implications, project planning, workflow considerations, Sponsor/CRO relationships, 21 CFR Part 11 compliance and strategies for leveraging the data.  
 “Since the FDA’s issuance of Final Guidance at the end of last year, we have seen a marked increase in the number of organizations who are turning to Instem to help them become SEND enabled,” comments Mike Harwood, Senior VP at Instem. “This session will provide further opportunity for organizations to understand the practical implications of SEND and will assist them in any stage of their planning”.  
“Practical SEND Planning and Implementation: Key Learnings from a Dedicated Community of Experience and Expertise” will take place Monday, March 23 at 4:45PM PDT in room 24C of the San Diego Convention Center. Complimentary appetizers and drinks will be provided.  
Instem is exhibiting at the Society’s ToxExpo, the largest exhibition dedicated to toxicology and the biomedical sciences, taking place March 23rd – 25th at the San Diego Convention Center. Instem’s product and industry experts will be on-hand at booth #1127 to discuss and demo the latest features of Provantis 9 as well as its submit-SEND solutions.   
The Society of Toxicology Annual Meeting and ToxExpo will welcome over 6,500 attendees from more than 50 countries around the world.  
About Instem  
Instem is a leading supplier of IT applications to the early development healthcare market, delivering compelling solutions for data collection, management and analysis across the R&D continuum. Instem applications are in use by customers worldwide, meeting the rapidly expanding needs of life science and healthcare organizations for data-driven decision making leading to safer, more effective products.  
Instem’s portfolio of software solutions increases client productivity by automating study-related processes while offering the unique ability to generate new knowledge through the extraction and harmonization of actionable scientific information.  
Instem supports over 400 clients through full service offices in the United States, United Kingdom and China with additional locations in India and a full service distributor based in Japan.  
Meeting clients at the intersection of investment & return™.  
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Global R&D Organization Places Order for Enhanced SEND Software Solution Suite   
Instem Selected to Provide SEND Solution with Integrated Cross-Study Search and Browsing Capabilities  
CONSHOHOCKEN, PA - (BUSINESS WIRE) – May 29, 2013 - - Instem, a leading provider of IT solutions to the global early development healthcare market, announced today that another of the world’s leading healthcare companies has purchased their submit™ solution suite to support CDISC’s Standard for Exchange of Nonclinical Data (SEND).  
SEND defines the organization, structure, and format of standard nonclinical tabulation datasets for interchange between organizations such as sponsors and contract research organizations and for submission to the US Food and Drug Administration (FDA).  
Instem will also be providing the client with a comprehensive Data Integration & Bioinformatics solution, powered by its SRS™ technology. Using SRS, the client will be able to access, integrate and query SEND data being created from their own preclinical data collection system as well as SEND data received from their external study partners. This cross-study search and browsing capability will enable them to identify patterns and trends in their data, generating new knowledge and actionable insight.  
Key Facts   
  
Global R&D client purchases Instem’s complete submit software solution suite to create and manage SEND datasets throughout their lifecycle  
SEND solution suite to include secure, 21 CFR Part 11 compliant dataset storage  
Instem software to reduce client time and effort by translating study data to controlled terminology and automatically checking against SEND guidelines to ensure compliance  
Instem’s SENDView™ solution for simplified data review part of submit delivery package  
  
“It’s terrific to see industry embrace SEND and continue to turn to Instem for solutions that allow CRO’s, study partners and regulators to share, visualize and analyze study data more efficiently,” comments John Anderson-Carter, VP Sales at Instem. “We are especially encouraged to see this client take that extra step and leverage our comprehensive Data Integration & Bioinformatics technology platform to further enhance the SEND data sets providing valuable intelligence in their mission to reduce suffering and improve the quality of life.”   
Instem has been providing industry education and outreach to promote SEND while demonstrating its own technology solution suite – submit. During 2012 Instem was recognized at the CDISC Interchange North America meeting for its outstanding contributions toward the completion of the SEND 3.0 Implementation Guide.   
On May 16, 2013, Instem received the VOLTAGE Technology Innovator Award for its submit-SEND solution at a ceremony in Philadelphia. The VOLTAGE awards program, sponsored by SmartCEO magazine and Comcast, celebrates the role that technology plays in the business community and the future impact the technology sector will have on economic growth. Instem’s submit solution was also featured in the May edition of SmartCEO magazine.   
Instem recently announced its strategic move into the early phase clinical trials market. Its expanded reach will additionally be providing a richer source of essential research and submission data to client Regulatory Affairs departments through a single common toolset using its submit suite.  
About Instem  
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Instem Reports Increased Market Demand for KnowledgeScan Target Safety Assessment Service  
Pioneering Service Delivers Comprehensive Insight into Biological Target Profiling  
CONSHOHOCKEN, PA – Business Wire December 17, 2018 - - Instem, a leading provider of IT solutions to the global life sciences market, is pleased to announce that demand for its KnowledgeScan™ target safety assessment (TSA) service for biological target profiling has increased by approximately 30% in the past year.  
Leading R&D organizations, including pharmaceutical, animal health and biotech companies, have increasingly turned to Instem for the production of target safety assessments and demand remains high.   
Using the proprietary KnowledgeScan translational informatics platform, Instem quickly and systematically reviews and distills millions of data records from a variety of published sources. These data are then carefully curated, evaluated and interpreted by Instem’s experienced team of life science professionals and presented to clients in a comprehensive, consistent report format.   
Dr. Gordon Smith Baxter, Chief Scientific Officer, Instem said “We are delighted to see increasing demand for our KnowledgeScan service and are especially pleased to see so many of our clients returning to us time and again for additional engagements. KnowledgeScan is setting new standards in target safety assessment and is helping clients to make crucial investment decisions based on the most comprehensive intelligence available.”  
About KnowledgeScan  
KnowledgeScan is a unique, technology-enabled service that harnesses cutting-edge augmented intelligence capabilities to deliver comprehensive insight into the potential toxicological risks and challenges associated with modulating drug targets. The service incorporates a unique combination of powerful, computer-aided data acquisition and manipulation, automated workflows and scientific expertise to help clients across the globe make faster, better informed drug development decisions.   
For further information download the fact sheet.  
Listen to Dr. Baxter’s recent presentation on the latest trends in Target Safety Assessment, presented at the ACT Meeting, Florida, November 7th – Access the Recording  
About Instem  
Instem is a global provider of leading software solutions and services that are helping over 500 clients bring their life enhancing products to market faster. We enable clients in the life sciences to more efficiently collect, analyze, report and submit high quality regulatory data, while maintaining compliance for their products around the world.   
Instem solutions are in use by customers worldwide, meeting the rapidly expanding needs of life science and healthcare organizations for data-driven decision making, leading to safer, more effective products.  
Instem supports its global roster of clients through offices in the United States, United Kingdom, France, Japan, China and India.   
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Instem Releases New Version of OmniViz Data Mining and Visual Analytics Software  
Highly Anticipated Software Release Offers More Processing Power and Speed for Industry and Academic Users  
CONSHOHOCKEN, PA - (BUSINESS WIRE) - November 29, 2012 - - Instem, a leading provider of IT solutions to the global early development healthcare market, announced today it has released the next version of its OmniViz™ software solution enabling organizations to process larger datasets at greater speeds.  
OmniViz is a powerful data mining and analytics solution allowing users to analyze and explore critical information through its interactive and intuitive visualization technology. Utilizing sophisticated statistical and clustering algorithms, OmniViz processes and serves data to organizations to help reveal hidden patterns and features, allowing users to discover fresh insight and easily share that information with both colleagues and clients.   
OmniViz is a key component of Instem’s Data Integration & Bioinformatics suite of offerings, which feature comprehensive solutions that help generate new knowledge through the extraction of actionable information across the research & development continuum.  
Key Facts   
  
OmniViz version 6.1 released adding support for Windows 7 32 & 64-bit operating systems  
Version 6.1 of OmniViz offers access to more memory for processing of larger datasets at greater speeds; approximately 25% faster than prior version  
OmniViz currently serving the following application areas  
  
Text Analytics, including scientific literature and patents  
Biomarker discovery and analysis  
Patient stratification from gene expression data  
Chemical analysis and discovery of structure activity relationships  
  
OmniViz 6.1 available as solution platform for additional areas of focus such as financial analysis and human resources  
  
“For over ten years, OmniViz has enjoyed a loyal user base from both industry and academia and we are delighted to offer this new version to help manage the larger volumes of data that organizations are now facing,” comments Paul Bradley, Head of Semantic and Visual Applications at Instem. “This is an important milestone in the development of OmniViz, and we look forward to enhancing the user experience as we move forward in helping clients increase productivity and their ability to make data-driven discoveries and decisions.”  
OmniViz is also offered as an Instem Enterprise Technology acting as an innovation platform that can be applied across a broad range of application areas. These platforms create synergies between what often are disparate sources of information delivering consolidated insight more quickly and at lower costs.  
As part of their global promotion of OmniViz 6.1, Instem is offering no obligation evaluations allowing organizations to experience the power and flexibility of their data mining and visual analytics solution for up to 2 weeks. Those interested can contact omniviz.support@instem.com.  
About Instem  
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Leading Japanese Pharmaceutical Organization Becomes SEND-Enabled with Instem's submit™ Software Suite  
Japanese Pharma Company Chooses submit™ and SENDView™ to Address Mandatory FDA Requirements for Nonclinical Data  
CONSHOHOCKEN, PA – December 2, 2016 - Instem, a leading provider of IT solutions to the global early development healthcare market, announced today that a research-based Japanese life sciences company has purchased Instem’s submit™ and SENDView™ solutions for the creation and management of SEND (The Standard for Exchange of Nonclinical Data) compliant data and documents.   
Key Facts  
  
Client has purchased the full submit™ software platform, a suite of integrated tools for the creation and management of SEND datasets and associated documents   
The company has also purchased Instem’s SENDView™ application for simplified QC review   
Client has signed a multi-year subscription agreement and will access submit and SENDView via Instem’s SaaS deployment model  
  
Neil Donaldson, VP Sales EU & Asia, Instem, said, “We are delighted to welcome this latest client to our growing SEND-submit community. The deployment of submit and SENDView will allow our client to implement SEND quickly for products with FDA submission targets, enabling them to maintain compliance with imminent FDA mandatory submission requirements for SEND, which begin this month. We look forward to working closely with them to automate their SEND capabilities.”   
The submit™ platform provides a suite of integrated tools and services for the creation and management of SEND datasets and associated documents. SENDView™ simplifies the review of SEND datasets, enabling the user to view the data and its relationships in meaningful combinations and to easily keep track of their dataset review progress. More information about SEND and Instem’s tools can be found here.   
This latest agreement illustrates Instem’s growing SEND leadership in Japan. Instem has been serving the Japanese marketplace since 2005 with its distribution partner CTC Life Science Corp and has embarked on an expansion plan to grow that relationship, while also providing increased direct market support. Instem has recently opened an office in Tokyo, has hired additional staff and has expanded its technology offerings. In June of this year, Instem signed a partnership deal with BoZo Research Center who selected Instem as their SEND outsourcing partner in Japan.   
About Instem   
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Instem Reporting Strong Start to 2020 for Target Safety Assessment Services  
Instem Continues to Ramp up as Demand for Target Safety Assessment Service Reaches New Heights  
CONSHOHOCKEN, PA – (BUSINESS WIRE) – April 29, 2020 - Instem, a leading provider of IT solutions to the global life sciences market, is pleased to announce that it has recorded the strongest year on year growth to date for its Target Safety Assessment service.   
Target Safety Assessments (TSAs) are undertaken during one of the earliest phases of drug development, to identify and assess unintended adverse consequences of potential treatments, before expensive investment is made.   
Leading pharmaceutical, biotech and animal health organizations are increasingly recognizing the huge importance of TSAs, and as a result, demand for KnowledgeScan™, Instem’s pioneering, technology-enabled TSA service has grown rapidly, with double digit growth reported during 2019. This trend is set to continue throughout 2020, with the company reporting a strong new business pipeline for the year, as it continues to meet growing demand.   
Over the past 18 months, Instem has significantly increased its TSA customer base and further extended relationships with several key clients. Many of its clients are choosing to outsource all their TSA activities to Instem, while others are utilizing Instem as an additional outlet to augment and complement their existing TSA departments, or to assist during times of peak demand.   
To support this continued demand for TSA services, Instem has expanded and strengthened its KnowledgeScan team, adding Data Scientists, Life Scientists and Analysts across its global locations. As part of this resource investment, Instem has appointed Jon Chambers PhD to the newly created role of Director, Data Science Solutions. Dr. Chambers previously worked for the European Bioinformatics Institute, Cambridge, UK and brings a wealth of expertise to the team.  
During this time of increased organic growth, Instem further expanded its capabilities through the acquisition of Leadscope, a prominent provider of in silico safety assessment solutions.   
Leadscope provides advanced informatics and prediction technology, along with database solutions that help organizations effectively unlock valuable knowledge contained in both public and proprietary sources of research data. Through the acquisition of Leadscope, Instem is poised to offer the market better starting points by combining a wider array of key data to help clients gain a clearer picture of candidates from early biology to early chemistry.  
Dr. Gordon Smith Baxter, Chief Scientific Officer, Instem said “This is an extremely exciting time for Translational Informatics at Instem. Our solutions deliver invaluable insight to our clients, providing support for critical decisions early in the development curve and avoiding unexpected and unnecessary spend.”  
For further information about KnowledgeScan download the fact sheet.  
About Instem  
Instem is a global provider of leading software solutions and services that are helping over 500 clients bring their life enhancing products to market faster. We enable clients in the life sciences to more efficiently collect, analyze, report and submit high quality regulatory data, while maintaining compliance for their products around the world.   
Instem solutions are in use by customers worldwide, meeting the rapidly expanding needs of life science and healthcare organizations for data-driven decision making, leading to safer, more effective products.  
Instem supports its global roster of clients through offices in the United States, United Kingdom, France, Japan, China and India.   
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Cyto Study Manager Selected by Roche to Harmonize Genetic Toxicology Assay Processes  
Instem Software Chosen by Roche to Integrate Data Acquisition, Reporting & Management Processes for Genetic Toxicology Investigations  
CONSHOHOCKEN, PA - (BUSINESS WIRE) – September 30, 2014 - -Instem, a leading provider of IT solutions to the global early development healthcare market, announced today that Roche has selected their recently launched Cyto Study Manager™ software system to support their genetic toxicology research program.  
Developed by Perceptive Instruments, which is now operating as part of Instem, Cyto Study Manager integrates data acquisition, auditing, reporting and study management processes into a single intuitive system that greatly improves efficiencies while ensuring data integrity during genetic toxicology investigations.  
“Following the recent launch of the Cyto Study Manager solution, it is exciting to see strong demand from leaders such as Roche,” comments Gary Mitchell, VP Global Marketing at Instem. “Roche has been a long time user of Instem technologies such as our Provantis® preclinical software suite, and it is encouraging to get their vote of confidence once again as they continue to streamline processes and harmonize systems.”  
Cyto Study Manager enables clients to combine comet and micronucleus data management processes within an easy-to-use system. Fully integrated with the software, researchers can now transfer data directly from automated slide scoring platforms, allowing them to seamlessly produce consolidated study reports.   
Key Facts   
  
Roche purchases Cyto Study Manager Software system for genetic toxicology laboratories in Basel, Switzerland   
Long-standing client Roche expands use of Instem technologies with purchase of Cyto Study Manager system  
Cyto Study Manager provides Roche GLP and FDA 21 CFR part 11 compliance for electronic signatures, comprehensive auditing, archiving and historical control features   
  
Perceptive Instruments (Perceptive), now operating as part of Instem, develops, manufactures and supplies image analysis and data processing solutions that are primarily focused on the areas of genetic toxicology, microbiology and immunology. Perceptive solutions are deployed in over 50 countries at leading universities and research institutes and are supporting various government programs such as those at the National Center for Toxicological Research, a Food & Drug Administration division. Perceptive products also serve small and medium-sized companies along with many of today’s multinational organizations, including many of the leading global pharmaceutical companies.   
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Instem’s portfolio of software solutions increases client productivity by automating study-related processes while offering the unique ability to generate new knowledge through the extraction and harmonization of actionable scientific information.  
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Instem at ICT 2022  
Helping our clients bring their life enhancing products to market faster  
Please stop by one of our booths to learn more about Instem’s powerful software solutions & services  
Preclinical Solutions - Booth #18  
Learn how Instem’s preclinical solutions keep our clients focused on their science, not their software.  
  
Provantis® is the #1 online solution for managing preclinical studies.   
Learn about submit™, the most widely adopted modular software suite for creating, reviewing and managing SEND data or ask our SEND experts about our new SEND Advantage services.   
Our Genetic Tox Solutions are in a class of their own, featuring Comet Assay IV and Cyto Study Manager.  
  
In Silico Solutions - Booth #19  
Learn how our software and outsourced services enable researchers to generate new scientific insights through the identification, extraction and analysis of data to create actionable information.   
  
KnowledgeScan™ Target Safety Assessment (TSA) Service: Delivering comprehensive TSAs for clients around the world, enabling them to make faster, better-informed decisions on their drug targets.  
Leadscope Model Applier: Easy-to-use software to apply prediction models, perform an expert review, and create reports.  
Genetic Toxicity (Q)SARs: Complete solutions for the computational assessment of genetic toxicity, including statistical-based and expert rule-based models.  
Predict™: A leading edge, technology-enabled service that delivers a combination of powerful computation models with expert scientific review, to help clients predict chemical safety more quickly, efficiently, and comprehensively.  
Poster Presentations:   
P21-01 – Poster Viewing II (PV02), Tuesday 20 September  
 Challenges and Practical Examples in Creation of SEND Data for Developmental and Reproductive Toxicity Studies   
 Co-authored: Showa University School of Medicine, G-SEND (Global SEND Alliance), Ina Research Inc., Instem  
Poster Viewing 1, Monday, September 19th, 2022, 1.00pm-2.00pm / e-poster number is LP-119  
EMA-Mutamind: Which properties determine the mutagenicity of API- derived nitrosamines?  
Presenter: Kevin Cross, VP Product Development, Instem Co-authored by; A. Bassan, I. Brandsma, S. Chang, M. Christmann, M.A. Djuari, U. Deppenmeier, L. Elenschneider, J. Fahrer, R. Frötschl, G. Johnson, B. Haas, T. Hansen, A. Londenberg, T. Osterlund, M. Schulz, M. Vogel, C. Ziemann and S.E. Escher  
   
  
  
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Instem to Present at Teratology Society Annual Meeting, Montreal   
Instem Presenting "SEND for DART: What Is It and When Is It Coming?"  
CONSHOHOCKEN, PA – June 23, 2015 - - Instem, a leading provider of IT solutions to the global early development healthcare market, is pleased to announce that Marc Ellison, SEND-submit™ Product Manager, Instem, will present at the 55th Annual Meeting of the Teratology Society, Montreal, Québec.   
The poster presentation, “SEND for DART: What Is It and When Is It Coming?” will discuss the status of the development of SEND (Standard for Exchange of Nonclinical Data) for Development and Reproductive Toxicology (DART) studies. This extension to the standard has been in development for a number of years and the first version is expected to be issued by CDISC in the near future.   
The presentation will discuss the ‘3 phase approach’ taken to divide DART into embryo/fetal development, fertility and early embryonic development and pup development, along with the impact of SEND in each of these areas. Specific Domains, Variables, Concepts and new Controlled Terminology making up version 1.0 will be reviewed and the timing and intentions of subsequent versions will be addressed.  
“The Teratology Society Meeting provides the ideal forum for Instem to help the Developmental & Reproductive Toxicology community prepare for the introduction of SEND; for many attendees, this presentation may be their first exposure to the standard,” said Mr. Ellison. “Our presence at this meeting supports Instem’s ongoing commitment to educating and preparing the community for SEND.”   
Instem offers the submit™ platform, a suite of integrated tools and services for the creation and management of SEND datasets and associated documents for Contract Research Organizations (CROs) and Sponsors. Licensed in 11 countries at over 31 sites, Instem’s community of customers using a single SEND solution is the largest in the world.  
“SEND for DART: What Is It and When Is It Coming?” will be on display during Poster Session I on Monday, June 29, 2015 at the Teratology Society Annual Meeting at the Hotel Bonaventure Montreal.   
About Instem  
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Instem Acquires Cambridge-Based BioWisdom; Leader in Delivering Healthcare Intelligence Solutions  
Acquisition of Leading Bio-Informatics Solutions Company to Strengthen Instem's Early Drug Development Solution Suite  
CONSHOHOCKEN, PA - (BUSINESS WIRE) – March 7, 2011 - - Instem, a leading provider of early development software applications, announced today that it has acquired BioWisdom, Ltd (BioWisdom). Based in Cambridge, UK, BioWisdom provides innovative solutions to accelerate access to scientific information for better decision support during product discovery, development and commercialization.  
Established in 2000, BioWisdom helps clients to navigate the complex scientific and commercial issues involved in developing successful healthcare products. The company provides a powerful suite of software tools for the acquisition, integration, visualization and high-value analysis of healthcare intelligence from an extensive collection of public and private sources. It allows researchers at companies like AstraZeneca, Johnson & Johnson, Merck and Abbott to gather information about their targets during program development, find patterns in their research data, and put their own results into a broader scientific context to predict likely outcomes.   
This key acquisition significantly enhances and complements Instem’s recently launched Centrus™ solution suite, accelerating their customers' ability to aggregate, analyze and extract knowledge from huge volumes of disparate internal and external data sources, unlocking considerable value from billions of dollars of prior research investments. Instem’s deeply entrenched position and global reach in the Life Sciences industry will enable increased market penetration and enhanced support of the BioWisdom  
 solutions and services. Instem clients will have access to a broader spectrum of solutions, realizing higher  
 value from their technology investments and enabling true enterprise information integration within and beyond early drug development.  
“Integrating the BioWisdom products into Instem’s Centrus suite will significantly accelerate the introduction of new capabilities that focus on data integration, visual analytics and knowledge extraction,” comments Phil Reason, CEO at Instem. “The BioWisdom products come with many prestigious and highly satisfied clients, which are always a key factor when building market penetration with a solution suite that is unique in the industry. The talented and complementary BioWisdom team has a very similar outlook, and integrating now with Instem will increase our ability to help clients bring new products to market quickly and cost effectively, while minimizing any possible safety implications.”  
Following this acquisition, all of the world’s top 12 pharmaceutical companies and 16 of the top 20 will be Instem clients, as well as thousands of academic and not for profit researchers. Adding over 50 new clients, Instem will be extending support through their comprehensive Customer Involvement Program which includes a mix of communications and events such as Customer Center Discussion Forums, Special Interest Groups, Webinar series and Instem’s International Conference.   
As expressed by a senior contact at a Top 20 Pharmaceutical client, BioWisdom solutions are mining legacy preclinical study reports and including that information within the larger pool of drug development data. Now through a single provider, this acquisition will enable industry to drill down from the study report level data that is being extracted into individual animal/result data within systems such as Provantis and will provide the technology that underpins access to CRO partner and wider industry data.   
Dr. Gordon Baxter, CEO and Founder of BioWisdom commented, “The acquisition of BioWisdom by Instem creates opportunities for both companies in new but closely related markets. The combined businesses have a fantastic depth of experience across both regulated and non-regulated data environments, which will stimulate the development of new products and services for our pharmaceutical industry customers. The BioWisdom team has already identified a number of areas where our existing business will be improved by the acquisition and we look forward to working with Instem to create new, compelling solutions for data collection, management and analysis right across the R&D continuum.”  
While maintaining responsibility for the success of the BioWisdom business unit and its clients, Dr. Baxter will also take on the new role of Chief Scientific Officer for the Instem group. In addition to a portfolio of leading bio-informatics products, BioWisdom’s blend of technology and computational biology expertise has delivered a wide array of elegant solutions to some seemingly intractable biology challenges. This capability will be maintained and developed under a focused ‘Instem Scientific’ operating unit. This will continue to advance Translational Science through consortium projects, content creation, scientific advisement and problem solving.  
BioWisdom products will be marketed within Instem’s Centrus™ suite; complementing Instem’s focused capabilities for preclinical study data aggregation and delivery to allow a complete global view of data from discovery to the clinic. Launched in September of 2010, Centrus provides a single, secure environment to access, harmonize and use early drug development information from a variety of sources, including current data acquisition systems, legacy systems, warehouses, partner and contract research applications, to meet the rapidly-expanding needs of life science organizations for data-driven decision making.  
During the next several months Instem will be speaking to and visiting clients to further demonstrate the value of the enhanced offerings this acquisition will bring to each of them. Instem has been a leading voice for the harmonization of software solutions and consolidation of mission-critical IT providers within the life sciences and believes organizations around the globe can carry out their essential research more efficiently and cost effectively.  
More information about BioWisdom solutions can be found at www.biowisdom.com  
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Instem Showcasing Leading GeneTox Solutions at UKEMS Meeting, Leuven, Belgium  
  
  
  
  
  
  
  
  
  
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Instem Showcasing Leading GeneTox Solutions at UKEMS Meeting, Leuven, Belgium  
Instem's Perceptive Instruments Group to Exhibit at Leading Environmental Mutagenesis Society Meeting  
CONSHOHOCKEN, PA– June 19, 2017 - - Instem, a leading provider of IT solutions to the global early development healthcare market, is pleased to announce that Perceptive Instruments, an Instem company, will be exhibiting at the 40th Annual Meeting of the United Kingdom Environmental Mutagen Society (UKEMS), Sunday 25th to Wednesday 28th June 2017, Leuven, Belgium.  
This is a joint meeting with the Dutch and Belgium Environmental Mutagen Societies that will cover all aspects in relation to DNA damage and mutations caused by environmental agents, with a focus on new technologies and innovative modalities.   
Visitors to the booth will learn how organizations across the globe are using Instem solutions to improve the integration between data acquisition, auditing and reporting for regulatory genetox assays. Solutions on display include:  
  
Comet Assay IV - the market leading live video imaging system for fast, accurate and reproducible slide comet scoring   
Cyto Study Manager - Data acquisition, integration and reporting for genetic toxicology assays, including modules for the comet assay, micronucleus test and chromosome aberrations  
Sorcerer Colony Counter – instant, automatic plate counting for GLP laboratories  
Ames Study Manager – plate counting, data management and reporting for the Ames test   
  
UKEMS serves scientists working in the UK in the area of DNA damage and mutations caused by environmental agents such as chemicals and radiation. It encompasses academic research into the mechanisms and consequences of mutagenesis, and applications of this knowledge to the testing of novel pharmaceutical, industrial and agricultural chemicals for genotoxic effects.   
About Instem  
Instem is a leading supplier of IT applications and services to the early development healthcare market delivering compelling solutions for data collection, analysis and regulatory submissions management. Instem solutions are in use by customers worldwide, meeting the rapidly expanding needs of life science and healthcare organizations for data-driven decision making leading to safer, more effective products.  
Instem’s portfolio of software solutions and consulting services increases client productivity by enhancing product development processes while offering the unique ability to generate new knowledge through the extraction and harmonization of actionable scientific information.  
Instem supports over 500 clients through offices in the United States, United Kingdom, France, Japan, China and India.  
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Instem to Present at Outsourcing Preclinical Development Conference, Berlin  
  
  
  
  
  
  
  
  
  
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Instem to Present at Outsourcing Preclinical Development Conference, Berlin  
Instem Presenting on SEND Status and Industry Deployment Plans  
CONSHOHOCKEN, PA – November 27, 2013 - -Instem, a leading provider of IT solutions to the global early development healthcare market, is pleased to announce that Neil Donaldson, VP European and Asian Operations, Instem, will be presenting at the Outsourcing Preclinical Development Conference, Berlin, 3rd – 4th December.  
The presentation, “The Impact of SEND on Outsourced Studies” will outline the status and industry deployment plans of the CDISC SEND (Standard for Exchange of Nonclinical Data) program and will discuss the implications of SEND for organizations that are outsourcing their preclinical studies, as well as outlining how companies can best prepare for these changes.  
Mr. Donaldson said “Instem has been a leading participant in the SEND initiative from the outset and it is pleasing to see that the industry continues to actively embrace SEND. Numerous organizations are now utilizing Instem solutions to create and manage their SEND data sets.”  
SEND defines the organization, structure, and format of standard nonclinical tabulation datasets for interchange between organizations such as sponsors and contract research organizations and for submission to the US Food and Drug Administration.  
Instem is a key proponent of the SEND initiative and has been providing industry education and outreach to promote SEND while demonstrating its widely deployed technology solutions submit™ and SENDView™.  
During 2012 Instem was recognized at the CDISC Interchange North America meeting for its outstanding contributions toward the completion of the SEND 3.0 Implementation Guide. In addition, earlier this year Instem received the VOLTAGE Technology Innovator Award for its submit-SEND solution at a ceremony in Philadelphia.   
Outsourcing Preclinical Development is organized by Informa Life Sciences and is Europe’s only preclinical outsourcing event. “The Impact of SEND on Outsourced Studies” takes place at 11:50am on Wednesday 4th December in the Niche Innovation Emporium.  
About Instem  
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Instem Showcasing Preclinical Software Solutions at Key Industry Events in Korea, Japan and China   
Instem Sponsors Leading Scientific Exhibitions While Further Promoting its Market-Leading Preclinical Study Management and SEND Software Solutions  
CONSHOHOCKEN, PA - - June 17, 2015 - - Instem, a leading provider of IT solutions to the global early development healthcare market, is pleased to announce its support and involvement at the following industry conferences in the coming weeks:  
AsiaTox 2015, The 7th International Congress of the Asian Society of Toxicology  
 June 23 – 26, 2015, ICCJEJU Jeju Island, Korea  
 Booth 9  
42nd Annual Meeting of the Japanese Society of Toxicology (JSOT)  
 June 29- July 1st  
 Ishikawa Ongakudo, Kanazawa Art Hall, Hotel Nikko Kanazawa, Kanazawa, Japan  
 Booth C-6   
The 5th Annual Meeting of the Chinese Society of Toxicology (CSOT)  
 June 29 – July 2   
 Golden Sunshine Hotspring Resort, Hainan Province, China  
“We are looking forward to once again exhibiting at the JSOT and CSOT, and for the first time, AsiaTox. These conferences afford us opportunities to interact with our clients about the latest features and functions of our software while introducing prospective clients to our process-enhancing portfolio of solutions and services,” said Neil Donaldson, Vice President of Sales, Europe and Asia. “Our goal in supporting AsiaTox, JSOT and CSOT is to reinforce our commitment to improving processes for research organizations and help educate the industry on SEND.” Conference delegates are encouraged to visit Instem at one of these events to learn more about its market-leading solutions: Provantis®, for preclinical study management; submit™, a suite of integrated tools and services for the creation and management of SEND datasets; and image analysis and data processing solutions for Genetic Toxicology studies.  
About Instem  
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Instem To Deliver SEND Education Course and Showcase Leading Software Solutions at Safety Pharmacology Society Conference, Berlin  
  
  
  
  
  
  
  
  
  
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Instem To Deliver SEND Education Course and Showcase Leading Software Solutions at Safety Pharmacology Society Conference, Berlin  
Instem Exhibiting and Presenting at Annual Safety Pharmacology Meeting   
CONSHOHOCKEN, PA – September 18, 2017 - -Instem, a leading provider of IT solutions to the global early development healthcare market is pleased to announce it will be exhibiting and presenting at the 2017 Safety Pharmacology Society Annual Meeting, September 24–27, 2017, at the Maritim Hotel, Berlin, Germany.  
NOTOCORD, an Instem company, will be exhibiting at booth #208. Visitors to the booth will learn more about:  
NOTOCORD-hem™ - The leading software platform for the acquisition, display and analysis of physiological signals. NOTOCORD-hem supports in vivo, in vitro and ex vivo experiments and offers over 160 modules for a customized analysis.   
NOTOCORD-sense - Booth visitors will be among the first to learn about NOTOCORD-sense®, a cutting edge, Cloud-based platform for scientific collaboration. NOTOCORD-sense combines laboratory notebook features with real-time data collection, while delivering a strong platform for Data Mining by preventing the development of silos and inefficient import of raw data.  
Submit™ for SEND Compliance - Instem has a wealth of experience of helping organizations to become SEND (Standard for Exchange of Nonclinical Data) enabled and its submit™ solution is the market’s most widely adopted suite of SEND software and outsourced services in 15 countries. Whether study data resides in an Instem/Notocord solution or is stored within an alternative software platform, Instem has open industry partnerships in place to ensure submit-for-SEND can provide clients with complete FDA Compliance.   
Lunchtime Mini-Course: “What’s That Elephant in the Room? SEND Submissions for Safety Pharmacology”  
Sunday September 24th   
12:30 – 13:30  
Salon 1 Moskau   
Instem will be delivering a Continuing Education course which will focus on how the CDISC SEND v3.1 standard applies to vital core battery Safety Pharmacology cardiovascular and respiratory studies, and how organizations that sponsor and/or perform these studies can prepare for its use. Instem SEND Expert, Marc Ellison, will co-chair the session and will also be available at the NOTOCORD booth on Monday September 25th to address any SEND related questions.  
Poster Presentation  
Additionally, during the conference NOTOCORD will co-present a poster presentation with Inria, the French National Institute for computer science and applied mathematics. The joint poster, #117, is titled "Automatic Ionic Profiling on iPSC-CM from MEA Signals Using Mathematical Modeling and Machine Learning" and will be on display from 6pm Sunday 24th September until 3:45pm Tuesday 26th September in the exhibit hall.  
The Safety Pharmacology Society is a nonprofit organization that promotes knowledge, development, application, and training in Safety Pharmacology—a distinct scientific discipline that integrates the best practices of pharmacology, physiology and toxicology.   
About Instem  
Instem is a global provider of leading software solutions and services that are helping over 500 clients bring their life enhancing products to market faster. We enable clients in the life sciences to more efficiently collect, analyze, report and submit high quality regulatory data, while maintaining compliance for their products around the world.   
Instem solutions are in use by customers worldwide, meeting the rapidly expanding needs of life science and healthcare organizations for data-driven decision making, leading to safer, more effective products.  
Instem supports its global roster of clients through offices in the United States, United Kingdom, France, Japan, China and India.  
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SEND-Readiness Seminar Being Held in Tokyo as Instem Continues to Expand in Japan  
Life Science Professionals to Discuss the Status of SEND and Options for Becoming SEND-Ready in Japan  
CONSHOHOCKEN, PA - (BUSINESS WIRE) – February 11, 2016 - -Instem, a leading provider of IT solutions to the global early development healthcare market, announced today that it will be holding an on-site SEND-Readiness seminar in Tokyo on Friday, February 19th.  
The free program, sponsored by Instem, is open to professionals within the Japanese life science community and will feature presentations by Instem, including members of the CDISC SEND Core team.   
Topics to be covered include current SEND status updates and upcoming changes to the standard, important CDISC/CJUG and PhUSE information and a review of options for SEND outsourcing at every stage of SEND-Readiness. The program has been designed to also foster networking opportunities with peers and Instem SEND experts.  
“This program will inform, encourage and provide sound guidance to our guests, whatever their stage of SEND-Readiness,” comments Gary Mitchell, VP Global Marketing at Instem. “Whether in the education phase or already working with SEND datasets, we thoroughly enjoy sharing our SEND expertise in the knowledge that we’re helping our customers bring their life enhancing drugs to market more quickly and efficiently.”  
Organizations in 13 countries at 35 sites have turned to Instem as their SEND partner for providing guidance, services and tools for efficiently becoming compliant.  
To request an invitation that includes a full agenda and registration details, please send an email to submit@instem.com.  
Instem’s market-leading submit™ platform provides a suite of tools and services for the creation and management of SEND datasets and is proudly supporting more clients and sites than any other vendor. Organizations wanting to submit™ with confidence can learn more at: www.instem.com/solutions/submit  
Instem in Japan  
Instem has been serving the Japanese marketplace since 2005 with its distribution partner CTCLS Life Science Corp and has embarked on an expansion plan to grow that relationship while also providing increased direct market support. Instem has recently opened an office in Tokyo, has hired additional staff and has expanded its technology offerings.   
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NOTOCORD Releases Latest Version of Leading Data Acquisition Software  
NOTOCORD-hem Version 4.3.0.75 Delivers Improved GLP Compliance and Further Extends Compatibility with Hardware Vendors  
CONSHOHOCKEN, PA– March 28, 2017 (Business Wire) - - Instem, a leading provider of IT solutions to the global early development healthcare market, is pleased to announce that NOTOCORD®, now part of the Instem Group, has released the latest version of its world-leading NOTOCORD-hem™ software solution.  
NOTOCORD-hem is an advanced software platform for the acquisition, display and analysis of physiological signals, with a focus on the areas of Cardiovascular, Respiratory and Nervous System research. This latest release, version 4.3.0.75, offers users further improved GLP compliance and is compatible with DSI Hardware Configuration 1.8 and Stellar Telemetry implantable devices.   
“This is an excellent achievement and an important release for NOTOCORD-hem customers” comments Gregor Grant, Executive Vice President at Instem, "This is an important step in the road to a more Open Strategy, facilitating greater choice and driven by the needs of our customers. We look forward to connecting NOTOCORD-hem to more and more 3rd party signal acquisition, hardware and telemetry devices. We believe there is a strong call for more data collaboration and access which ultimately aids data-driven decision making; improving the science and leading to safer, more effective products.”   
About NOTOCORD-hem   
NOTOCORD-hem is an advanced software platform designed to acquire, display and analyze physiological signals. Covering Cardiovascular, Respiratory and Nervous system research areas, NOTOCORD-hem offers:  
  
Over 160 modules for a customized analysis  
In vivo, In vitro and Ex vivo  
Large range of hardware compatibility from analogue to implantable devices   
Simultaneous acquisition from different sources and systems  
Flexible user interfaces offering easy configuration and displays  
Ultra-fast access to data regardless of experiment file size  
Unique Microsoft Excel® Add-in for individualized reporting  
Compliance with GLP & 21 CFR Part 11  
  
About Instem  
Instem is a leading supplier of IT applications and services to the early development healthcare market delivering compelling solutions for data collection, analysis and regulatory submissions management. Instem solutions are in use by customers worldwide, meeting the rapidly expanding needs of life science and healthcare organizations for data-driven decision making leading to safer, more effective products.  
Instem’s portfolio of software solutions and consulting services increases client productivity by enhancing product development processes while offering the unique ability to generate new knowledge through the extraction and harmonization of actionable scientific information.  
Instem supports over 500 clients through offices in the United States, United Kingdom, France, Japan, China and India.  
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Instem Awarded EMA Research Grant  
Instem Secures Portion of €2.5m Grant as Member of Research Consortium Investigating the Mutagenicity of N-nitrosamines  
PHILADELPHIA, PA – (BUSINESS WIRE) – May 10, 2022 - Instem, a leading provider of IT solutions and services to the global life sciences market, announced today that it has been awarded a European Medicines Agency (EMA) grant as part of an EMA-funded research project to better understand the mutagenicity of N-nitrosamines.   
Nitrosamines (NAs) are a class of organic chemical compounds that humans may be exposed to by tobacco use or by consuming certain foods. N-nitrosamines have been categorized in the ICH M7 guideline as belonging to the “cohort of concern” group of high-potency mutagenic carcinogens. Some active pharmaceutical ingredients carry NAs as impurities from production and/or storage or may cause their formation in the gastrointestinal tract.  
As part of an industry and academic consortium of 9 beneficiaries, funded by EMA and led by Fraunhofer Institute for Toxicology and Experimental Medicine (ITEM), Instem is collaborating on a 2-year research project to further investigate the mutagenicity of different classes of NAs to distinguish highly potent from less potent carcinogens.   
Experts from Instem’s In Silico Solutions group will be participating in the project, and the Leadscope Model Applier computational toxicology software suite and toxicity and carcinogenicity databases will be used to help the consortium develop novel in silico test systems that will improve risk assessment and derive reference doses such as acceptable intake values.  
Dr. Glenn Myatt, VP Informatics, Instem commented, “We are delighted to have been invited to contribute to this important research program and to have the opportunity to work with leading researchers in developing new testing methodologies to help reduce drug safety risks.”   
Renowned for their advanced informatics and prediction technology, together with comprehensive database solutions, Instem’s in silico solutions enable organizations around the world to effectively unlock valuable knowledge contained in both public and proprietary sources of research data. Clients can also access well over 500,000 toxicology studies for more than 200,000 chemicals, enabling fast, accurate, defendable and regulatory-accepted predictions.  
In Silico Insider  
 For the latest in silico industry and regulatory insights, visit In Silico Insider, a bi-weekly Blog developed specifically for scientists and professionals working in the field of Computational Toxicology.   
About Instem  
A global provider of leading software solutions and scientific insight services, Instem is helping clients to bring their life enhancing products to market faster.  
We enable organizations in the life sciences to more efficiently collect, report and submit high quality regulatory data, while offering them the unique ability to generate new knowledge through the extraction and harmonization of actionable scientific information.  
Every day, across the entire drug development value chain, Instem solutions are meeting the rapidly expanding needs of life science organizations for data-driven decision making, leading to safer, more effective products.  
Instem supports its global roster of clients through offices in the United States, United Kingdom, France, Switzerland, Japan, China, and India.  
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Instem Chosen by SRI International as New Preclinical System Provider  
SRI Purchases Provantis Preclinical SaaS to Meet Needs of Growing Biosciences Operations  
CONSHOHOCKEN, PA - (BUSINESS WIRE) – November 30, 2011 – Instem, a leading provider of early development software applications, announced today that SRI International (SRI) has selected the Provantis® Preclinical software solution suite to support their preclinical research and development.  
Headquartered in Silicon Valley, and celebrating its 65th anniversary this year, SRI has been providing industry leaders, emerging companies, and government agencies with a broad range of pharmaceutical discovery and development capabilities for decades.   
SRI’s Biosciences Division is a unique organization of approximately 270 people taking chemical and biological research programs from Idea to IND®— from initial discoveries to investigational new drug applications to start human clinical trials.   
Key Facts  
  
SRI selected integrated Provantis General Toxicology, Pathology, Clinical Pathology and Reproductive Toxicology modules  
SRI to use SaaS delivery model from Instem’s U.S.-based data center, which supports both GLP and non-GLP study environments  
Provantis selected for functionality, ease of use and reporting capabilities  
Provantis to help increase capabilities for SRI, supporting continued growth as seen in recent contract wins from the National Cancer Institute, National Institute of Allergy and Infectious Diseases, and National Institute of Mental Health totaling nearly $190 million   
Instem providing validation services on project  
  
“We are honored that SRI has selected Instem as part of their system integration strategy,” said Shawn MacInnis, Sales Executive at Instem. “In addition to the proven functionality of our software, our demonstrated experience in managing a market-leading SaaS delivery model will benefit SRI.”  
“SRI has been conducting toxicology studies compliant with FDA Good Laboratory Practice (GLP) regulations since their inception in 1978,” said Jon Mirsalis, Ph.D., D.A.B.T., managing director of SRI’s Biosciences Division. “We have until recently used multiple data capture systems and have grown to the point where they were no longer meeting all of our needs. Our team evaluated a number of leading products and selected Provantis® as the system that could best support our objectives.”  
SRI is joining other leading organizations and government agencies by accessing Instem solutions from a secure centralized data center that meets the highest standards for reliability, security and redundancy and is managed by experienced staff 365 days a year.  
About Instem  
Instem is a leading supplier of IT applications to the early development healthcare market, delivering compelling solutions for data collection, management and analysis across the R&D continuum. Instem applications are in use by customers worldwide, meeting the rapidly expanding needs of life science and healthcare organizations for data-driven decision making leading to safer, more effective products.  
Instem’s portfolio of software solutions increases client productivity by automating study-related processes while offering the unique ability to generate new knowledge through the extraction and harmonization of actionable scientific information.  
Instem supports over 400 clients through full service offices in the United States, United Kingdom and China with additional locations in India and a full service distributor based in Japan.  
Meeting clients at the intersection of investment & return™.  
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Instem Kicks-Off Powerful Presentation Series Focusing on Their Use of Artificial and Augmented Intelligence Techniques to Improve Drug Development Processes  
  
  
  
  
  
  
  
  
  
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Instem Kicks-Off Powerful Presentation Series Focusing on Their Use of Artificial and Augmented Intelligence Techniques to Improve Drug Development Processes  
Presentation to Debut at the 55th Annual Eurotox Conference, Helsinki, Finland  
CONSHOHOCKEN, PA - (BUSINESS WIRE) - September 3, 2019 - - Instem, a leading provider of IT solutions to the global life sciences market, is pleased to announce that as part of its strategy to help bring life enhancing products to market more quickly and safely it will begin delivering a powerfully unique series of presentations to the industry.  
For the balance of 2019, at key exhibitions, user group meetings and events, Instem will be outlining ways in which artificial and augmented intelligence technologies are being used to support the continuous exploration of safety topics from structured and unstructured, and public and private sources of data. The presentation series will also explore the opportunities and barriers to leveraging public and private data sources for commercial advantage in drug research and development.   
Instem will formally kick off the series by delivering a presentation at this year’s 55th annual Eurotox conference in Helsinki, Finland. The presentation will be delivered by Frances Hall, Instem’s Director of Scientific Solutions and Marc Ellison, Director of SEND Solutions. Instem’s presentation, entitled, “Leveraging the combined power of technology, expertise and regulatory standards for safer outcomes” considers how the deployment of powerful automated technologies to enhance both production and analytical processes does not yet eliminate the need for skilled human intervention in these areas. The manual, labor-intensive nature of this work leads to questions of productivity and quality that need to be explored together with the potential for further optimization as new techniques and tools arise.  
Dr. Hall said, “As a leading provider of technology-enabled services to the life sciences, this presentation and our assertions draw heavily from our vast experience of working with the SEND standard, as well as our expertise in the curation and analysis of unstructured public and private scientific source materials for regulatory and decision-making purposes, specifically in support of Target Safety Assessments.”  
Mr. Ellison added “The conclusions in the presentation are based on empirical evidence drawn from our practical experience of delivering regulatory and research services to drug development organizations around the world. This fully supports our mission to help our clients bring their products to market faster and more safely, and I’m excited to further expand this conversion as the drive for new innovation and efficiencies continues to grow.”   
Join Instem as they get underway with their series, “Leveraging the combined power of technology, expertise and regulatory standards for safer outcomes” on Tuesday 10th September 2019, 12:30pm in Veranda 1 at Eurotox.  
Instem will also be available at their booth (#30) throughout the Eurotox exhibition.  
For more information about Instem’s technology-enabled services visit the submit-for-SEND and KnowledgeScan Target Safety Assessment service web pages or contact info@instem.com  
  
About Instem  
Instem is a global provider of leading software solutions and services that are helping over 500 clients bring their life enhancing products to market faster. We enable clients in the life sciences to more efficiently collect, analyze, report and submit high quality regulatory data, while maintaining compliance for their products around the world.   
Instem solutions are in use by customers worldwide, meeting the rapidly expanding needs of life science and healthcare organizations for data-driven decision making, leading to safer, more effective products.  
Instem supports its global roster of clients through offices in the United States, United Kingdom, France, Japan, China and India.   
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Instem to Present at Applied Pharmaceutical Software Conference  
Presentations by Instem Industry Experts Ranging from SEND to Efficient Instrument Interfacing Techniques  
CONSHOHOCKEN, PA – June 20, 2014 - -Instem, a leading provider of IT solutions to the global early development healthcare market, announced today that Vice President, Jennifer Feldmann and Senior Application Specialist, Joel Usansky will present at the Applied Pharmaceutical Software (APS) conference in Cambridge, MA on June 26th.   
Ms. Feldmann’s presentation, Nonclinical Data and the FDA Guidance for Regulatory Submissions in Electronic Format: Leveraging SEND for CRO, Sponsor and Regulatory Data Exchange, will discuss how SEND can be turned into an opportunity to gain access to detailed data for all nonclinical studies conducted by an organization, and leverage that data to improve the drug development process.   
Ms. Feldmann said, “The release of the FDA’s draft guidance has caused SEND to pick up momentum more than ever before. I am happy to represent Instem at APS to educate the industry on SEND and to share solutions to the challenges contract research organizations and their sponsors will face when implementing the standard.” Instem is a key proponent of the SEND initiative and has been providing industry education and outreach to promote SEND while demonstrating its widely deployed submit solution suite.   
Mr. Usansky’s talk, Challenges and Opportunities for the Efficient Interfacing of Lab Instruments to LIMS, will discuss the different methods of transferring data to and from an instrument such as file interfaces, APIs and Web services, and the pros and cons of each technique.   
“APS is unique among conferences because it deals exclusively with the data systems and computerized technologies in use at pharmaceutical and biotech companies and their supporting contract research organizations,” commented Mr. Usansky. “I am thrilled to have been invited to speak and will take this opportunity to describe in detail the challenges of instrument interfacing and best practices for efficient and effective lab inter-system data exchange.”   
The Applied Pharmaceutical Software conference is organized by the Boston Society, a non-profit organization founded in 2004 as a forum to facilitate education, training, discussion, and scientific activities in support of drug discovery, development and allied topics.   
About Instem  
Instem is a leading supplier of IT applications to the early development healthcare market, delivering compelling solutions for data collection, management and analysis across the R&D continuum. Instem applications are in use by customers worldwide, meeting the rapidly expanding needs of life science and healthcare organizations for data-driven decision making leading to safer, more effective products.  
Instem’s portfolio of software solutions increases client productivity by automating study-related processes while offering the unique ability to generate new knowledge through the extraction and harmonization of actionable scientific information.  
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Instem Exhibiting at Chinese Society of Toxicology Meeting  
Instem to Showcase Preclinical Solutions and Outsourced Services at China’s Leading Toxicology Conference  
CONSHOHOCKEN, PA – May 8, 2018 - - Instem, a leading provider of IT solutions to the global life sciences market, is pleased to announce it will be once again exhibiting at the Annual Meeting of the Chinese Society of Toxicology, taking place May 12 – 15 in Nanjing, Jiangsu Province.   
The annual meeting features stimulating lectures and presentations on the latest scientific breakthroughs and research results, highlighting cutting-edge technology and developments within China and overseas and sharing the latest policies, regulations and technical guidelines. Approximately 700 delegates are expected to attend this year’s conference.  
During the conference, visitors to Instem’s exhibition booth #B11 can learn more about:  
  
Instem’s submit™-for-SEND software and outsourced study services, the most widely adopted in the industry. Come hear about the latest updates, including:  
  
Submit™, a suite of integrated tools and services for the creation and management of SEND datasets and associated documents  
SEND Explorer® for advanced SEND data visualization & analysis  
SENDTrial™; enabling clients to reduce the time required for trial design creation by up to 80%  
Hear about the steady stream of clients that are turning to Instem as their partial or full exclusive SEND outsourcing partner.  
  
Provantis® for preclinical study data management; the #1 SaaS software solution that keeps you focused on your science, not your software. Online clients also have full access to the Provantis Academy of eLearning; stop by and let us demonstrate how we can make you even better at what you do.   
KnowledgeScan™; helping clients reduce the time & costs of target safety assessment by up to 50%.   
NOTOCORD-hem™; The leading solution for the acquisition, display and analysis of physiological signals.   
Comet Assay IV - the market leading live video imaging system for accurate and reproducible slide comet scoring. Be sure to ask for a demo and a free trial!  
Cyto Study Manager - integrating genetox data acquisition, auditing, reporting and study management into a single system. Reduce costs while increasing efficiencies and improving regulatory compliance, all within one intuitive system.   
Ames Study Manager – plate counting, data management and reporting for the Ames test  
  
About Instem  
Instem is a global provider of leading software solutions and services that are helping over 500 clients bring their life enhancing products to market faster. We enable clients in the life sciences to more efficiently collect, analyze, report and submit high quality regulatory data, while maintaining compliance for their products around the world.   
Instem solutions are in use by customers worldwide, meeting the rapidly expanding needs of life science and healthcare organizations for data-driven decision making, leading to safer, more effective products.  
Instem supports its global roster of clients through offices in the United States, United Kingdom, France, Japan, China and India.   
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Logos Technologies launches PDAQ™ for ePRO data collection  
  
  
  
  
  
  
  
  
  
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Published originally by Logos Technologies prior to Instem ownership, included here for information purposes  
Logos Technologies launches PDAQ™ for ePRO data collection  
1st March 2013  
Logos Technologies is delighted to announce the release of its ePRO data collection tool, PDAQ™ (Patient Data AcQuisition) which has been specifically designed to improve the collection and review of electronic Patient Reported Outcome (ePRO) clinical data.  
“We are both delighted and immensely proud of this app. This outstanding addition to the utility of ALPHADAS, exploiting the latest in device and platform technologies, along with the current, market tested integrations that already exist with ALPHADAS and our peerless implementation team puts Logos Technologies truly at the forefront of electronic data collection in early phase clinical trials.” said Mark Cusack, VP Business Development, Logos Technologies.   
  
Fully validated & regulatory compliant Web App  
Utility end to end through all stages of the clinical trial process – offering ground breaking efficiencies in critical areas such as screening  
Can be stand alone or as inherent part of ALPHADAS® - one user interface and system for the entire trial management, data collection & review process, integrating with other clinical trial systems & medical devices  
Shown produce data of highest accuracy & quality which is then available for real time review by the site and sponsor alike – whether the study subject is within and away from the clinical unit  
Developed in partnership with Inflamax Research Inc, Toronto, a client partner of Logos and world leaders in Environmental Exposure Chambers (EEC) studies  
Is available on a variety of devices – both Windows & Android tablets, phones…  
Has been presented as a poster titled ’A Novel Validated Electronic Patient Data Acquisition Tool Standardizes Patient Reported Outcomes (PRO) Data Acquisition Across Multi-Center Environmental Exposure Chamber and Field Studies’ co-authored with Inflamax Research  
Already in use in clinical pharmacology trials  
  
 Data collection features include:  
  
on-screen questionnaires,   
visual analog scales (VAS),  
response time metrics,   
coordination tasks  
high resolution image capture  
Evaluator interview via video conferencing  
Subject data recorded is available in real-time to sponsors allowing for real-time data query and resolution, reducing costs & transcription errors  
  
Mark Cusack continues. “It is now beyond doubt that Logos set the path for others to follow. Key to our industry leadership are the collaborations with our client partners – development being driven by real life needs and solutions. The co-development of PDAQ with Dr Piyush Patel, a Key Opinion Leader in his field & Inflamax Research is a demonstration of how Logos Technologies view their clients as partners. Our end users are the true owners of ALPHADAS.”   
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Instem Enables Clients to Leverage ICH S1B Weight of Evidence Guideline  
Advance™ technology-enabled solution enables R&D organizations to cut study timelines, deliver cost savings and reduce animal experimentation.  
PHILADELPHIA, PA – (BUSINESS WIRE) - January 25, 2024 - Instem, a leading provider of IT solutions and services to the global life sciences market, announced today that its latest in silico solution offering known as Advance™ , is providing clients with a technology-enabled approach for assessing carcinogenicity based on the ICH S1B Weight of Evidence (WoE) Addendum.  
The ICH S1B guideline has introduced a WoE approach to assess human carcinogenic potential of small molecule pharmaceuticals and determine whether a 2-year rat carcinogenicity study would add value. Application of this integrated analysis supports the 3Rs principles, while promoting safe and ethical development of new small molecule pharmaceuticals.  
In early 2022, in response to the directive, Instem established a collaborative cross-industry working group to develop a protocol that could support the carcinogenicity WoE integrated assessment in a transparent, consistent, and defendable manner.  
Since that time, Instem’s team of in silico experts have been instrumental in driving forward a solution to support the S1B guideline. In addition to leading the cross-industry working group, Instem has delivered numerous presentations, posters and workshops at key global industry conferences and events, as well as creating, developing, and delivering the Advance™ technology-enabled service in consultation with key industry stakeholders.   
One of the global pharmaceutical organizations who collaborated with Instem on the development of the Advance™ solution said, “The Advance™ services are a living embodiment of more than a decade of effort from scientists and regulators across the globe. We now have an avenue for leveraging a scientific-based argument to reduce the emphasis on animal use in the post marketing space without compromising patient safety. It’s an opportunity for us to embrace innovation and to deliver medicines in a more efficient way”.  
The benefits of this revolutionary WoE approach are multi-fold. In addition to saving time, money and the need for animal experimentation, a literature and data-based reasoning provides scientists confidence in the experimental approach and prompt alerts to potential safety concerns. This ultimately enables pharmaceutical organizations to bring their life enhancing products to market faster.   
Dr. Gordon Baxter, Chief Scientific Officer, Instem, commented: “The introduction of the Advance™ technology-enabled service is another important step for us all to recognize the ongoing demand for reliable alternatives to traditional testing methods. By reimagining the carcinogenicity assessment in this way, it will unlock numerous possibilities to progress the drug discovery and development journey for many organizations globally. The Advance™ assessment is robust enough to provide intelligent insights in the present, but can also be updated in the future when more research information becomes available.”   
The Advance™ service is comprised of six areas, which mirror the six WoE factors. Instem can provide a full assessment of all six WoE factors, including database searches and in silico experimentation. Alternatively, a single WoE factor can be completed to complement an in-house workflow.   
As the compound progresses through the pipeline, and more data or information becomes available, the WoE assessment can be updated and refreshed in real time.   
Industry and regulators are increasingly recognizing the huge benefits of in silico approaches, which are driving forward this strong and sustained growth in the acceptance and adoption of alternative methods in drug discovery. The introduction of Advance™ has further enabled organizations to replace, reduce or refine their efforts within animal research.  
To learn more about Advance™ and how it can help streamline your R&D processes, download the factsheet or contact info@instem.com.   
About Instem  
A global provider of leading software solutions, technology enabled outsourced services and powerful scientific insights, Instem is helping clients to bring their life enhancing products to market faster.   
We enable organizations in the life sciences to more efficiently collect, report and submit high quality regulatory data, while offering them the unique ability to generate new knowledge through the extraction and harmonization of actionable scientific information.  
Every day, across the entire drug development value chain, Instem solutions are meeting the rapidly expanding needs of life science organizations for data-driven decision making, leading to safer, more effective products.  
Instem supports its global roster of clients through offices in the United States, United Kingdom, France, Switzerland, Japan, China, and India.   
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Instem Reports Another Year of High Growth for In Silico Solutions  
High Demand for Target Safety Assessment Services and Computational Toxicology Solutions Continues Throughout Discovery and Nonclinical  
CONSHOHOCKEN, PA – (BUSINESS WIRE) – Jan 27, 2021 - Instem, a leading provider of IT solutions to the global life sciences market, reported today that 2020 was again a high growth year for its In Silico Solutions suite of software and outsourced services.   
  
Instem’s pioneering In Silico solutions enable researchers to generate new scientific insights through the identification, extraction and analysis of data to create actionable information.  
  
Target Safety Assessments  
   
One of Instem’s leading offerings in this area is KnowledgeScan™, a technology-enabled service for the creation of Target Safety Assessments (TSAs). A critical part of Drug Discovery, TSAs help organizations to identify and assess unintended adverse consequences of potential treatments before expensive investment is made. This enables researchers to mitigate against target-related toxicities, or to prioritize targets with lower safety risks across the early drug discovery portfolio.  
  
Research organizations continue to recognize the importance of TSAs, and as a result, demand for Instem’s KnowledgeScan™ service has continued to grow rapidly year on year, with double digit growth reported during 2020. During the year, Instem further expanded its KnowledgeScan customer base, adding new clients across the globe. Instem expects demand for its TSA services to continue throughout 2021, as a strong new and repeat business pipeline for the year develops.   
  
During 2020, Instem invested heavily in next generation technology and innovative process enhancements to ensure even higher levels of service and faster turnaround times for its growing TSA client roster. As a result, Instem is now able to offer clients an expanded portfolio of TSA reports, ranging from condensed, rapid turnaround TSAs to comprehensive, full TSAs including detailed toxicological interpretations.   
  
Additionally, during 2020, Instem’s Target Safety Assessment experts set the scientific community abuzz with the creation and release of a detailed report into the ACE2 receptor, a target that is currently receiving a significant amount of attention. The report was made available free of charge to the scientific community and Instem is committed to providing additional insights into ACE2 throughout 2021.   
  
Computational Toxicology  
   
Another key component of Instem’s In Silico offering is a suite of powerful Computational Toxicology solutions and services, developed by Leadscope, an Instem company. Known for their advanced informatics and prediction technology, together with comprehensive database solutions, Leadscope helps organizations around the world effectively unlock valuable knowledge contained in both public and proprietary sources of research data. Clients searching Leadscope’s toxicity databases can access well over 500,000 toxicology studies for more than 200,000 chemicals, enabling fast, accurate, defendable and regulatory-accepted predictions.  
  
In December 2020, following the first full year after Instem’s acquisition of Leadscope, Instem was proud to launch the Predict™ In Silico Toxicology service. Predict™ is a leading edge, technology-enabled service that delivers a combination of powerful computation models with expert scientific review, to help clients predict chemical safety more quickly, efficiently and comprehensively.  
  
The new Predict™ service leverages Instem’s expertise in delivering technology-enabled services across a large area of the R&D continuum, alongside best-in-class computational models, to deliver comprehensive, unbiased, high quality, regulatory-accepted assessments of chemical safety.  
  
The Predict™ service is delivered by an experienced team, in conjunction with external consultants, who have a deep understanding of applicable guidelines and regulatory agencies’ processes, as well as extensive experience in computational methodologies, toxicology, and chemistry. All assessments and expert reviews are based on a documented standard operating procedure and leverage an infrastructure that ensures the latest information is being used, including historical databases of toxicity studies.   
  
Predict™ supports a variety of applications including the ICH M7 pharmaceutical impurities guideline, assessment of extractables and leachables, and classification and labelling.   
  
Industry Resources:  
  
For additional information about KnowledgeScan download the fact sheet.   
  
For additional information about Predict download the fact sheet.   
  
Request a copy of the ACE2 Report  
About Instem  
A global provider of leading software solutions and scientific insight services, Instem is helping clients bring their life enhancing products to market faster.   
  
From Concepts to Cures, Instem enables organizations in the life sciences to more efficiently collect, report and submit high quality regulatory data, while offering them the unique ability to generate new knowledge through the extraction and harmonization of actionable scientific information.  
  
Across the entire drug development value chain, every day Instem solutions are meeting the rapidly expanding needs of life science organizations for data-driven decision making, leading to safer, more effective products.  
  
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Instem Specialist Presenting at Joint FDA and University of Texas Training Course at NIH, Maryland  
Presentation to Compare and Contrast Paper and Electronic Data Collection  
CONSHOHOCKEN, PA – April 24, 2014 - -Instem is pleased to announce that Shawn MacInnis, Senior Application Specialist, has been invited to participate as a faculty member at a joint University of Texas Medical Branch (UTMB) and U.S. Health and Human Services Food and Drug Administration (FDA) training course taking place at the National Institute of Health (NIH) in Bethesda, MD on April 28-May 2, 2014.  
The training course, “Assuring Data Quality and Integrity in Maximum Containment Laboratories” is a collaborative effort between FDA and UTMB to cross educate sponsors, scientists, veterinarians, quality assurance personnel, regulators, reviewers and policy-makers to enable the conduct of regulated studies supporting the advancement of medical countermeasures.   
In addition to being invited to contribute to the development of the course content, Mr. MacInnis will also be delivering a case study presentation which will compare and contrast collection of data in a paper and electronic mechanism and identify the regulatory risks of both systems.   
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Cyto Study Manager Showcasing at Society of Toxicology Meeting Phoenix, Arizona  
Integrated Data Acquisition, Reporting and Management Software Solution for Comet and Micronucleus Assays Now Available  
CONSHOHOCKEN, PA - (BUSINESS WIRE) – March 19, 2014 - - Instem, a leading provider of IT solutions to the global early development healthcare market, announced today that it will be showcasing its new Cyto Study Manager solution at this year’s Society of Toxicology (“SOT”) meeting in Phoenix, Arizona March 24th -26th.  
Supporting Genetic Toxicology investigations, the Cyto Study Manager integrates all comet and micronucleus data management processes into one simple, easy-to-use system that can be accessed securely from the laboratory and the office via an organization’s own internal network.  
Data acquisition and scoring systems such as Comet Assay IV are fully integrated with the system, sending data directly to the Cyto Study Manager database. All reports can then be seamlessly generated from within the system and automatically combined into final study reports.  
Live demonstrations of Cyto Study Manager will be offered throughout the SOT at Perceptive Instruments booth #924  
“We've recently added a range of exciting new features to Cyto Study Manager” commented Gary Kyle, Support and Development at Perceptive Instruments, “These features include fully customizable sample coding systems, simple-to-use historical data controls, and an experiment checklist which automatically guides users through the process of running their study.”   
Perceptive Instruments (Perceptive), now operating as part of Instem, develops, manufactures and supplies image analysis and data processing solutions that are primarily focused on the areas of genetic toxicology, microbiology and immunology. Perceptive solutions are deployed in 49 countries at leading universities and research institutes and are supporting various government programs such as those at the National Center for Toxicological Research, a Food & Drug Administration division. Perceptive products also serve small and medium-sized companies along with many of today’s multinational organizations, including many of the leading global pharmaceutical companies.   
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Instem Announces SEND Advice Clinic at Society of Toxicology Meeting; Phoenix, Arizona  
  
  
  
  
  
  
  
  
  
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Instem Announces SEND Advice Clinic at Society of Toxicology Meeting; Phoenix, Arizona  
Instem SEND Booth Offers Industry Advice, Tools and Latest FDA Timelines  
CONSHOHOCKEN, PA - (BUSINESS WIRE) – March 20, 2014 - - Instem, a leading provider of IT solutions to the global early development healthcare market, announced today that it will be providing a SEND (Standard for Exchange of Nonclinical Data) Advice Clinic stand during this year’s Society of Toxicology conference from March 24th – 26th in Phoenix, Arizona.  
Following the release of the FDA’s draft guidance for electronic submissions in February, Instem has invested in an exclusive space at this year’s conference to help organizations learn more about SEND and what they should be doing to prepare for it.  
Found at booth #1724 (across from the SOT Pavilion), the SEND Advice Clinic will also feature daily express presentations on topics such as the latest FDA timelines, details of the SEND format and SEND data management for sponsors.  
SEND defines the organization, structure, and format of standard nonclinical tabulation datasets for interchange between organizations such as sponsors and contract research organizations and for submission to the US Food and Drug Administration (FDA).  
Visitors to the Advice Clinic will also be able to learn more about Instem’s market-leading submit™ software solution suite. Instem is the leading provider of SEND technology and through its fully integrated submit™ software solution suite enables organizations to convert data from any source system into SEND files while allowing sponsors, CRO’s and regulators to share, visualize and analyze study data more efficiently.  
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Multi-National Organization Places $490k Order with Instem for Preclinical Software Suite at Singapore Laboratory  
  
  
  
  
  
  
  
  
  
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Multi-National Organization Places $490k Order with Instem for Preclinical Software Suite at Singapore Laboratory  
Instem Continues its Asia-Pacific Expansion  
CONSHOHOCKEN, PA - January 26, 2012 - - Instem, a leading provider of early development software applications, announced today that a leading multi-national organization has placed an order for its Provantis® Preclinical solution suite to automate processes at a research and development facility located in Singapore.   
The new client has purchased Instem’s integrated General Toxicology, Clinical Pathology and Pathology modules upon conclusion of a thorough evaluation of vendors and their solutions.   
“The key decision was based upon our market-leading position, our track record, experience and expertise in the implementation and ongoing support of GLP solutions in conjunction with our proven understanding of both their technical and functional needs,” commented Neil Donaldson, VP Regional Operations – Europe/Asia.   
Instem officially entered the Asia Pacific market in 2006 with its Provantis solution supporting one of the largest and most advanced vivariums in China. Since that time, Instem has established full-service offices in Shanghai, Tokyo and with additional resource locations is now serving clients throughout China, India, Japan and Australia.  
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Instem Presenting at the Society of Toxicologic Pathology's Annual Symposium  
Instem Presenting on Use of Legacy Data and Literature Analytics to Understand Digestive Tract Toxicity  
CONSHOHOCKEN, PA – June 4, 2013 - - Instem, a leading provider of IT solutions to the global early development healthcare market, is pleased to announce that Instem Life Scientist, Stephanie Berry, will be presenting at the 32nd Annual Society of Toxicologic Pathology Meeting and Symposium in Portland, Oregon.   
The poster presentation, “Using Legacy Data and Literature Analytics to Understand Digestive Tract Toxicity”, will discuss how Instem's visual analytics platform, OmniViz can be used to find safety signals in large volumes of unstructured text and how its Safety Intelligence Program, Instem’s Reference Knowledgebase, expands the understanding of compounds flagged as possible toxicants.  
Poster co-author and Director of the Safety Intelligence Program with Instem, Jane Reed commented, “This research shows how Instem’s approach to integrating public domain literature and other data sources provides real insight into a topic such as inflammatory bowel disease (IBD). This enables researchers to carry out a rapid and comprehensive “background check” into what existing drugs are known to be associated with IBD. This approach can easily be applied to any other system toxicity, which is key for pharmaceutical companies looking to improve attrition rates by ensuring good visibility of legacy data.”  
The Society of Toxicologic Pathology (STP) is a nonprofit association of pathologists and other scientists who focus on advancing pathology as it applies to changes in pharmacological, chemical, or environmental agents.  
“Using Legacy Data and Literature Analytics to Understand Digestive Tract Toxicity” will be on display at the STP Exhibit Hall from Sunday evening, June 16th through Wednesday afternoon, June 19th, 2013.  
This year’s annual meeting is expected to attract over 550 attendees and 28 exhibitors from around the world to the Oregon Convention Center. Instem will be exhibiting at booth #114 during the Exhibit Hall which will be open from Monday, June 17th through Wednesday, June 19th.  
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Instem Sponsors Indian Society of Toxicologic Pathology Conference  
Instem Committed to Supporting Growth of R&D Community in India  
CONSHOHOCKEN, PA – October 27, 2014 - - Instem, a leading provider of IT solutions to the global early development healthcare market, is pleased to announce its support of the 5th Society of Toxicologic Pathology – India (STP-I) Conference taking place in Bangalore from October 31st – November 2nd, 2014.  
The theme of this year’s conference, which is jointly organized by the STP-I and the International Federation of Societies of Toxicologic Pathologists (IFSTP), is “Continuing Education in Toxicologic Pathology – Endocrine and Gastrointestinal System”. The conference will feature 3 full days of technical sessions focussing on the toxicology and pathology of the Endocrine and Gastrointestinal system, as well as a half day International Academy of Toxicologic Pathology (IATP) seminar on Pathology Peer Review.  
Throughout the conference, STP-I delegates can visit Instem’s booth to learn more about its market leading preclinical solutions, including the Provantis® Pathology software solution for the collection, processing and reporting of data for gross and histopathology and the submit™ suite of solutions for creating, managing and reviewing SEND data sets.   
Instem’s VP Global Sales, Europe & Asia, Neil Donaldson, said “We are extremely delighted to once again sponsor the STP-I Conference. Instem recognizes the key role that Indian organizations play in the global pharmaceutical market and we are committed to supporting the future growth and development of the R&D community in this region”.  
Instem entered the early drug development market in India during 2005 when they welcomed their first Indian customer, Advinus Therapeutics. Since then, Instem’s market-leading preclinical software solution, Provantis, has grown to enjoy the largest user base in India.   
In 2012 Instem further demonstrated its commitment to the region through the establishment of an office in Pune. Since then, the Pune office footprint has doubled in size and resources have trebled. The office employs staff across Product Development, Testing and Customer Support, with an active recruitment program currently in place.   
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Instem at the ACT 2020 Virtual Meeting  
 November 12–19  
Exhibitor Hosted Presentation  
Ensuring Good In Silico Practice: Supporting Regulatory Submissions and the Implementation of Protocols  
Friday November 13th, 10:00 AM–10:55 AM   
Description  
 This presentation will review Leadscope’s leading in silico products and services while outlining how their latest updates efficiently support regulatory submissions including the ICH M7 guideline. We will also discuss an implementation of the recently published in silico toxicology protocols to ensure results are generated, communicated, and archived in a reproducible manner.   
Education needs/learning objectives  
 Attendees will learn how Leadscope’s in silico solutions are used to help organizations efficiently and accurately predict toxicity and support an expert review for submission to regulatory authorities. Attendees will also learn how published in silico toxicology protocols have been implemented within Leadscope to ensure good in silico practice.   
Presented by: Leadscope, Inc. - an Instem Company  
Virtual Booths at ACT 2020  
Instem  
Leading IT Solutions - Leading IT Results  
 Submit™: The most widely adopted SEND software & outsourced study services. Learn how you can, submit with confidence.   
 Provantis®: The #1 solution for preclinical study management, accessed online (SaaS) or on-premise. KnowledgeScan™ Target Safety Assessment (TSA) Service: Setting new standards in biological target profiling - a pioneering technology-enabled service delivering comprehensive, consistent, high quality TSAs more quickly and efficiently.  
Watch the video  
Leadscope - an Instem Company  
Visit our virtual booth to learn more about our market leading In Silico products and services that deliver fast, accurate, defendable toxicity predictions. Our advanced informatics and prediction technology, along with database solutions, are helping organizations worldwide to effectively unlock valuable knowledge contained in both public and proprietary sources of research data.   
Watch the video   
Poster Presentations  
Developing Mechanism-Based Models for Complex Toxicology Study Endpoints Using Standardized Electronic Submission Data  
Implementation and validation of a skin sensitization protocol for in silico hazard assessment  
 Monday 16th November from 5-6:30 pm  
  
In Silico Strategy for Predicting Globally Harmonized System (GHS) Categories  
 Monday 16th November from 5-6:30 pm  
  
  
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Instem Provides Free SEND Services to COVID-19 Related Research & Development  
20 April 2020  
The U.S. Food & Drug Administration almost always requires electronic submission of non-clinical data, in an electronic format called SEND, prior to a drug or vaccine being approved for testing in humans for the first time and again before the product is released for general use.  
Instem is widely acknowledged as having the world’s leading technology for creating SEND submissions. In addition, Instem has the preeminent team of over 50 SEND consultants and information scientists who undertake SEND dataset creation and submission on an outsourced services basis for many of the drugs and vaccines in the global R&D pipeline.  
The Instem team has been inspired by the selfless redirection of resources and capital by the life sciences industry (among many others) to fight the COVID-19 pandemic, as well as the front-line work of doctors, nurses and others caring for today’s COVID-19 patients. We are therefore delighted to be in a position as a business and as individuals to contribute free of charge some of the world’s leading SEND related talent and technology to help rapidly advance promising new vaccines and treatments through the regulatory R&D process.  
Instem is initially setting aside £100,000 of capacity to undertake free COVID-19 related SEND services. It would be fantastic to see much of this go towards supporting candidates being funded by the not-for-profit sector, such as the “COVID-19 Therapeutics Accelerator”, funded by the Bill & Melinda Gates Foundation. However, our goal is to deploy our SEND resources quickly and productively, so we will support work for ANY sponsoring organization, no matter their type or size.  
We recognize that our SEND team is already heavily committed to clients for other important drug development programs and so we will limit the rate at which we undertake this additional free COVID-19 related work. We will work closely with existing clients where things need to be rescheduled to create space for this additional work and our team has committed to work outside normal hours, if necessary, to keep COVID-19 drugs on schedule (as they have already).  
It is rare for us to be able to make such a unique and direct contribution to a global crisis, but it reminds us of the valuable work we do every day helping our clients bring their life changing products to market faster.  
To take advantage of our free COVID-19 related services, clients can reach out to their usual Instem contact or email Free-COVID-19-Services@instem.com. We are happy to work directly with sponsors or via contract research organizations who are passing on Instem’s SEND services work to their clients without charge. To give every organization equal opportunity, this only applies to new COVID-19 related requests.  
If there is more that you believe Instem can do to support your COVID-19 related R&D activities, please let us know.  
We remain committed to the safety and success of our staff and clients around the world.  
Read our March 24th Update  
  
  
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Lupin Purchases Instem Preclinical Software for Novel Drug Discovery & Development Program  
Provantis Preclinical Software Selected to Automate Study Processes at Lupin's Global R&D Hub in Pune, India  
CONSHOHOCKEN, PA - (BUSINESS WIRE) - May 1, 2012 - - Instem, a leading provider of IT solutions to the global early development healthcare market, announced today that Lupin Limited (Lupin) has purchased the Provantis® preclinical software solution. Provantis will be deployed at the Lupin Research Park, the company’s state-of-the art global R&D hub in Pune, India, housing over 1,000 scientists.  
Lupin is an innovation led transnational pharmaceutical company producing a wide range of quality, affordable generic and branded formulations and active pharmaceutical ingredients (APIs) for the developed and developing markets of the world. Lupin is the 5th largest and fastest growing generics player in the US (5.1% market share by prescriptions, IMS Health), the only Asian company to achieve that distinction. The company is also the fastest growing top 10 pharmaceutical player in India, Japan and South Africa (IMS).   
Key Facts  
  
Integrated Inlife Toxicology and Pathology modules purchased as well as a number of Clinical Pathology interfaces  
A range of Professional Services contracted including validation and training to ensure quicker, smoother implementation  
Instem’s Data Import module purchased for rapid entry of Clinical Pathology data  
Competitive evaluation undertaken; Provantis selected for product functionality and technology  
  
Dr. Rajender Kamboj, President, Novel Drug Discovery & Development, Lupin comments “We were looking for a world-class solution to support the automation of our laboratory processes, further improve productivity and ensure GLP compliance for Lupin’s core Novel Drug Discovery & Development research programs. Following a thorough competitive review, we are satisfied that Provantis is the right solution to help us meet these needs.”  
Demand for regulatory toxicology services has grown within India in recent years, fueled by the internal investments of Indian pharmaceutical and chemical companies, the recent addition of India within the OECD Mutual Acceptance of Data program and the demand from elsewhere in the world for high-quality, cost-effective non-clinical services.  
Instem’s VP of Asian and European Operations, Neil Donaldson adds “We are delighted to welcome Lupin to our growing roster of clients in the Asia Pacific region. Instem recognizes the important role that Indian organizations play in this increasingly competitive global market and given our presence in the region and our commitment to the Indian R&D community, we are ideally placed to support their future growth.”  
Instem entered the early drug development market in India in 2005 with its first customer, Advinus Therapeutics. Instem has maintained a physical resource location in India for several years and further cemented its commitment to the market in March with the establishment of Instem India, a wholly owned subsidiary of the company based in Pune.   
About Lupin Limited   
Headquartered in Mumbai, India, Lupin is an innovation led transnational pharmaceutical company producing a wide range of generic and branded formulations and APIs. The Company today has significant presence in the Cardiovascular, Diabetology, Asthma, Pediatrics, CNS, GI, Anti-Infectives and NSAID space in addition to holding global leadership positions in the Anti-TB and Cephalosporin segments.  
Lupin is the 5th largest and fastest growing generics player in the US (5.1% market share by prescriptions, IMS Health), the only Asian company to achieve that distinction. The company is also the fastest growing top 10 pharmaceutical player in India, Japan and South Africa (IMS).  
For the financial year ended March 2011, Lupin's Consolidated Revenues and Profit after Tax were Rs.57,068 Million (USD 1.28 Billion) and Rs. 8,626 Million (USD 193 Million) respectively.   
Please visit www.lupinworld.com for more information on Lupin Ltd.  
About Instem  
Instem is a leading supplier of IT applications to the early development healthcare market, delivering compelling solutions for data collection, management and analysis across the R&D continuum. Instem applications are in use by customers worldwide, meeting the rapidly expanding needs of life science and healthcare organizations for data-driven decision making leading to safer, more effective products.  
Instem’s portfolio of software solutions increases client productivity by automating study-related processes while offering the unique ability to generate new knowledge through the extraction and harmonization of actionable scientific information.  
Instem supports over 400 clients through full service offices in the United States, United Kingdom and China with additional locations in India and a full service distributor based in Japan.  
Meeting clients at the intersection of investment & return™.  
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Instem at Eurotox 2023  
Instem, Booth 49  
Discover our innovative Study Management, Regulatory & In Silico Solutions  
Provantis®  
 As the #1 preclinical software suite for organizations engaged in non-clinical evaluation studies, Provantis streamlines processes and workflows with straightforward, intuitive functionality for simple and complex studies within both GLP and non-GLP environments.  
Learn more about our new standalone modules within our Pathology suite, including modules for Tissues Processing, Image Management, and Spotlighter™ , our historical data solution that helps you find the hidden value in your reference data.  
  
SEND Solutions  
 The most comprehensive and widely deployed set of software (submit™) and services (SEND Advantage™) supporting the creation and management of SEND datasets. Stop by our booth to learn more about our two NEW software solutions, DefineNow™ for the creation and editing of define.xml files and GuidePro™, Instem’s Study Data Reviewer’s Guide generator.  
  
Genetic Toxicology   
 Image analysis and data management solutions helping users better collect, manage, review and extract data while transitioning information into insight, utilizing our Comet Assay IV and Cyto Study Manager tools. Also, don’t miss the opportunity to learn more about our new Transgenic Rodent Assay module!  
(NEW) Advance™ Weight of Evidence Assessments: Instem’s latest In Silico service which is re-imagining the way organizations perform carcinogenicity assessments via the 6 Weight of Evidence (WoE) factors under the ICH S1B guideline.  
KnowledgeScan™ Target Safety Assessment (TSA) Service: Delivering comprehensive TSAs for clients around the world, enabling them to make faster, better-informed decisions on their drug targets.  
Watch the KnowledgeScan Explainer video   
Leadscope Model Applier™: Advanced informatics and prediction technology, together with comprehensive database solutions that are helping organizations effectively unlock valuable knowledge contained in both public and proprietary sources of research data. Ask about our new module Leadscope N-nitrosamine CPCA.  
Predict™ In Silico Toxicology service: A leading edge, technology-enabled service that delivers a combination of powerful computation models with expert scientific review, to help clients predict chemical safety more quickly, efficiently and comprehensively.  
Centrus®: An innovative technology platform that delivers a combination of pioneering, well-integrated computing modules, along with a comprehensive catalogue of non-clinical and clinical data.  
If you would like to schedule a discussion with us during Eurotox contact us at info@instem.com indicating your area of interest.  
  
Instem Event Schedule  
Tuesday, September 12  
Exhibitor Hosted Event: From Safety Testing to Success: ICH S1B and the Power of Data Sharing  
Tuesday, September 12, 12:00 PM - 1:00 PM (CEST), Room Urška 2  
  
 This presentation will explain how data sharing and data-based dossiers are inspiring innovation and propelling progress. In line with the 3Rs principles and the universal emphasis on in silico approaches, here we will discuss two examples of how data is inspiring acceleration and driving transformative breakthroughs within pharma R&D.  
 Presented by: Frances Hall, PhD, Senior Director, In Silico Solutions, Instem and Brenda Finney, PhD, Vice President, In Silico & Translational Science, Instem  
  
We are also pleased to be involved in the following posters:  
Abstract Number/Poster Board number: P25-13 (#351)  
Abstract Title: Polo-like kinase 4 (PLK4) Safety Review – distilling the risks with a rapid augmented intelligence approach   
Presenting Author: Frances Hall, PhD and Brenda Finney, PhD  
Session Title: Risk Assessment & Communication  
Session Date and Time: Monday, September 11, 9:30am – 4:00pm (CEST)  
  
Abstract Number/Poster Board number: P24-27 (#503)  
Abstract Title: Appropriate Responses to the Standard for Exchange of Nonclinical Data (SEND) and the activities of the Global SEND Alliance (G-SEND)  
Presenting Author: Anzai Takayuki, PhD  
Session Title: Regulatory Toxicology   
Session Date and Time: Monday, September 11, 9:30am – 4:00pm (CEST)  
  
   
  
  
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FDA SEND 3.1 Mandate Goes Into Effect  
Scope of SEND Widens to Include Support for Cardiovascular and Respiratory Studies   
CONSHOHOCKEN, PA – March 15, 2019 - - Instem, a leading provider of IT solutions to the global life sciences market, announced today that the next major milestone in the FDA’s adoption of SEND (Standard for Exchange of Nonclinical Data) came into force today.   
Studies starting after today, March 15, 2019, which are in support of an NDA or BLA application to FDA, need to be submitted in SEND 3.1 format. The move from SEND 3.0 to SEND 3.1 sees the scope of SEND widen to now include support for Cardiovascular and Respiratory studies. SEND 3.1 also provides certain improvements to the standard, particularly around the nominal dates for report grouping and also providing additional variables for better describing Microscopic findings.  
“This next milestone shows FDA’s continued adoption of the developing SEND Standard and means that more study data can now be submitted to the agency. In anticipation of this, we have seen our clients implement the latest version of our submit™ suite which supports SEND 3.1,” stated Marc Ellison, Director, SEND Solutions at Instem.  
In-progress studies that started prior to March 15th may remain in SEND 3.0 format, however, failure to comply with the SEND 3.1 Mandate for studies starting after today’s date can result in the FDA’s technical rejection or refusal to file a submission.   
Instem has unparalleled experience in helping companies to prepare for SEND, and its software and outsourced services are the most widely adopted in the industry at over 80 client sites across 15 countries. Instem’s team of SEND experts has helped to organize, educate and guide clients to becoming SEND-enabled, identifying specific approaches that maximize the benefits of SEND, while ensuring regulatory compliance.  
Find out more about Instem’s submit™ solution suite software and outsourced services for the creation, management, visualization and analysis of SEND datasets.  
About Instem  
Instem is a global provider of leading software solutions and services that are helping over 500 clients bring their life enhancing products to market faster. We enable clients in the life sciences to more efficiently collect, analyze, report and submit high quality regulatory data, while maintaining compliance for their products around the world.   
Instem solutions are in use by customers worldwide, meeting the rapidly expanding needs of life science and healthcare organizations for data-driven decision making, leading to safer, more effective products.  
Instem supports its global roster of clients through offices in the United States, United Kingdom, France, Japan, China and India.   
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Center for Predictive Medicine and Emerging Infectious Diseases Expands Biosafety Lab, Purchases Provantis SaaS  
  
  
  
  
  
  
  
  
  
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Center for Predictive Medicine and Emerging Infectious Diseases Expands Biosafety Lab, Purchases Provantis SaaS  
NIH Grant Helps University of Louisville Expand Facilities and Research Program Capabilities  
CONSHOHOCKEN, PA - (BUSINESS WIRE) – October 22, 2014 - -Instem, a leading provider of IT solutions to the global early development healthcare market, announced today that The University of Louisville (UofL) Center for Predictive Medicine for Biodefense and Emerging Infectious Diseases (CPM) has purchased their Provantis® preclinical software solution as part of an expansion program.  
UofL funding for the expansion of its facilities and the purchase of Provantis were awarded through a National Institutes of Health (NIH) initiative to improve the nation’s top research facilities.   
Provantis will be used within the Regional Biocontainment Laboratory (RBL), a state-of-the-art facility providing scientific expertise and biosafety level three (BSL-3) laboratories for the discovery of therapeutics for serious pathogens, and an infrastructure to meet pandemic or bioterrorism emergency needs. The RBL, one of 11 in the country, serves as a valuable shared resource to others in academic, not-for-profit and private sectors for BSL-3 training, basic research and translational discovery efforts.  
Instem’s Provantis preclinical software will replace manual paper-based processes with an integrated and automated approach to long term efficacy/product evaluation studies. Researchers will more easily collect and share critical data with the NIH in their efforts to develop vaccines aimed at fighting bioterrorism and emerging infectious diseases.  
CPM at UofL will be using Instem’s SaaS (Software-as-a-Service) model to access Provantis offering simpler, more cost effective ways to provide software functionality, maintenance, and support over the Internet. Instem’s professionally managed cloud platforms are run from a centralized state-of-the-art data center, which is being used by clients running GLP and non-GLP studies around the world.  
Key Facts   
  
University of Louisville Center for Predictive Medicine and Infectious Diseases purchases Provantis General Toxicology and Pathology modules   
University of Louisville Center for Predictive Medicine and Infectious Diseases using Instem’s SaaS delivery model   
Provantis being deployed in biosafety level three laboratories at Regional Biocontainment Facility  
Provantis replacing paper-based processes, streamlining workflows within research center and with NIH  
  
About the CPM at UofL  
The mission of the CPM at the University of Louisville is to improve human health by conducting basic and translational research that leads to the development of effective diagnostic biomarkers, vaccines, antivirals and therapeutics for emerging, re-emerging, neglected or rare infectious diseases.  
About Instem   
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Instem’s portfolio of software solutions increases client productivity by automating study-related processes while offering the unique ability to generate new knowledge through the extraction and harmonization of actionable scientific information.  
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Instem Releases Version 9 of Provantis  
Next Major Version of Instem's World-leading Preclinical Software Solution Suite Offers Rich Features with Clear Benefits  
CONSHOHOCKEN, PA - Feb 7, 2013 - - Instem, a leading provider of IT solutions to the global early development healthcare market, is pleased to announce the release of version 9 of its world-leading, preclinical software suite, Provantis®.  
Version 9 was developed in close collaboration with Instem clients as part of its overarching Customer Involvement Program (CIP). This included a comprehensive Beta Test Program involving valued clients such as Bristol-Myers Squibb, GlaxoSmithKline, MPI Research, Roche, Sanofi and Sequani, as well as Webcasts, product demonstrations, Special Interest Group meetings and dedicated sessions at the Instem International Conferences.   
The eagerly anticipated release contains major enhancements to the Clinical Pathology module, delivering a more flexible, scalable, cost-effective and highly efficient sample-driven solution. Provantis 9 offers Clinical Pathology professionals a complete, end-to-end, integrated solution, which delivers additional efficiency gains at each step of the way; from the taking of the sample, through the Clinical Pathology laboratory, to the presentation of results.  
Provantis version 9 also contains:  
  
Enhancements to Instem’s unique Protocol & Report Assembly module, enabling the assembly of fully searchable PDF study reports with minimal QA review  
Significantly enhanced Clinical Observations reporting and analysis; unlimited modifiers facilitating more comprehensive reporting and analysis of Clinical Observations data  
New Fetal Pathology Tables; enables summary of data by classification  
Improved reporting flexibility through the introduction of new General Toxicology tables and enhancements to the Tables & Statistics module  
New post dose activity schedule reports; enables planning and scheduling of workflow against time-critical data collection points and provides the ability to check actual data collection points against scheduled workflow  
New Interface from Instem’s formulation system, Dispense, to the Quantos™ Dosing System   
  
In addition to new capabilities at the application level, Provantis version 9 also incorporates a major technology upgrade, ensuring that clients are able to take advantage of the latest investments in 64-bit technology and the Oracle and Microsoft platforms.   
Mike Harwood, Instem’s Senior Vice President comments “Client feedback throughout this development project has been extremely positive and has helped to ensure that version 9 is a robust, high quality, fit-for-purpose application for the Tox/Path market. The features included in version 9 are in high demand; numerous clients have committed to upgrading with several more poised to sign shortly.”  
Provantis 9 is a comprehensive release that will be supported by a global awareness program aimed at demonstrating the specific benefits it brings in terms of increased productivity, ease of use and efficiency gains in the short and longer terms. This will begin with a series of launch Webcasts taking place during the week of Monday, February 11th.  
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Instem Delivers Centrus Solution to Multi-National Pharmaceutical  
Newly Introduced Centrus Solution to Help Pharma Gain More Insight from Preclinical Data  
CONSHOHOCKEN, PA - (BUSINESS WIRE) – October 28, 2010 - - Instem, a leading provider of early drug development software solutions, announced today that one of the world’s five largest pharmaceutical organizations has purchased a module from its newly announced Centrus™ solution suite.   
The Centrus module will assist research and regulatory scientists at the company to realize more value from the vast amount of data that has been collected across multiple locations.  
Developed specifically to simplify the extraction and delivery of preclinical study data, this highly flexible Centrus module will populate the client’s integrated data warehouse, where it will then be combined with other scientific information enabling them to improve the safety profiles of drugs in early development.  
Instem’s Centrus solution suite provides a single, secure environment to access, harmonize and use early drug development information from a variety of sources, including current data acquisition systems, legacy systems, warehouses, and partner and contract research applications, to meet the rapidly-expanding needs of life science organizations for data-driven decision making.  
Based on innovative Instem technology already licensed to clients to support electronic FDA submissions, the core of the Centrus suite is its open, service-oriented architecture with vendor-neutral communications and a data transformation strategy providing connectivity both inside and outside of an enterprise.   
More information about this project and the entire Centrus solution suite is available upon request.   
About Instem  
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BoZo Research Center Selects Instem as SEND Outsourcing Partner for Japanese Market  
BoZo Research Responds to Strong Market Demand and Becomes SEND-Enabled  
CONSHOHOCKEN, PA - (BUSINESS WIRE) – June 2, 2016 - -Instem, a leading provider of IT solutions to the global early development healthcare market, announced today that BoZo Research Center (BoZo) has chosen them as their exclusive SEND outsourcing partner in Japan.   
BoZo has been serving the preclinical research community for over 40 years and is one of the leading contract research organizations in Japan with nearly 500 employees located across four sites.   
Helping them meet increased market demand, Instem will be complementing the existing team at BoZo, providing SEND data conversion and consulting services for organizations throughout Japan. Instem will begin providing services this year and BoZo expects up to 100 preclinical studies will need to be converted into SEND during 2017.  
“The market in Japan requires high quality results that are reliable and can be produced cost effectively,” states Koji Takashima, Vice President, Sales and Market Development at BoZo. “Through Instem, we now have access to the world’s foremost experts in SEND and our entire client community will be able to Submit with Confidence™.”  
Instem’s submit™-SEND tools and services are the most widely adopted in the industry, supporting over 34 client sites across 13 countries. The Instem team has led and participated in the creation of the SEND standard for more than 10 years and brings over 30 years of experience in developing, delivering and supporting world-class nonclinical systems and solutions for the scientific community.  
“BoZo has a long track record of providing excellent customer support and their development of this strategic relationship has shown us how committed they are to SEND and their mission of creating a safer society,” comments Terukazu Kitahara, Japan Regional Manager at Instem. “Through our agreement, BoZo will be able to meet immediate demand for SEND study data conversions while ensuring it is well positioned to handle what will be a large influx of orders in 2017 as the SEND mandate continues to permeate the global market.”  
The Food & Drug Administration reports that 11% of new drug approvals in 2015 were from Japanese organizations and that rate is expected to continue and possibly rise in the future. Instem has been serving the Japanese marketplace since 2005 and during 2015 has opened a new office in Tokyo, has hired additional local staff and increased its technology offerings to help meet market demand. Instem has already signed two other SEND contracts during 2016 in Japan and along with this agreement from BoZo is well poised to further increase its global leadership position.  
SEND Showcase at the 43rd Annual Meeting of the Japanese Society of Toxicology (JSOT)  
BoZo, along with representatives from Instem, will be holding an open luncheon during this year’s JSOT exhibition that is being held in Nagoya, Japan from June 29 through July 1st. Anyone interested in learning more are encouraged to contact BoZo for more details at info@bozo.co.jp.   
About BoZo Research Center   
BoZo Research offers a wide range of services from the initial stages of drug development to safety studies through its Japanese-based facilities as well as through their Montreal-based subsidiary, ITR Canada. In addition to the pharmaceutical market, BoZo supports government research programs and agencies as well as public and private universities.  
Learn more about their mission and purpose at www.bozo.co.jp   
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Instem Appoints Jerry Hacker as SVP Global Sales  
Hacker Selected to Help Further Accelerate Instem's Growth  
CONSHOHOCKEN, PA - August 17, 2016 - -Instem, a leading provider of IT solutions to the global early development healthcare market, announced today that Jerry Hacker has joined its leadership team as Senior Vice President, Global Sales.  
Hacker has held a number of roles within health & life sciences where he has successfully built and led both high performing software and consulting services sales teams and partner programs. His body of work includes significant accomplishments in revenue growth, sales productivity and operations.   
“Jerry’s strong leadership skills centered on principles of attitude, work ethic and a commitment toward continuous improvement will be vital during this time of transformational growth,” comments Phil Reason, CEO at Instem. “Demand for Instem solutions has never been stronger, and Jerry’s experience in developing and implementing formal, consultative sales processes coupled with his strong drive for results will have an immediate positive impact for us and our clients.”  
Prior to joining Instem, Hacker was SVP Worldwide Sales at LabVantage Solutions, where he helped drive record revenue growth for their Laboratory Information Management Systems while greatly increasing productivity of his sales teams.   
 “I was impressed by Instem’s passion for helping its clients bring products to market more efficiently and believe they are poised for another stage of exciting growth,” states Hacker. “Instem already has a strong international sales team and I believe my experience of implementing strategies for both products and technology-driven outsourced services will assist them in getting to the next level of operational excellence.”   
In this role, Hacker will be using his decades of solution-oriented sales leadership to help further increase Instem’s market share around the world while also helping open up new segments with Instem’s expanded set of capabilities.  
The announcement of Hacker’s appointment comes at a time when Instem has been actively fulfilling its mission to consolidate and harmonize what they see as a fragmented IT marketplace. Instem believes it is one of very few organizations that have clearly developed the financial strength necessary to maintain global leadership with established products, while introducing new regulatory compliant solutions and outsourced services options that are delivering the step change in productivity that clients are aggressively pursuing.   
Instem has been increasing its presence and expanding its capabilities through the opening of new offices, new solution development activities and through key strategic acquisitions.   
Instem is enabling its clients to more easily access data and help convert it to actionable knowledge and has become uniquely positioned across key application areas of the R&D landscape, acting as a strategic partner for its clients throughout the Pharmaceutical, Government Research, Medical Device, Chemical and Agrochemical industries.  
About Instem   
Instem is a leading supplier of IT applications and services to the early development healthcare market delivering compelling solutions for data collection, analysis and regulatory submissions management. Instem solutions are in use by customers worldwide, meeting the rapidly expanding needs of life science and healthcare organizations for data-driven decision making leading to safer, more effective products.  
Instem’s portfolio of software solutions and consulting services increases client productivity by enhancing product development processes while offering the unique ability to generate new knowledge through the extraction and harmonization of actionable scientific information.  
Instem supports over 500 clients through offices in the United States, United Kingdom, Japan, China and India.  
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Instem Announces Expanded Global ACIS (Animal Care Information System) Capabilities  
Instem Launches Comprehensive Outreach Program for Animal Management Solution  
CONSHOHOCKEN, PA – (Business Wire) - June 5 2014 - - Instem, a leading provider of IT solutions to the global early development healthcare market, is pleased to announce an extensive outreach program to showcase the enhanced capabilities of its ACIS (Animal Care Information System) software solution.  
ACIS is the complete animal management solution; efficiently managing the requisition, procurement and reporting of animal usage within research establishments. ACIS is fully scalable, supporting small single site animal facilities through to global organizations with multiple sites across several regions.  
ACIS has been successfully supporting organizations within Europe, providing Instem’s clients with a flexible, user-friendly software solution that streamlines animal management processes and supports the changes introduced by European Directive 2010/63/EU. Most recently ACIS has been selected by one of the world’s Top 10 Pharma companies for a multi-site SaaS deployment.  
  
 Building on this success, Instem has made significant investments in the ACIS solution, including the addition of new Protocol Review/Approval functionality to manage IACUC workflows for the North American market.  
Instem is now embarking on a comprehensive outreach program to demonstrate the benefits that ACIS delivers including enabling the efficient requisition and procurement of animals, optimizing laboratory capacity and streamlining regulatory compliance and year-end reporting.   
Outreach activities begin this month with 2 identical live Express Webcasts taking place on June 11th & June 12th. Instem will also be showcasing ACIS at the 65th AALAS National Meeting in San Antonio, Texas, October 19-23.  
Gregor Grant Senior Vice President, Instem said. “Our clients confirm that ACIS delivers clear benefits in terms of streamlining processes, boosting efficiencies and providing robust regulatory reporting. We are excited to extend these and other benefits to a wider range of organizations.”  
About Instem  
Instem is a leading supplier of IT applications to the early development healthcare market, delivering compelling solutions for data collection, management and analysis across the R&D continuum. Instem applications are in use by customers worldwide, meeting the rapidly expanding needs of life science and healthcare organizations for data-driven decision making leading to safer, more effective products.  
Instem’s portfolio of software solutions increases client productivity by automating study-related processes while offering the unique ability to generate new knowledge through the extraction and harmonization of actionable scientific information.  
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Leading Biotechnology Company Selects Instem's submit™ Software Suite  
Company to Deploy submit™ for Complete SEND Management  
CONSHOHOCKEN, PA – December 11, 2015 -Instem, a leading provider of IT solutions to the global early development healthcare market, announced today that a major biotechnology company based in California has purchased its submit™ solution suite to automate the creation and management of nonclinical data in accordance with CDISC’s Standard for Exchange of Nonclinical Data (SEND).   
In alignment with the FDA’s final Guidance for Standardized Study Data for providing regulatory submissions in electronic format (December 2014), Instem offers the submit™ solution suite of tools and services to address the complexities of creating, managing and storing SEND data. The biotechnology company’s team will deploy submit™ to efficiently prepare nonclinical data according to the required formats, standards and terminologies.   
Key Facts  
  
The client will use submit™ to compile data from any source and efficiently convert it to SEND compliant datasets  
The company will also use Instem’s SENDView™ product to uniquely simplify the QC review and exploration of SEND datasets   
Submit™ to fully automate workflows for securing and processing datasets   
Submit™ suite includes a fully version-controlled file store of all data files and SEND datasets  
  
Compliance with the SEND initiative is a market imperative for the entire drug development community. Companies around the world continue to choose the submit™ solution suite due to its proven results, combined with Instem’s unparalleled practical experience and SEND leadership. Instem experts help R&D teams across the industry to implement its submit™ solution to optimize SEND processes and help ensure complete and accurate submissions to the FDA.   
Gary Mitchell, Vice President of Marketing at Instem said “We are elated to add a top biotechnology company to our rapidly growing submit™ client list. We look forward to partnering with their team to add value as they create, manage and submit SEND data more efficiently.”  
Instem’s submit™-SEND tools and services are the most widely adopted in the industry, operating at over 34 sites across 12 countries. The Instem team has led and participated in the creation of the SEND standard for over 10 years and brings over 30 years of experience in developing, delivering and supporting world-class nonclinical systems and solutions for the scientific community.   
About Instem  
Instem is a leading supplier of IT applications to the early development healthcare market delivering compelling solutions for data collection, management and analysis across the R&D continuum. Instem applications are in use by customers worldwide, meeting the rapidly expanding needs of life science and healthcare organizations for data-driven decision making, leading to safer, more effective products.  
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Instem Now Part of ARCHIMED to Further Accelerate Growth and Impact  
Healthcare investment specialist ARCHIMED has the expertise, experience, enthusiasm and financial strength to fully back Instem’s ambitions.  
PHILADELPHIA, PA – (BUSINESS WIRE) – November 27, 2023 - Instem, a leading provider of IT solutions and services to the global life sciences market, announced today that it has been acquired by ARCHIMED as an integral part of the company’s mission to enable clients to bring their life enhancing products to market faster.   
ARCHIMED is a global investment firm exclusively supporting the critical health and life science industries, focused on helping its portfolio-companies accelerate innovation and growth. ARCHIMED believes human, animal and environmental health is a common value among all people and a key condition for long-term development.  
“I’m truly excited about this next chapter in our transformational growth story and one that keeps our clients at the center,” comments Phil Reason, CEO at Instem. “Instem has never been healthier, and the future has never been brighter for our client community and staff. By strategically partnering with ARCHIMED, it will empower us to accelerate our growth initiatives, expand our market presence, and pursue new opportunities that will drive our company to new heights.   
Reason continues, “Our Vision is a future transformed for the benefit of everyone, with intelligent solutions empowering collaboration and life-enhancing science. This Vision requires us to be bold and creative. Supported by great people and a set of core values that completely align with our own, ARCHIMED shares in our Vision and they have the capital, expertise, enthusiasm and a proven track record to help us reach our next level of success.”  
“Instem is the de-facto market leader in the preclinical software and technology services space,” says ARCHIMED managing partner, Vincent Guillaumot. “We intend to expand and improve on that position through long-term investment and through acquisitions to consolidate what remains a fragmented industry.”   
Instem - Doing More. Going Further™.  
Through its acquisitive and organic growth initiatives, Instem has been consolidating key application areas that have helped clients streamline and accelerate their research and development processes, while enabling clients to access data from across the R&D continuum. Now, as part of ARCHIMED, Instem sees exceptional opportunity to increase the power of current and future in silico modelling and prediction projects, leveraging its new technology and data sharing platform Centrus®, which uniquely provides a range of translational science solutions. Instem will also be accelerating its plans to further enhance and expand the capabilities of its market leading study workflow and analytics solutions.   
To learn more about how Instem can help create a more connected ecosystem that materially reduces the time it takes to bring life enhancing products to market, please email us at info@instem.com.  
About Instem  
A global provider of leading software solutions, technology enabled outsourced services and powerful scientific insights, Instem is helping clients to bring their life enhancing products to market faster.   
We enable organizations in the life sciences to more efficiently collect, report and submit high quality regulatory data, while offering them the unique ability to generate new knowledge through the extraction and harmonization of actionable scientific information.  
Every day, across the entire drug development value chain, Instem solutions are meeting the rapidly expanding needs of life science organizations for data-driven decision making, leading to safer, more effective products.  
Instem supports its global roster of clients through offices in the United States, United Kingdom, France, Switzerland, Japan, China, and India.  
About ARCHIMED  
With offices in Europe, North America and Asia, ARCHIMED is a leading investment firm focused exclusively on healthcare industries. Its mix of operational, medical, scientific, and financial expertise enables ARCHIMED to serve as both a strategic and financial partner to healthcare businesses. Prioritized areas of focus include Biopharma Products, Consumer Health, Healthcare IT, In Vitro Diagnostics, Life Science Tools & Biologic Services, MedTech, and Pharma Services. ARCHIMED helps partners internationalize, acquire, innovate and expand their products and services. ARCHIMED manages €7 billion across its various funds. Since inception, ARCHIMED has been a committed Impact investor, both directly and through its EURÊKA Foundation.  
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Government Research Agency Selects Instem Preclinical Software Solution  
Provantis Preclinical Software Chosen to Advance Key NIAID Research Programs  
CONSHOHOCKEN, PA - (BUSINESS WIRE) - November 8, 2012 - - Instem, a leading provider of IT solutions to the global early development healthcare market, announced today that the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), has selected Instem’s integrated Provantis® preclinical software suite to help advance research programs against infectious, immunologic, and allergic diseases.  
Provantis is being deployed within U.S.-based laboratories where NIAID conducts basic and applied research activities aimed at improving public health in the United States and around the world.  
Key Facts   
  
NIAID purchased the integrated Inlife Toxicology and Pathology modules, including Instem’s powerful Report Assembly product  
NIAID will utilize the Instem Specialized Solutions program for rapid deployment using a more tailored approach to implementation, training, validation and support  
  
“We are honored to be a part of NIAID’s rich tradition of supporting innovative scientific approaches using cutting edge techniques and technologies,” comments Gary Mitchell, VP Global Marketing at Instem. “Every morning throughout the United States NIH institutes and their contractor laboratories log-into Instem supplied software systems to advance their missions. Adding NIAID to that roster not only increases our footprint within the government research community, but it instills even a greater passion for our own global mission to improve and advance life.”   
About Instem  
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Promising New Tools and Techniques in Search for Alzheimer's Disease Biomarkers  
Researchers at King's College London Undertake Text Mining Exercise with Instem; Research Published in Journal of Translational Medicine  
CONSHOHOCKEN, PA - November 5, 2012 - - Instem, a leading provider of IT solutions to the global early development healthcare market, announced today that research, led by King’s College London’s Institute of Psychiatry and published in the Journal of Translational Medicine, is the first to use a new technology on a large scale to look for potential biomarkers for disease.   
The new research proves that ’text mining’, or using the power of computers to ‘read’ the entire biomedical knowledge base, is a promising new tool in the search for Alzheimer’s disease biomarkers.   
Alzheimer’s is the most common form of dementia, and currently affects approximately 500,000 people in the UK. During the course of Alzheimer’s disease, ‘tangles’ or ‘plaques’ develop in the brain leading to the death of brain cells. However, how and why these develop is still poorly understood and is likely to be due to a combination of factors, including age, genetics and environment. Identifying reliable biomarkers for the disease is important for developing early diagnostic tests, and finding new therapies.  
Professor Simon Lovestone, lead author of the paper and Professor of Old Age Psychiatry at King’s College London says: “To our knowledge, this is the first time text mining has been used on this scale in the hunt for biomarkers. Essentially, we used the power of computers to ‘read’ everything that has ever been written in all biomedical science. We prove that text mining works, and we will take this forward in our hunt for Alzheimer’s biomarkers. Our results also demonstrate the value of large data in biomedical science; you could go beyond Alzheimer’s disease and use the same approach for other conditions where biomarkers are needed, from cancer to diabetes.”  
Researchers at King’s worked with international colleagues and Instem (originally BioWisdom) to develop a series of ‘axioms’, or statements, about what a blood biomarker might look like. They then turned this into computer code and by using textual and linguistic analysis, searched for relevant information in all publicly available databases, combining neuro-imaging, genetic and proteomic data.   
This derived a total of 25 potential biomarkers. The team then validated these - some had previously been identified as potential biomarkers, and in two other cases, they examined the proteins against large sample sets, and showed that the computer approach was correct.  
Professor Lovestone adds: “So far, our search for Alzheimer’s disease biomarkers has focused either on an 'omics approach looking at as many proteins or genes as possible, or using a candidate approach looking for the obvious things. However, despite substantial international effort, neither has proved satisfactory. This technology offers an exciting and powerful new tool to advance our research in this field.”   
Dr Jane Reed, Director of Life Sciences at Instem Scientific and co-author of the paper, says: “This research is a great example of academic-industry collaboration and shows the power of a translational approach (via data harmonization and integration) to re-use current and legacy data. There is a demand for better methods to predict biomarkers, and this paper validates our in- silico approach to biomarker discovery in human disease.”  
About Instem  
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Instem Announces Acquisition of The Edge; Extends Reach within Discovery R&D  
Instem’s Acquisition of Discovery Technology Solutions Provider, The Edge, Represents Another Advancement of its Mission in the Life Sciences  
PHILADELPHIA, PA – (BUSINESS WIRE) – March 1, 2021 - Instem, a leading provider of IT solutions and services to the global life sciences market, announced today that it has acquired The Edge Software Consultancy Ltd. (“The Edge”) as part of its mission to enable clients to bring their life enhancing products to market faster. The further consolidation of key application areas will help customers streamline and accelerate their research and development processes, while access to a broader range of data from across the R&D continuum will increase the power of future in silico modelling and prediction solutions.   
The Edge offers technology and services to improve the efficiency of drug discovery research and development, improving client productivity while ensuring that critical high-quality data from studies and experiments are efficiently captured, stored and shared, maximizing their value to organizations around the world.  
Formed in 2005 and headquartered in Guildford, United Kingdom, The Edge’s flagship BioRails® platform enables automated high-quality data capture over the entire drug discovery and development process. The Edge are Pharmaceutical domain experts, especially in the areas of drug metabolism and pharmacokinetics, in vitro & in vivo Pharmacology and Formulations, and their platform incorporates a broad range of software modules which can be deployed individually or as a suite, either in isolation or across an enterprise.  
Designed by scientists for scientists, The Edge technology solutions offer a perfect blend of Laboratory Information Management Systems, Electronic Lab Notebooks and data analytics in one seamless workflow. The Edge are well known for offering the perfect blend of IT and science to keep their clients productive as they look to identify and advance drug candidates in the journey towards clinical trials.   
Since their founding, The Edge have captured the attention of many of the world’s most influential pharmaceutical, biotechnology, biopharmaceutical and contract research organizations.They have cemented strong collaborative relationships with their clients by helping them to eliminate bottlenecks, increase innovation and more cost effectively reduce their times to market.  
“The go-to partner for many of our Instem clients looking to revolutionize their R&D processes, we couldn’t be happier to welcome The Edge into the Instem family,” comments Gregor Grant, Executive Vice President of Instem’s Study Management Solutions group. “We have been very interested in strengthening our position within Discovery to help us meet growing interest for the wider sharing of data. Clients of The Edge that are using our Provantis® software suite for preclinical safety assessment study management, for example, will certainly benefit by being better aligned and ultimately interconnected. The Edge are very well versed in helping clients bring together data from disparate sources, which is a complete fit into our overall mission in the life sciences.”  
Grant continued, “The Edge have established an excellent delivery reputation and their products are pivotal systems trusted by biologists and chemists alike to help them collaborate using insights from safe, centrally stored data. They excel in translating their scientific credentials into tangible technology-driven benefits, and along with their excellent support model, are fully aligned with our commitment to deliver an exceptional client experience.”  
Instem sees the acquisition of The Edge as an integral part of its transformational growth strategy, enabling it to further deliver solutions that meet the rapidly expanding needs of life science organizations for faster data-driven decision making, leading to safer, more effective products.  
“Combining our story with a well-established and proven life science leader like Instem further validates our entire approach in the market and offers new and exciting opportunities for our clients and staff,” states Andrew Lemon, Managing Director at The Edge. “Our missions are nearly identical, and our customers are the real winners here. Harnessing the global resources, processes and reach of Instem will give us exactly what we need to take the next step in our journey to bring our innovative solutions to more scientists around the world.”   
More about The Edge Solutions, now part of Instem  
The Edge helps create new and efficient processes for capturing and analyzing data in the laboratory that can easily be distributed across scientific teams. Through highly-refined, automated data capture software, clients are able to reduce cycle times by establishing reliable scientific workflows which enables them to execute tests more quickly and efficiently.   
BioRails®   
 BioRails is a multi-tiered platform for workflow-driven data management, which can be deployed on-premise or via SaaS, offering the following modules:   
  
BioHub™ – A single consolidated store for corporate knowledge that acts as a central location for all of a client’s research data   
BioRails DM™ – A comprehensive approach to study definition, data collection, analysis and data management   
BioRails PTO™ – Study project planning, tracking, ordering and optimization  
BioRails INV™ – Study inventory management, ordering and tracking  
BioRails MT™ – Materials registration for biospecimens, biologics and formulations   
  
Morphit™   
 Morphit provides powerful features for reading, managing and visualizing data. Clients are able to uniquely and seamlessly analyze biological data from instruments and transform raw data into validated results. The capabilities of Morphit empower clients to gather extensive knowledge about experiments, which in turn refines subsequent tests for greater success.   
About Instem   
A global provider of leading software solutions and scientific insight services, Instem is helping clients bring their life enhancing products to market faster.   
From Concepts to Cures, we enable organizations in the life sciences to more efficiently collect, report and submit high quality regulatory data, while offering them the unique ability to generate new knowledge through the extraction and harmonization of actionable scientific information.  
Every day, across the entire drug development value chain, Instem solutions are meeting the rapidly expanding needs of life science organizations for data-driven decision making, leading to safer, more effective products.  
Instem supports its global roster of clients through offices in the United States, United Kingdom, France, Japan, China, and India.  
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Instem Leading Sessions at the Society of Quality Assurance Symposium   
Instem to Address Regulatory Compliance in Cloud Computing   
CONSHOHOCKEN, PA – September 29, 2015 - - Instem, a leading provider of IT solutions to the global early development healthcare market, is pleased to announce that Vince D’Angelo, VP Global Quality Assurance at Instem will be leading multiple sessions at the Society of Quality Assurance (SQA) Special Symposium, October 1st and 2nd at the Cleveland Marriott Downtown at Key Center.   
“I’m delighted to be involved in this exciting and very relevant Cloud Computing Symposium,” commented Vince D’Angelo. “Cloud Computing is here and without specific regulatory guidance it is up to industry leaders to recommend best practices in order to pass agency inspections. The symposium will tackle this challenge with a consistent and agreed upon approach along with the necessary tools to ensure regulatory compliance.”  
 The SQA Symposium will take place at the end of the Fall Quality College, now in session, with eight sessions that will educate, inform and initiate debate.   
About The Society of Quality Assurance  
 SQA is a professional quality assurance organization whose mission is to promote and advance the principles and knowledge of quality assurance essentials to human, animal and environmental health.  
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Instem International Conference Deemed Resounding Success by Delegates  
Instem Reports Successful User Conference, Including Live Streaming to Global Customer Base  
CONSHOHOCKEN, PA - November 9, 2015 - -Instem, a leading provider of IT solutions to the global early development healthcare market, announced today that the 2015 Instem International Conference (IIC) has been deemed another successful event by clients.  
The IIC is a key component of Instem’s Customer Involvement Program (CIP), providing opportunities for Instem clients across the globe to hear the latest news on product strategy, gain in-depth knowledge of Instem’s products and services, help shape and influence product development and become more engaged with key industry initiatives such as SEND. The IIC also provides excellent networking opportunities, enabling delegates to connect with their industry peers and key members of the Instem team, sharing best practice and learning opportunities.   
The conference was held at the Hilton Penn’s Landing Hotel, Philadelphia on October 6th & 7th and provided 2 full days of platform presentations, interactive breakout sessions, 1:1 Advice Clinics and Group Workshops with Instem Specialists, as well as a lively networking and social program. New for 2015, for clients unable to travel to Philadelphia, Instem offered Virtual IIC passes, giving clients the opportunity to join sessions via live streaming right from their desktop.   
The agenda featured presentations from the Instem team alongside excellent guest speakers from organizations such as Bristol-Myers Squibb, Charles River Laboratories, WIL Research, Datapipe and Integrated Clinical Systems – the creators of JReview®.   
The conference covered a range of topics including Transformational IT projects, Preparing For & Implementing SEND, Software System Validation, Leveraging Online Platforms and Future Technologies. The Philadelphia conference followed on from two highly successful user meetings held in China and Japan earlier in the year.   
Julie Jones, Marketing Manager, Instem said “The conference was extremely interactive, with existing relationships renewed and strengthened as well as connecting with many clients who were attending the IIC for the first time. Feedback has been very positive, with delegates indicating that they had gained tangible value, knowledge and insight from the event. It is very pleasing to see that 100% of delegates who completed our post event survey said that they would recommend the IIC to their colleagues."   
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Study Management Solutions  
Instem preclinical solutions keep our clients focused on their science, not their software. Provantis®, the #1 online solution for managing preclinical studies. Come see our new “Insights” feature in our Pathology module. Learn about Submit™, the most widely adopted modular software suite for creating, reviewing, visualizing and managing SEND data. Our Genetic Tox Solutions are in a class of their own, featuring Comet Assay IV and Cyto Study Manager. Leading IT Solutions - Leading IT Results.  
Watch the 2 minute Preview Video  
SEND Solutions  
Instem - the SEND experts. From study conversions to data verifications or consulting, we are the leading SEND authority. Our comprehensive services deliver exactly what our clients need, when they need it. Our intuitive submit™ software enables our DIY clients to create, QC review and visualize SEND datasets.  
Our unmatched credentials enable organizations around the world to, submit™ with confidence.  
Let us help SEND work for you.  
Expertise. Speed. Quality.  
Watch the 2 minute Preview Video  
  
In Silico Tox Solutions  
Instem’s In Silico Solutions suite of software and outsourced services enable researchers to generate new scientific insights through the identification, extraction and analysis of data to create actionable information.  
KnowledgeScan™ Target Safety Assessment (TSA) Service: Delivering comprehensive TSAs for clients around the world, enabling them to make faster, better informed decisions on their drug targets.  
Watch the KnowledgeScan Explainer video  
Model Applier from Leadscope - an Instem Company: Advanced informatics and prediction technology, together with comprehensive database solutions that are helping organizations effectively unlock valuable knowledge contained in both public and proprietary sources of research data  
Predict™ In Silico Toxicology service: A leading edge, technology-enabled service that delivers a combination of powerful computation models with expert scientific review, to help clients predict chemical safety more quickly, efficiently and comprehensively.  
If you would like to schedule a discussion with us during SOT contact us at info@instem.com indicating your area of interest.   
  
Instem Presentations   
Please join us for an Exhibitor Hosted Presentation, no advance registration is required:  
Leadscope - An Instem Company  
Hot Topics in Computational Toxicology: New Developments that Support Regulatory Submissions  
Monday, March 15  
 3:00pm - 4:00pm EST  
   
This session considers how the latest developments in computational toxicology address critical regulatory and industrial use cases. We will discuss how N-Nitrosamine structure-activity relationships support carcinogenic potency categories, as well as how (Q)SAR models can be used for classification and labeling, the assessment of drug-drug interactions and skin sensitization.  
   
Now Available On Demand  
  
Today's SEND Challenges: How to Overcome Them and Realize Tomorrow's R&D Opportunities  
  
Tuesday, March 16  
 9:00am - 10:00am EST  
By working with customers from discovery through to regulatory approval we are uniquely positioned to see the reality and potential for SEND. We will review the common challenges of SEND, give practical advice on overcoming them, and then discuss the opportunities arising from the standardization of nonclinical data.  
Now Available On Demand  
  
Revolutionizing Target Safety Assessment: Technology Advancements and COVID-19 Target Case Study   
Wednesday, March 17  
 9:00am - 10:00am EST  
   
In a pandemic-dominated year, coronavirus-related scientific publications escalated. Instem engaged big-data analytics to stay ahead of the data surge. Biological target safety remains immensely important to the pharmaceutical industry. Here, we demonstrate our R&D advancements, including innovative infographics and dynamic data visualizations, using the ACE2 receptor as an example target.  
Now Available On Demand  
  
Scientific Paper of the Year Award  
  
We are delighted to announce that a scientific paper co-authored by Dr. Glenn Myatt, Instem’s Vice President of Informatics, has been awarded the Society of Toxicology (SOT) Computational Toxicology Speciality Section (CTSS) scientific paper of the year.  
The open access paper, published in Regulatory Toxicology and Pharmacology, is titled “A cross-industry collaboration to assess if acute oral toxicity (Q)SAR models are fit-for-purpose for GHS classification and labelling”.   
Dr. Myatt, along with a team of industry collaborators, assesses whether currently available acute oral toxicity (AOT) in silico models, provided by the widely employed Leadscope software, are fit-for-purpose for categorization and labelling of chemicals.   
DOWNLOAD THE PAPER  
Dr. Myatt has been invited to accept the award on behalf of his co-contributors on Tuesday March 16th at the SOT-CTSS Virtual reception at the SOT’s upcoming Virtual 2021 Annual Meeting and ToxExpo.  
The authors have generously donated the award money to support ongoing CTSS activities.  
  
We are also pleased to be involved in the following poster:   
Abstract Title: Predicting Acute Toxicity Using Computational Models  
Presenting Author: Glenn Myatt  
Session Title: Computational Toxicology II  
Session Time: Tuesday, March 23 - 1:00pm to 2:45pm EST  
   
  
  
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Instem’s Genetox Software Solution Complements Litron’s State-of-the-Art Genetic Toxicology Testing Methods  
  
  
  
  
  
  
  
  
  
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Instem’s Genetox Software Solution Complements Litron’s State-of-the-Art Genetic Toxicology Testing Methods  
Instem Reports that Leading R&D Organizations are Deploying Cyto Study Manager & Cutting-Edge Flow-Cytometric Regulatory Genetox Testing Techniques  
CONSHOHOCKEN, PA - (BUSINESS WIRE) - February 05, 2019 - - Instem, a leading provider of IT solutions to the global life sciences market, is pleased to announce that leading research organizations are deploying the Cyto Study Manager software solution to support pioneering regulatory genetox testing techniques.  
Clients across Europe and North America are using 'MicroFlow®' micronucleus kits from Litron Laboratories, in conjunction with the Micronucleus Module of Cyto Study Manager. By combining the MicroFlow method with Cyto Study Manager’s experiment set-up and automatic reporting, those clients are benefiting from considerable time savings, while ensuring accurate and reproducible results.  
Key Facts   
  
MicroFlow micronucleus kits utilize flow cytometry to offer quick and reproduceable, high-quality data generated by an internationally validated method  
Cyto Study Manager integrates genetox data acquisition, auditing, reporting and study management into a single GLP compliant system to deliver a range of measurable benefits  
Organizations around the world are now able to make use of the extensive reporting capabilities within Cyto Study Manager and more efficiently submit their data to regulatory agencies  
  
“Bringing flow-cytometric methodologies into regulatory genetox testing is something we’re seeing increase in popularity,” comments Dr. Stephen Dertinger, Director Research at Litron Laboratories. “The ability to collect many thousands of data points in just a few minutes has significant time savings compared to traditional, microscopic analysis. Study management of all these data is critical.”   
Gregor Grant, Executive Vice President Preclinical Solutions, Instem, said: “We are delighted to see an increasing number of clients recognizing the potential of Cyto Study Manager to deliver dramatic efficiency gains in their genetic toxicology operations. Cyto Study Manager is an extremely flexible solution that can be easily customized to meet our clients’ individual genetox workflows.”   
About Cyto Study Manager  
Cyto Study Manager, originally developed by Perceptive Instruments and now part of the Instem solution portfolio, integrates genetox data acquisition, auditing, reporting and study management into a single system. This GLP compliant solution is revolutionizing genetox study workflows, and leading R&D organizations across the globe are deploying Cyto Study Manager to help them streamline genetic toxicology operations, reduce costs, increase efficiencies and improve regulatory compliance.  
Learn more at instem.com or download a Case Study – Leading EU Pharma Company Revolutionizes Genetox Study Workflow with Cyto Study Manager  
About MicroFlow®   
Litron’s In Vivo MicroFlow kits use flow cytometry to measure a type of chromosome damage known as a micronucleus event. Micronuclei occur in immature red blood cells when chromosomal loss or breakage leads to displaced chromatin, thereby creating a second nucleus (micronucleus). OECD Test Guideline 474 requires that a variety of new compounds be evaluated for their ability to induce micronuclei events in order to keep dangerous products off the market. Importantly, each kit also contains a calibration standard to ensure reproducible results, day-to-day and lab-to-lab. With these benefits, scientists are able to complete more studies in less time.  
Data generated by MicroFlow meet global regulatory requirements and are accepted by both domestic and international regulatory agencies.   
About Litron Laboratories  
Litron has a vision to transform the genetic toxicology industry with a variety of research kits and services based on high-speed flow cytometry. Litron scientists have developed flow cytometric research kits for in vivo and in vitro micronucleus (MicroFlow), in vivo and in vitro gene mutation (MutaFlow Pig-a) and most recently a suite of high-content in vitro screening kits (MultiFlow).   
At Litron, we like to stay close to our clients and collaboration is important to us. We want our customers to have the ability to interact with the same scientists who developed these advanced research kits. Litron routinely provides these services to pharmaceutical, medical device, government and contract research organizations around the world.  
In this way, Litron is transforming the genetic toxicology industry one test at a time.  
Visit LitronLabs.com for more information.   
About Instem  
Instem is a global provider of leading software solutions and services that are helping over 500 clients bring their life enhancing products to market faster. We enable clients in the life sciences to more efficiently collect, analyze, report and submit high quality regulatory data, while maintaining compliance for their products around the world.   
Instem solutions are in use by customers worldwide, meeting the rapidly expanding needs of life science and healthcare organizations for data-driven decision making, leading to safer, more effective products.  
Instem supports its global roster of clients through offices in the United States, United Kingdom, France, Japan, China and India.   
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Instem Acquires Perceptive Instruments; Leader in Image Analysis and Data Management Solutions  
Perceptive Products to Increase Study Management Efficiencies within Life Sciences  
CONSHOHOCKEN, PA - (BUSINESS WIRE) – November 22, 2013 - -Instem, a leading provider of IT solutions to the global early development healthcare market, announced today that it has acquired Perceptive Instruments (“Perceptive”) as it continues to consolidate the life sciences IT marketplace.  
Located in Suffolk, United Kingdom, Perceptive develops, manufactures and supplies image analysis and data processing solutions that are primarily focused on the areas of genetic toxicology, microbiology and immunology. Perceptive solutions are deployed in 49 countries at leading universities, research institutes and are supporting various government programs such as those at the National Center for Toxicological Research, a Food & Drug Administration division. Perceptive products also serve small and medium-sized companies along with many of today’s leading multinational organizations, including all of the top 10 pharmaceutical companies worldwide.   
Operating as part of Instem, Perceptive Solutions include:  
  
Comet Assay IV; live video-based system for scoring cells supporting DNA damage and repair studies and genetic toxicology testing  
Ames Study Manager; comprehensive suite of software for conducting and reporting Ames studies in accordance with OECD 471  
Cyto Study Manager; system for integrating all data acquisition, reporting and management during genetic toxicology investigations for individual and combined comet and micronucleus assays  
Sorcerer Systems  
  
Colony Counter; combining image processing and analysis with an innovative Petri-viewer providing fast and accurate counts for bacterial and mammalian colonies for a wide range of applications  
Image Analysis System; live video-based analytical tool for research and quality control  
UDS; complete system for Unscheduled DNA Synthesis assays using live-video cell images and software for creating studies, randomization and slide scoring   
Perceptive solutions are frequently referenced in scientific journals, during industry conferences and are featured in numerous case studies. All Perceptive products are designed to fulfil the requirements of Good Laboratory Practice, FDA 21 CFR Part 11 and other international regulatory guidelines. Perceptive remains one of a handful of image analysis & data processing companies worldwide whose management processes have been officially registered to ISO 9001:2008.  
“The team here at Perceptive is excited and eager to join Instem,” states Colin White, Managing Director at Perceptive. “Various assays such as comet are playing an increasingly important role in the drug development process. Instem’s leadership position will allow us to further our mission of providing quality solutions and excellent after-sales service to a growing set of clients.”  
 “This acquisition is another win for our market,” comments Phil Reason, CEO at Instem. “Our clients will now have the ability to turn to one global supplier for their data management needs across broader segments, providing them with greater efficiencies. Many of the tests Perceptive products support are a required part of the regulated study process and our commanding position across early development will enable us to help users better collect, manage, review and extract data while transitioning information into valuable insight.”  
As part of the Instem group, the staff at Perceptive will now have access to additional capabilities in marketing, sales, management and software development. Current Perceptive clients can also expect additional regional support services before and after purchasing a solution from Instem offices around the globe.  
Perceptive solutions will enhance Instem’s Study Workflow and Automation Suite, enabling organizations of all sizes to collect, manage, review and submit study data that streamline processes, increase quality and enhance development programs.  
Instem has been developing, releasing and introducing a stream of technology solutions to the market as part of their mission to deliver compelling solutions for data collection, management and analysis across the R&D continuum. Earlier this year Instem entered the early phase Clinical Market through another strategic acquisition and is planning to remain active in expanding the reach of its product portfolio into related scientific domains.   
To request information about a Perceptive solution, please send an email to info@instem.com or sales@perceptive.co.uk.  
Information about Perceptive Instruments and their solutions can be found at:  
http://www.perceptive.co.uk/  
About Instem  
Instem is a leading supplier of IT applications to the early development healthcare market, delivering compelling solutions for data collection, management and analysis across the R&D continuum. Instem applications are in use by customers worldwide, meeting the rapidly expanding needs of life science and healthcare organizations for data-driven decision making leading to safer, more effective products.  
Instem’s portfolio of software solutions increases client productivity by automating study-related processes while offering the unique ability to generate new knowledge through the extraction and harmonization of actionable scientific information.  
Instem supports over 400 clients through full service offices in the United States, United Kingdom and China with additional locations in India and a full service distributor based in Japan.  
Meeting clients at the intersection of investment & return™.  
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Instem Acquires PDS Life Sciences to Help Clients Bring Life Enhancing Products to Market Faster and More Efficiently  
 Acquisition of PDS Life Sciences Consolidates Non-Clinical Market; Further Extends Instem’s Leadership in Study Management and Regulatory SEND Submission Support   
PHILADELPHIA, PA – (BUSINESS WIRE) – September 1, 2021 - Instem, a leading provider of IT solutions and services to the global life sciences market, announced today that it has acquired PDS Life Sciences (PDS) as part of its mission to enable clients to bring their life enhancing products to market faster. This further consolidation by Instem of key application areas will help customers streamline and accelerate their research and development processes, while enabling clients to access data from across the R&D continuum, increasing the power of current and future in silico modelling and prediction solutions.  
Headquartered in Switzerland, with offices in the United States and Japan, PDS has been a direct competitor of Instem, providing software and outsourced services for non-clinical study management and regulatory submissions using SEND (the Standard for the Exchange of Non-clinical Data). Seven of the world’s top ten pharmaceutical companies rely on PDS, as do leading Contract Research Organizations, chemical companies, universities, and regulatory agencies.  
“This is good news for Instem, PDS and the entire industry,” comments Gregor Grant, Executive Vice President at Instem. “For decades, both Instem and PDS have been providing innovative solutions that help organizations accelerate non-clinical development, and we have always been impressed with their highly experienced team. This acquisition will enable us to concentrate our investment into a single line of products, and we are looking forward to advancing what will be a very exciting roadmap. By combining our technologies and talents we will be able to more quickly develop and deliver solutions that provide even higher value to our clients.”   
“This was a natural next step in our quest to help clients do more and go further than ever before,” states Vicente Nogués, CEO at PDS. “Despite having been competitors, our mission, values and overall company cultures are aligned very well – which was the highest of priorities for PDS. As part of Instem, our clients will now have access to the most comprehensive range of solutions available in the market today backed by excellent customer service, while our staff will enjoy additional opportunities for professional growth. Together with Instem, we are looking forward to advancing the ever-important mission of helping clients to bring their life enhancing products to market faster.”  
Instem expects to retain all staff and this acquisition will allow them to immediately increase their operational capacity. Plans are in place to rapidly integrate the PDS group into the Instem organization, which is made easier with the US offices of both organizations being closely located to one another in New Jersey and Pennsylvania. The acquisition will also provide an important opportunity to combine teams operating in the significant Swiss/German and Japanese markets.   
Instem sees the acquisition of PDS as another key step in its transformational growth strategy, extending its ability to further deliver solutions that meet the rapidly expanding needs of life science organizations for faster data-driven decision making, leading to safer, more effective products.  
This third acquisition of 2021, along with its strong organic growth, has now positioned Instem as the foremost authority and driving force in generating, analyzing and leveraging data from Discovery through late-stage Clinical Trials.   
Learn more about Instem’s mission here.   
About Instem  
A global provider of leading software solutions and scientific insight services, Instem is helping clients to bring their life enhancing products to market faster.   
We enable organizations in the life sciences to more efficiently collect, report and submit high quality regulatory data, while offering them the unique ability to generate new knowledge through the extraction and harmonization of actionable scientific information.  
Every day, across the entire drug development value chain, Instem solutions are meeting the rapidly expanding needs of life science organizations for data-driven decision making, leading to safer, more effective products.  
Instem supports its global roster of clients through offices in the United States, United Kingdom, France, Switzerland, Japan, China, and India.  
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Leading R&D Organizations Deploy Instem SEND Solutions  
Organizations Around the Globe Continue to Become SEND-Enabled with Instem’s Submit Software Platform Following 2014 FDA Mandate  
CONSHOHOCKEN, PA - (BUSINESS WIRE) – July 1, 2015 - -Instem, a leading provider of IT solutions to the global early development healthcare market, is pleased to announce that its customers are deploying Instem SEND solutions at a record pace. Numerous world- leading healthcare organizations have recently completed their deployment of Instem’s submit™ software platform enabling them to fully support CDISC’s Standard for Exchange of Nonclinical Data (SEND).  
In December 2014, the FDA issued the final Guidance for providing Regulatory Submissions in Electronic Format using standardized Study Data. Instem has been extensively involved in the creation and development of SEND since its inception, working closely with SEND pilot organizations, the FDA and industry to help define the standard and align it with industry practices.   
  
 As a result of this detailed involvement, Instem developed the first commercially available SEND data management system and is proud to provide the most widely adopted set of SEND tools in the market, with Instem SEND solutions licensed across 11 countries at over 32 sites.   
Instem’s leadership position has also attracted prominent SEND subject matter experts to join Instem, including Lou Ann Kramer, Instem’s VP Regulatory Submissions and current CDISC SEND team leader.   
“We are delighted to see members of our global SEND client community such as Allergan, Charles River, MPI Research and many others continue to implement submit to meet the requirements of SEND,” comments Mike Harwood, Senior Vice President, Instem. “Enabling these clients with our proven technologies will give them real advantages with upcoming submissions.”  
Instem’s submit platform provides a suite of integrated tools and services for the creation and management of SEND datasets and associated documents for Contract Research Organizations, Sponsors and their study partners. More information about SEND and Instem’s tools can be found at http://www.instem.com/industries/send.php   
About Instem  
Instem is a leading supplier of IT applications to the early development healthcare market, delivering compelling solutions for data collection, management and analysis across the R&D continuum. Instem applications are in use by customers worldwide, meeting the rapidly expanding needs of life science and healthcare organizations for data-driven decision making leading to safer, more effective products.  
Instem’s portfolio of software solutions increases client productivity by automating study-related processes while offering the unique ability to generate new knowledge through the extraction and harmonization of actionable scientific information.  
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Meeting clients at the intersection of investment & return™.  
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SEND Implementation Guide v3.1 Now Available  
Study Design Coverage Expanded  
CONSHOHOCKEN, PA - July 8, 2016 - The CDISC/SEND Leadership Team has announced that the CDISC/SEND Implementation Guide, v3.1 has now been released. This important extension of the SEND standard addresses issues identified in SEND 3.0, expands the range of study designs that can be accommodated and also resolves ambiguity in some of the timing variables.  
The SEND Implementation Guide (IG) is intended to guide the organization, structure, and format of standard nonclinical tabulation datasets for interchange between organizations such as sponsors and CROs and for submission to the US Food and Drug Administration (FDA). The SENDIG is based upon, and should be used in conjunction with, the newly released Version 1.5 of the CDISC Study Data Tabulation Model (SDTM), which is included in the document package.  
To access the document package interested parties are encouraged to visit the CDISC announcement www.cdisc.org/send.  
Instem will be holding an Express Webcast that will provide an explanation of the changes to the standard, along with guidance on implementation considerations.   
There will be two identical, live Webcasts that you can join right from your desktop, tablet or phone. Please register below:  
 Tuesday July 26th 9:30am – 10am US Eastern  
 Wednesday July 27th 1:30pm – 2pm US Eastern  
Register  
Instem has been extensively involved in the creation and development of SEND since its inception, working closely with SEND pilot organizations, the FDA and industry to help define the standard and align it with industry practices.  
As a result of this detailed involvement, Instem developed submit™, the first commercially available SEND data management system and is now proud to provide the most widely adopted set of SEND tools and services in the industry, operating at 45 sites across 15 countries.   
Instem’s submit platform provides a suite of integrated tools and services for the creation and management of SEND datasets and associated documents for Contract Research Organizations, Sponsors and their study partners. More information about SEND and Instem’s tools can be found here.   
About Instem   
Instem is a leading supplier of IT applications to the early development healthcare market delivering compelling solutions for data collection, management and analysis across the R&D continuum. Instem applications are in use by customers worldwide, meeting the rapidly expanding needs of life science and healthcare organizations for data-driven decision making leading to safer, more effective products.  
Instem’s portfolio of software solutions increases client productivity by automating study-related processes while offering the unique ability to generate new knowledge through the extraction and harmonization of actionable scientific information.  
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Shanghai Institute of Materia Medica Chooses Provantis Software Solution  
Provantis Software-as-a-Service Model Chosen by Leading Shanghai-Based Drug Development Institute  
CONSHOHOCKEN, PA - (BUSINESS WIRE) –October 6, 2010 - - Instem, a leading provider of early development software applications, announced today that the Shanghai Institute of Materia Medica (SIMM) has purchased an online subscription to the Provantis® preclinical software solution suite. SIMM will be using a range of Provantis modules across the areas of general toxicology, clinical pathology and pathology as part of their wider strategy to automate scientific processes to help bring more medical breakthroughs to the People’s Republic of China.   
SIMM, part of the Chinese Academy of Sciences, ranks at the top in China for its drug discovery and development activities with more than 70 drugs having been developed since its establishment. The major research directions of SIMM include drugs for diseases seriously endangering the health of the Chinese population, such as tumors as well as, cardiovascular, neurological, metabolic, autoimmune and infectious diseases.   
As the overwhelming standard in western facilities, Provantis is a modern preclinical research technology solution that is easy to use and will offer SIMM compliance to national and western standards, dual language operation and proven protocol-driven automation that will produce high quality study output in greatly reduced timescales.  
  
“As the primary participant in the newly established Research Center for Modernization of Traditional Chinese Medicine, we are honored that SIMM has chosen Instem’s Provantis software to automate their research laboratories,” comments Phil Reason, CEO at Instem. “SIMM is one of the leading interdisciplinary research centers in China, and recognized worldwide by its outstanding achievements in both basic and applied research fields. We are looking forward to closely working with their staff so they can quickly realize the benefits of Provantis and continue their excellent scientific contributions.”  
  
SIMM will be using Instem’s SaaS (Software-as-a-Service) model offering simpler, more cost effective ways to provide software functionality, maintenance, and support over the Internet. Since 2005, Instem has utilized state of the art data centers, which are being used by clients running GLP and non-GLP studies.  
 Specifically for Asia-Pacific organizations seeking to reduce the costs and complexity of their on-site technical footprints, Instem offers a localized online access point to its Provantis preclinical application. Their Shanghai-based data center meets the highest standards for reliability, security and redundancy and is managed by experienced staff 365 days a year. Strategically located in PuDong, this purpose built data center features a state-of-the-art network, power and environmental infrastructure and is ISO 9001 and SunTone™ certified.  
“SIMM’s decision to purchase was strongly endorsed by other leading organizations and government laboratories,” comments Neil Donaldson, Instem’s VP of European and Asian operations. “We encourage each of our prospective clients to interact with existing Provantis users, but it is not just to discover the benefits of our technology. By speaking directly to clients, they can hear first-hand how responsive our staff is and how as an organization we become a cost effective extension of their business.”  
Instem in the People’s Republic of China (PRC)  
As the first western toxicology/pathology software supplier to enter the Chinese market, Instem officially deployed its first China-based system in one of the largest and most advanced vivariums during 2006.  
 Understanding that by 2014 the PRC would be the second largest pharmaceutical market in the world; Instem established a full-service office in Shanghai, recruited local staff and has localized the Provantis product suite into Mandarin Chinese. Instem is supporting both international organizations and domestic laboratories exclusively serving the PRC.  
  
About Provantis®  
Provantis is a modern, fully integrated software system for single users and global organizations engaged in preclinical evaluation studies. Orchestrating every facet of preclinical drug safety assessment, Provantis streamlines processes and workflows with straightforward, intuitive functionality for simple or complex studies within a GLP or non-GLP environment, on-site or over the Web.   
About SIMM  
The Shanghai Institute of Materia Medica (SIMM), Chinese Academy of Sciences (CAS), evolved from the Institute of Materia Medica of Peking Academy of Sciences founded in 1932. Its current location is within the heart of Zhang Jiang Hi-Tech Park, Pudong New District.  
 SIMM’s mission is to provide a comprehensive solution in drug discovery and development. By combining basic and applied research efforts and through cross-fostering between chemistry and biology, scientists at SIMM carry out studies toward the elucidation of the structural basis of bioactive substances, discovery of new targets or mechanisms of action, comprehensive pre-clinical evaluation of drug candidates, and promotion of commercialization, thereby playing an indispensable role in building China’s drug innovation capabilities.   
About Instem  
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INTOX, India Deploys Provantis Preclinical Software Solution  
Provantis Selected to Improve Study Turnaround Times and Further Increase Data Quality at Pune Facility  
CONSHOHOCKEN, PA – Business Wire, March 3, 2020 - Instem, a leading provider of IT solutions to the global life sciences market, announced today that Indian Contract Research Organization, INTOX PVT Ltd. (INTOX), has deployed the Provantis® preclinical software solution to manage preclinical processes at its GLP certified research facility in Pune.  
Founded in 1995, INTOX performs a wide range of study types, including Toxicological, Mutagenicity, Ecotoxicological and Chemical. Their client base includes leading pharmaceutical, crop protection/agrochemical, biotech, chemical and medical device organizations worldwide.   
  
 Provantis was selected following a detailed competitive evaluation and replaces existing manual processes at INTOX, delivering increased efficiencies in the collection, storage and reporting of preclinical data. Provantis enables INTOX to improve study turnaround time for their sponsors and will deliver further improvements in data quality, integrity and traceability.  
Key Facts  
  
INTOX has deployed an extensive suite of Provantis modules including General Toxicology, Pathology, Clinical Pathology, and Report Assembly  
Contract awarded following a detailed competitive evaluation; Provantis recognized as the global leader in the field of preclinical IT solutions  
INTOX to harness the power of the Provantis Academy e-learning platform and a range of professional services, facilitating quick implementation and a rapid return on investment   
Provantis replaces existing manual processes to automate and streamline vital preclinical activities   
  
The Co-Founders and Directors of INTOX, Dr. P.Y. Naik, Dr. M. P. Pore and Dr. Narendra Deshmukh were extremely impressed with the extensive capabilities of Provantis and its straightforward, intuitive functionality. They said “Provantis will dramatically reduce our study turnaround time and enable us to take our client service to the next level. Provantis is the gold standard globally and we are looking forward to realizing the transformational benefits that our investment in Provantis will bring”. Dr. Deshmukh asserted on the role Provantis will play in strengthening data integrity in the test facility, which will give a further boost to the client and regulator confidence that they already enjoy.   
Jon Sparkes, Senior Director Sales, Europe & Asia, Instem, commented, “We are delighted to welcome INTOX to our growing client community within India and look forward to supporting them in their mission to provide high quality, reliable research and testing services in the field of product safety assessment to clients throughout the world.”   
Instem anticipates that 2020 will be another growth year for the Provantis solution. This follows on from a sustained period of strong demand for Provantis across all its global markets during 2019, which saw the company welcome 13 new organizations to the Provantis client community   
About Intox  
Headquartered in Pune, India, INTOX celebrates its 25th year of foundation in 2020.  
INTOX performs a wide range of safety assessment studies in the domains of Mammalian Toxicology, Mutagenicity, Environmental Toxicology, Biology and Chemistry, for Pharmaceutical, Crop Protection, Biotechnological, Chemical and Medical device organizations who wish to obtain National and International registration for their new products. In recent years the CRO has significantly expanded its strengths with additional infrastructure, manpower and equipment and made significant strides in its bioanalytical capabilities. The CRO considers the acquisition of Provantis as one of its strategic decisions in this direction.   
For further information visit http://www.intoxlab.com/index.html  
About Instem  
Instem is a global provider of leading software solutions and services that are helping over 500 clients bring their life enhancing products to market faster. We enable clients in the life sciences to more efficiently collect, analyze, report and submit high quality regulatory data, while maintaining compliance for their products around the world.   
Instem solutions are in use by customers worldwide, meeting the rapidly expanding needs of life science and healthcare organizations for data-driven decision making, leading to safer, more effective products.  
Instem supports its global roster of clients through offices in the United States, United Kingdom, France, Japan, China and India.   
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Instem Presenting at British Society of Toxicological Pathology Annual Meeting  
Instem to discuss how public and private literature can provide insight into which preclinical models best represent drug-induced pathology in humans  
CONSHOHOCKEN, PA – November 12, 2014 - - Instem, a leading provider of IT solutions to the global early development healthcare market, is pleased to announce that Paul Bradley, Head of Life Sciences at Instem, will be presenting a poster at the British Society of Toxicological Pathology (BSTP) 29th Annual Scientific Meeting in Cheshire, UK.  
The poster presentation, "What does the literature tell us about the relationship between drug-induced stomatitis in preclinical models and man?" will discuss how Instem’s suite of insight solutions can be used to search, model and visualize both publicly available literature and Instem’s in-house knowledgebase to determine which preclinical models best represent drug-induced pathology in humans.  
The 29th Annual BSTP meeting is being held jointly with the Association of Comparative Clinical Pathology (ACCP) and the Minipig Research Forum (MRF). The theme of the meeting is “Rational Selection of the Non-Rodent Species: Toxicology, Pathology and Relevance to Man”. The meeting is being held at AstraZeneca’s Alderley Park site, Cheshire, UK on November 13th & 14th.  
The poster will be on display in the BSTP Exhibit Hall throughout the meeting. Instem will also be exhibiting at booth # 4, where delegates will have the opportunity to try out Instem’s powerful insight solutions for themselves. Delegates are invited to bring along a specific compound or Pathology finding that they would like to know more about, and Instem’s booth team will undertake an initial no-fee literature search.  
At the BSTP booth, Instem will also be showcasing its market-leading Provantis® Pathology solution for the collection, processing and reporting of data for gross and histopathology and its submit™ solution suite for creating, managing and reviewing SEND data sets.  
The BSTP is a non-profit organization that seeks to advance pathology for the public benefit in all its aspects pertaining to the effects of extraneous substances and environmental agents to which man or other species are exposed through design or adventitiously. Additionally it seeks to foster training and advance education in toxicological pathology by providing continuing professional development seminars and educational training modules.  
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Instem Expands In Silico Toxicology Service To Meet Growing Demand  
Newly Added Services to Support Latest Regulatory Guidance and Growing Demand for Alternative Testing Methods  
PHILADELPHIA, PA – (BUSINESS WIRE) – November 22, 2021 - Instem, a leading provider of IT solutions and services to the global life sciences market, announced today that it has further enhanced its Predict™ In Silico Toxicology service portfolio by adding four new services.   
Predict™ is a leading edge, technology-enabled service that delivers a combination of powerful computation models with expert scientific review, to help clients predict chemical safety more quickly, efficiently, and comprehensively. Since its successful launch in December 2020, Instem has seen strong interest in the Predict™ service from clients across the globe.  
These latest service offerings have been developed to address new regulatory guidance and will deliver further efficiencies and increased regulatory compliance for clients.   
New service highlights:  
  
Establishing Acceptable Limits for N-nitrosamines - to support recent guidance from US FDA, EMA, and other regulatory authorities regarding the assessment and control of N-nitrosamine impurities and degradants.   
Assessment of Abuse Liability – provides an in silico assessment of abuse liability for CNS-active substances to support their assessment in early discovery, the development of a testing strategy for abuse liability, and to answer regulatory questions.   
Assessing Bioactivation – supports FDA guidance regarding the assessment of structural alerts for metabolites associated with mechanism-based inhibition (MBI). The service will generate and report the results of an in silico profile for MBI potential, including an expert review, and can also support the assessments of potential liver toxicity attributable to bioactivation.  
SD File Generation - The US FDA recommends that pharmaceutical companies submit an electronic format (SD File) for chemicals included in their regulatory submissions (including impurities). This Predict™ service offering will process the molecules, validate, and create an SD file.  
  
Dr. Glenn Myatt, Instem’s Vice President of Informatics said, “We have been delighted to see such high demand for our Predict services from existing and prospective clients alike and are pleased to add these new offerings to our portfolio.” Dr. Myatt continued “As the demand for reliable alternatives to traditional testing methods continues to grow, organizations of all sizes are recognizing the benefits that our Predict™ service can deliver. This includes small and medium sized organizations that may not have the necessary team to perform an expert review, through to larger organizations with in-house expertise and technology, who are using Predict™ to complement their in-house capabilities or to assist during times of peak demand.”   
Predict™ leverages Instem’s expertise in delivering technology-enabled services, powered by advanced informatics and prediction technology, and comprehensive database solutions, that help organizations around the world unlock valuable knowledge contained in both public and proprietary sources of research data. Instem’s toxicity databases access well over 500,000 toxicology studies for more than 200,000 chemicals, enabling fast, accurate, defendable and regulatory-accepted predictions.   
Predict™ harnesses these world-leading computational models and databases and combines them with expert scientific review by a team of professionals with deep knowledge of computation modelling, toxicology, and chemistry. This winning combination delivers comprehensive, unbiased, high quality, regulatory-accepted assessments of chemical safety.  
The Predict™ service supports a variety of applications including the ICH M7 pharmaceutical impurities guideline, SD file generation to include in the Electronic Common Technical Document, assessment of extractables and leachables, and classification and labelling.  
To learn more about Predict™, including the 4 new service offerings download the fact sheet.   
About Instem  
A global provider of leading software solutions and scientific insight services, Instem is helping clients to bring their life enhancing products to market faster.  
We enable organizations in the life sciences to more efficiently collect, report and submit high quality regulatory data, while offering them the unique ability to generate new knowledge through the extraction and harmonization of actionable scientific information.  
Every day, across the entire drug development value chain, Instem solutions are meeting the rapidly expanding needs of life science organizations for data-driven decision making, leading to safer, more effective products.  
Instem supports its global roster of clients through offices in the United States, United Kingdom, France, Switzerland, Japan, China, and India.  
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Instem Announces Shanghai-Based Data Center for Asia-Pacific Provantis Clients  
Instem Partners with Datapipe, Global Leader in Remote Systems Management  
CONSHOHOCKEN, PA - (BUSINESS WIRE) –June 3, 2010 - - Instem, a leading provider of early drug development software solutions, announced today it has signed a collaborative agreement with Datapipe®, a global provider of managed and hosted IT services. Under the agreement Datapipe will deliver managed hosting services from its Shanghai Data Center to support Instem’s offerings in the Asia-Pacific preclinical market.  
For Asia-Pacific organizations seeking to reduce costs and the complexity of their on-site technical footprint, Instem will now offer a localized online access point to its Provantis® preclinical application. Datapipe’s Shanghai-based facility meets the highest standards for reliability, security and redundancy and is managed by experienced Datapipe staff 24 hours a day, 7 days a week, 365 days a year.  
Strategically located in PuDong, this purpose built data center features a state-of-the-art network, power and environmental infrastructure that will ensure Provantis is fast, secure and monitored every moment of every day. Instem will be able to offer 100% up-time availability through Datapipe’s multiple redundant network connections and a redundant router and switch configuration. The facility is ISO 9001 and SunTone™ certified.  
“As interest grows in this region for using Provantis over the Internet, having a strong partner operating the data center is vital,” comments Penny Stockley, General Manager of Instem Shanghai. “Of course connectivity and performance is important, but clients now can have peace of mind by knowing their data is protected in an environment more secure than they could ensure themselves. We are looking forward to giving tours of this facility and know all of our clients will be very impressed.”  
  
 This additional service follows other significant investments made by Instem in Asia, including the establishment of a regional office in Shanghai, recruitment of local staff and the localization of the Provantis software product.  
  
 Datapipe provides hosted application management services around the world and is a recognized leader for its dedication to stability, security and connectivity. Winning numerous awards for reliability and technical innovation, Datapipe offers best-in-class service to organizations running business critical applications across multiple high profile industries.  
Using Instem’s hosted remote delivery model offers simpler, more cost effective ways to provide software functionality, maintenance, and support over the Internet. Clients have complete in-application access to their data just as if their software was deployed on-site, yet they no longer require additional hardware or dedicated resources. Removing the need for on-site software ensures clients can access the latest major releases of Provantis without the delays and costs sometimes involved with site-based installations.   
 Instem’s turn-key subscription includes all 3rd party licenses such as Oracle and SAS, along with training, maintenance and unlimited local help desk support.  
Since 2005, Instem has offered the hosted remote delivery model to the global preclinical IT marketplace, which is in use by clients of all sizes running GLP and non-GLP studies.   
About Provantis®  
Provantis is a modern, fully integrated software system for single users and global organizations engaged in preclinical evaluation studies. Orchestrating every facet of preclinical drug safety assessment, Provantis streamlines processes and workflows with straightforward, intuitive functionality for simple or complex studies within a GLP or non-GLP environment, on-site or over the Web.  
About Datapipe  
Datapipe provides custom managed hosting solutions for businesses with complex Internet facing infrastructures. We proactively manage security, monitoring, storage, data center operations, servers, and applications including database administration and the full software stack. The company provides services to more than 1000 customers in six data centers and eight office locations in the United States, the United Kingdom, and China. Datapipe was founded in 1998 and is headquartered in Jersey City, New Jersey. http://www.datapipe.com  
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Meeting clients at the intersection of investment & return™.  
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Instem Participates in SEND Panel Program Sponsored by the Pistoia Alliance  
Pistoia Alliance Debates Webinar Reviewing Key Principles of FDA-Adopted CDISC Preclinical Standard  
CONSHOHOCKEN, PA – March 17, 2016 - -Instem, a leading provider of IT solutions to the global early development healthcare market, announced today that it has participated in a Webinar organized by the Pistoia Alliance, which took place on March 16th.  
The webinar, part of the “Pistoia Alliance Debates” series, introduced the audience to the key principles of SEND. Using web-based presentations and discussion, the webinar panel members outlined how efficient management, exchange and submission of non-clinical development study data can be implemented using SEND.   
Furthermore, the webinar identified some of the key, due-diligence questions that need to be addressed before considering exchanging information with other companies in the information ecosystem including CROs.  
Along with key industry leaders from Sanofi, Bristol-Myers Squibb and Merck KGaA, Instem’s Vice President of Regulatory Submissions and CDISC/SEND Team Leader Lou Ann Kramer participated in this program as a panelist.   
  
Listen to a recording of the webcast.  
  
Additional details about the Pistoia Alliance can be found at:  
http://www.pistoiaalliance.org  
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Instem Software Deployed for Translational and Personalized Oncology Programs  
Instem Solutions Being Utilized for Testing Efficacy of Established Oncology Drugs While Increasing Speed of Drug Development for BioPharma  
CONSHOHOCKEN, PA - (BUSINESS WIRE) - April 17, 2012 - - Instem, a leading provider of IT solutions to the global early development healthcare market, announced today that its integrated Provantis® preclinical software suite has been deployed for a US-based research laboratory specializing in the personalized development and use of oncology drugs by both physicians and patients as well as their BioPharma clients.  
Key facts  
  
Integrated In-life Toxicology, Protocol, Tables & Statistics and Reporting modules being used at US-based facility  
Instem’s Data Import module being used to migrate legacy data seamlessly into Provantis system  
Provantis chosen to replace existing laboratory information system, offering client more functionality with advanced reporting capabilities  
Client realized quick and efficient deployment using Instem’s Specialized Solutions Services  
  
“We are pleased to see Provantis being used not only for translational oncology programs for new drug development, but also excited to see Provantis being used for testing established drugs against tumors directly for oncologists and their patients,” comments Gary Mitchell, VP Global Marketing at Instem. “We are eager to expand our footprint in this critical area of personalized medicine and look toward the future with great hope as we join forces with yet another world-class organization that is enhancing and advancing life.”  
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Bio-Safety Laboratory Deploys Provantis Software Solution to Help Streamline Non-Clinical Evaluation Studies  
Provantis Selected to Automate Processes in the Research of Deadly Pathogens, Emerging Diseases and Bioterror Agents  
CONSHOHOCKEN, PA – June 21, 2016 - Instem, a leading provider of IT solutions to the global early development healthcare market, announced today that Texas Biomedical Research Institute (Texas Biomed), based in San Antonio, Texas, has purchased the Provantis® preclinical solution suite to support bio-safety level 4 (BSL-4) research and documentation processes.  
Key Facts  
  
Texas Biomedical Research Institute to implement the Provantis General Toxicology and Pathology modules.   
Client to deploy Instem’s unique Logbook ELN solution for paper form replacement. Logbook will digitize all paper forms with built-in workflows and advanced search capabilities to further improve productivity and accuracy.  
Provantis replaces existing paper-based data collection processes.   
Texas Biomed selected Instem’s Software as a Service (SaaS) deployment option, providing software functionality, maintenance and support over the Internet 24 hours a day; seven days a week.   
  
Texas Biomedical Research Institute is one of the world's leading independent biomedical research institutions, dedicated to advancing health worldwide through innovative biomedical research. A BSL-4 lab designation offers a safe environment where scientists study deadly pathogens with no known treatments or vaccines.   
Ricardo Carrion, Jr., Associate Scientist and BSL-4 Laboratory Associate Director at Texas Biomedical Research Institute, commented, “The Provantis suite will enable us to streamline preclinical data collection, processing, review and reporting activities while still maintaining all of the precautions necessary to support our BSL-4 designation.”   
Gary Mitchell, Vice President of Marketing at Instem, added, “Texas Biomedical Research Institute is a great illustration of how Instem’s Provantis solution is supporting leading organizations across the globe in their missions to protect and enhance lives. Texas Biomed has gained worldwide recognition for the quality of its research, and we are honored to welcome them to our growing user community.”   
Provantis is a fully integrated, scalable, Windows-based solution used by organizations across the globe, from single user remote Pathologists to multi-site laboratories. It is used by pharmaceutical, biotech, medical device, contract research, academia, chemical/agrochemical, consulting and government research institutions.   
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Instem Receives VOLTAGE Award for Submit-SEND Software Solution Suite  
Submit-SEND Solution Recognized for Innovation & Industry Leadership  
CONSHOHOCKEN, PA - May 17, 2013 - -Instem, a leading provider of IT solutions to the global early development healthcare market, announced today it has received the VOLTAGE Technology Innovator Award for its submit™ solution at a ceremony in Philadelphia on May 16th.   
The VOLTAGE awards program, sponsored by SmartCEO magazine and Comcast, celebrates the role that technology plays in the business community and the future impact the technology sector will have on economic growth. Instem’s submit solution was also featured in the May edition of SmartCEO magazine.   
Submit™ is a fully integrated nonclinical solution suite developed to support companies using  
CDISC’s Standard for Exchange of Nonclinical Data (SEND). The submit solution creates and manages SEND study datasets throughout their lifecycle, and allows sponsors, CROs and regulators to share, visualize and analyze study data more efficiently.   
SEND defines the organization, structure, and format of standard nonclinical tabulation datasets for interchange between organizations such as sponsors and contract research organizations and for submission to the US Food and Drug Administration (FDA).  
Instem has been providing industry education and outreach to promote SEND while demonstrating its own technology solution suite – submit. During 2012 Instem was recognized at the CDISC Interchange North America meeting for its outstanding contributions toward the completion of the SEND 3.0 Implementation Guide.   
About Instem  
Instem is a leading supplier of IT applications to the early development healthcare market, delivering compelling solutions for data collection, management and analysis across the R&D continuum. Instem applications are in use by customers worldwide, meeting the rapidly expanding needs of life science and healthcare organizations for data-driven decision making leading to safer, more effective products.  
Instem’s portfolio of software solutions increases client productivity by automating study-related processes while offering the unique ability to generate new knowledge through the extraction and harmonization of actionable scientific information.  
Instem supports over 400 clients through full service offices in the United States, United Kingdom and China with additional locations in India and a full service distributor based in Japan.  
Meeting clients at the intersection of investment & return™.  
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Instem Expands SEND Suite with Data Visualization and Analysis Solution  
Instem Signs Agreement with Integrated Nonclinical Development Solutions, Inc.; Becomes Exclusive Global Supplier of SEND Explorer®   
CONSHOHOCKEN, PA - (BUSINESS WIRE) – July 29, 2016 - -Instem, a leading provider of IT solutions to the global early development healthcare market, announced today that it has reached an agreement with Integrated Nonclinical Development Solutions, Inc. (“INDS”) to market, sell and support its SEND Explorer solution worldwide.  
SEND Explorer provides advanced single and multi-study viewing, data summarization, and visualization capabilities for study data produced in SEND (Standard for Exchange of Nonclinical Data) format. SEND Explorer is an intuitive web-based application with optional data warehousing capabilities allowing data sources other than SEND to be integrated and available for querying and analysis.   
“SEND Explorer is the perfect complement to Instem’s current SEND offerings,” comments Jennifer Feldmann, Vice President of SEND Product Strategy at Instem. “Our clients can create and manage their SEND datasets using submit™, QC the datasets with SENDView™ to ensure a submission-ready package, and use those SEND datasets with SEND Explorer as part of the ongoing analysis to support the scientific findings submitted with a drug application.”  
Instem views SEND Explorer as an effective solution for organizations to further leverage their investment in SEND data. The SEND Explorer solution, an INDS technology, will become an integral part of Instem’s submit solution suite.  
“INDS designed SEND Explorer to help scientists efficiently visualize and communicate data patterns and trends within and across studies, thereby accelerating the drug evaluation process,” states Joyce Zandee, Chief Operating Officer at INDS. “As the global SEND market leader, Instem has both the expertise and resources to make SEND Explorer accessible to scientists at large and small organizations, allowing our industry to greatly benefit from the data standardization imposed by SEND.”  
Instem developed submit, the first commercially available SEND software solution in 2005 and its comprehensive set of tools are now the most widely adopted in the market, supporting over 45 client sites across 15 countries. The submit platform is meeting the very wide range of demands that span the needs of the largest multi-national pharmaceutical organizations and CROs to the smallest organizations and their advisors.  
During this period of preparation and especially following FDA’s long awaited final guidance (December 18, 2014) for standardized study data for providing submissions in electronic format, the demand for outsourced SEND services has rapidly grown. Now across every stage of SEND-Readiness, clients can choose from one or more Instem solution-services that will help them in their journey towards SEND compliance, while minimizing the impact within their organization. This includes the option for organizations to completely turn to Instem as their fully-outsourced SEND department.  
More information about how organizations can Submit with Confidence™ can be found here.   
About Instem   
Instem is a leading supplier of IT applications and services to the early development healthcare market delivering compelling solutions for data collection, analysis and regulatory submissions management. Instem solutions are in use by customers worldwide, meeting the rapidly expanding needs of life science and healthcare organizations for data-driven decision making leading to safer, more effective products.  
Instem’s portfolio of software solutions and consulting services increases client productivity by enhancing product development processes while offering the unique ability to generate new knowledge through the extraction and harmonization of actionable scientific information.  
Instem supports over 500 clients through offices in the United States, United Kingdom, Japan, China and India.  
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Leading Contract Research Organization Selects Instem SEND Software Suite  
CRO to Deploy Submit Software Suite for Complete SEND Management  
CONSHOHOCKEN, PA – November 3, 2014 - -Instem, a leading provider of IT solutions to the global early development healthcare market, announced today that a Top 5 Contract Research Organization (CRO) has selected Instem’s submit™ solution suite to support CDISC’s Standard for Exchange of Nonclinical Data (SEND).   
Headquartered in the U.S., the CRO serves Sponsors from 30 different countries and is sought after for their regulatory experience and track record of success in all major global markets. The CRO provides safety evaluation, discovery, bioanalytical and analytical services to the biopharmaceutical, medical device and chemical industries.  
Instem’s submit solution suite creates and manages SEND study data sets throughout their lifecycle and allows sponsors, CRO’s and regulators to share, visualize and analyze study data more efficiently.  
Instem’s submit software solution will enable this leading CRO to merge data from multiple sources and automate workflows to improve their operational efficiencies while simplifying day-to-day operations around SEND. Using the SENDView™ module, which can be integrated with submit or used stand-alone, will additionally allow the CRO to view SEND files for simplified data review and study search.  
“Clients are finding that our submit-SEND solution is efficient, compliant and complete – and of course extremely powerful,” comments Gary Mitchell, VP Global Marketing at Instem. “Using submit, CRO’s are able to meet and exceed the expectations of their Sponsors for SEND without placing additional burdens on their research and IT staff. Our SEND solution was launched in 2005, is market proven and with 30 licensed sites and growing, we have gained the confidence of organizations around the globe as their SEND management experts.”  
Instem has been involved with SEND since 2004, has been recognized by CDISC for its exceptional SEND contributions and remains an active member of PhUSE.  
Key Facts   
  
Leading CRO Purchases Instem submit software to support SEND  
U.S.-headquartered CRO deploying integrated submit package including capabilities for SEND file receipt and creation, data review and search, define.XML and define.pdf creation, automatic term translations, SEND rule checking, secure version-controlled 21 CFR Part 11 storage of SEND files  
Leading CRO selects Instem for SEND market leadership, proven product capabilities and corporate stability   
About Instem   
Instem is a leading supplier of IT applications to the early development healthcare market delivering compelling solutions for data collection, management and analysis across the R&D continuum. Instem applications are in use by customers worldwide, meeting the rapidly expanding needs of life science and healthcare organizations for data-driven decision making leading to safer, more effective products.  
Instem’s portfolio of software solutions increases client productivity by automating study-related processes while offering the unique ability to generate new knowledge through the extraction and harmonization of actionable scientific information.  
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Instem Launches New SEND Blog  
Bi-weekly blog to provide best-practice insight, observations and opinions to help navigate the challenges and opportunities of SEND  
CONSHOHOCKEN, PA – October 22, 2020 - Instem, a leading provider of IT solutions to the global life sciences market, announced today that it has launched Sensible SEND, a bi-weekly blog authored by SEND Specialist Marc Ellison, Instem’s Director of SEND Solutions.  
Marc is responsible for Instem’s complete SEND software and outsourced services portfolio. As a long term CDISC volunteer, he is a member of their extended SEND leadership team and the sub-team lead for the working group developing the Pharmacokinetic domains. Marc also remains an active member of the Reproductive Toxicology workstream supporting the SENDIG-DART standard. Marc is a regular and sought-after speaker at scientific conferences, providing his expert knowledge of the SEND standard.  
“Marc’s practical SEND experience, combined with a genuine passion for seeing our clients fully leverage this important standard, makes him uniquely qualified to author this value-added blog,” comments Christine Duncan, Marketing Manager at Instem. “Marc has a pulse on the current and future regulatory environment, which readers will surely benefit from as they look to go beyond being compliant and begin exploiting additional benefits from SEND” comments Christine Duncan, Marketing Manager at Instem.  
To read the first blog post and to subscribe for future bi-weekly updates, please visit https://sensiblesend.blog.   
About Instem  
Instem is a global provider of leading software solutions and services that are helping over 500 clients bring their life enhancing products to market faster. We enable clients in the life sciences to more efficiently collect, analyze, report and submit high quality regulatory data, while maintaining compliance for their products around the world.   
Instem solutions are in use by customers worldwide, meeting the rapidly expanding needs of life science and healthcare organizations for data-driven decision making, leading to safer, more effective products.  
Instem supports its global roster of clients through offices in the United States, United Kingdom, France, Japan, China and India.   
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Instem Presenting at Chinese National Safety Evaluation Workshop, Shanghai  
Instem to Discuss Comet Assay IV and Systems for Genetic Toxicology  
CONSHOHOCKEN, PA – November 24, 2014 - -Instem, a leading provider of IT solutions to the global early development healthcare market, is pleased to announce that Mrs. Bing Li, Business Development Consultant, Instem, will present at the 2014 National Workshop on Non-clinical Safety Evaluation and Quality Management in Shanghai, November 27th – 29th.  
The presentation,“Comet Assay IV and Systems for Genetic Toxicology” will discuss techniques for automating the collection and reporting of the comet assay and other genetic toxicology studies, including an overview and brief demonstration of the world-leading Comet Assay IV system developed by Perceptive Instruments, now a part of Instem.  
The workshop, which has been organized by the National Shanghai Center for Drug Safety Evaluation and Research (NCDSER), will feature 3 full days of presentations, workshops and panel discussions. Instem is also proud to be the Gold Sponsor of this event.   
Mr. Neil Donaldson, VP Sales, Europe & Asia said “We are extremely honored to have been invited to speak at this prestigious national meeting. Instem is firmly committed to supporting the growth of the preclinical R&D market within China and we recognize the importance that workshops such as this bring to the region.”   
Instem was the first western toxicology/pathology software supplier to enter the Chinese market, deploying its initial China-based system in one of the largest and most advanced vivariums during 2006. As the Chinese preclinical market continues to grow, Instem is leading the market with Instem solutions deployed at more sites within the region than any competing product.   
Acknowledging analyst projections that the People’s Republic of China (PRC) is on pace to becoming the second largest pharmaceutical market in the world, Instem has an established full-service office in Shanghai and has localized the Provantis product suite into Mandarin Chinese. Instem supports organizations serving the PRC through traditional on-site systems as well as through their SaaS delivery model from a secure, professionally managed data center based in Shanghai.  
   
About Instem   
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Eurofins Product Safety Labs Selects Provantis Preclinical Software to Automate NJ Research Facility  
Provantis Chosen to Help Bring New Efficiencies for Collecting, Analyzing & Reporting Study Data  
CONSHOHOCKEN, PA - (BUSINESS WIRE) – May 18, 2010 - - Instem®, a leading provider of early drug development software solutions, announced today that Eurofins Product Safety Labs (EPSL) has purchased an online subscription to the Provantis® Preclinical Software solution.   
A contract research laboratory located in Dayton, New Jersey, EPSL provides a broad range of services including toxicology, analytical and bioanalytical chemistry and pharmacology.  
During the second half of 2009, EPSL ran extensive competitive vendor evaluations with an emphasis on reproductive and fetal pathology. EPSL concluded that the Provantis solution, in conjunction with Instem’s tailored services, would propel them to the next level of operational effectiveness and customer-sponsor satisfaction.  
EPSL will be using Instem’s Software-as-a-Service model allowing them to access Provantis over the Internet. Their online subscription includes all 3rd party licenses such as Oracle and SAS, along with training, maintenance, unlimited help desk support and Instem’s Validation Pack. Removing the need for on-site software ensures clients like EPSL can access the latest major releases of Provantis without the delays and costs sometimes involved with site-based installations.   
Since 2005, Instem has utilized a state-of-the-art data center based in the US, which is being used by clients running GLP and non-GLP studies.   
“In addition to the benefits of their software solution, it’s obvious to me that Instem will become a true extension of our business, ensuring we receive the highest amount of value from our investment,” states Gary Wnorowski, President of EPSL. “The approach they use allows our staff to learn the system at their own pace by leveraging features and functions that are tailored to our needs. Automating with Provantis will additionally enable us to expand our services and conduct more complex and longer term studies.”  
EPSL is also benefiting from Instem’s Specialized Solutions program, which is specifically designed for clients needing a more tailored approach to implementation, training, validation and support services. With dedicated client specialists and extended customer care, this program is perfect for smaller laboratories, those conducting research in academic or government settings, non-GLP environments or those running non-traditional toxicology studies.  
The Specialized Solutions program features a Continuous Learning Model, helping users learn faster and retain more without the distractions and disruptions other vendors may cause during “deliver everything at once” implementations. Using this exclusive method, clients stay connected with Instem when they need them the most, which often is for one year following their first Provantis study. EPSL now has ON-demand access to educational industry experts to help with a new study design, more advanced learning or anything else that can maximize their use of Instem software solutions.   
About Provantis®  
Provantis is a modern, fully integrated software system for single users and global organizations engaged in preclinical evaluation studies. Orchestrating every facet of preclinical drug safety assessment, Provantis streamlines processes and workflows with straightforward, intuitive functionality for simple or complex studies within a GLP or non-GLP environment, on-site or over the Web.  
About Eurofins Product Safety Labs (EPSL)  
Eurofins Product Safety Labs provides research and testing services to the agrichemical, chemical, pharmaceutical, dietary supplement/functional foods, personal care, animal health, biotechnology and household product industries. EPSL offers a broad range of services including toxicology, analytical and bioanalytical chemistry and pharmacology.  
More information can be found at www.productsafetylabs.com  
About Instem  
Instem is a leading supplier of IT applications to the early development healthcare market, delivering compelling solutions for data collection, management and analysis across the R&D continuum. Instem applications are in use by customers worldwide, meeting the rapidly expanding needs of life science and healthcare organizations for data-driven decision making leading to safer, more effective products.  
Instem’s portfolio of software solutions increases client productivity by automating study-related processes while offering the unique ability to generate new knowledge through the extraction and harmonization of actionable scientific information.  
Instem supports over 400 clients through full service offices in the United States, United Kingdom and China with additional locations in India and a full service distributor based in Japan.  
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FDA Issues Draft Guidance, Moves Closer to making SEND a Requirement  
NEWS FLASH  
FDA has issued the long-awaited draft guidance for providing regulatory submissions in electronic format. For those of you following SEND, please review via the link below and contact Instem to help you understand how to best leverage the standard in preclinical.  
Guidance for Industry - Providing Regulatory Submissions in Electronic Format  
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Instem Releases Next Version of Provantis Preclinical Software Suite  
Provantis Version 9.4 Delivering Increased Reporting Capabilities and New Features for Pathology  
CONSHOHOCKEN, PA - - December 12, 2014 - -Instem, a leading provider of IT solutions to the global early development healthcare market, is pleased to announce the latest release of its world-leading Provantis® preclinical software solution.  
Provantis version 9.4 delivers new features and functions within the Reporting, Tables & Statistics and Pathology modules.  
Highlights of the release include:  
  
New Clinical Observation reports  
Enhanced statistical marking to help further simplify the presentation of statistical outcomes  
New enhancements to Histology data entry screens and expansion of glossary  
New Gross Pathology auditing and raw data report features  
  
“We are extremely excited about the release of version 9.4, which builds upon the success of the Provantis 9 platform,” comments Gregor Grant, Senior Vice President at Instem. “Leading up to this release we conducted a comprehensive outreach program, which included a series of Express Webcasts outlining the key changes in 9.4 and the benefits that it can deliver. Interest in Provantis version 9.4 is very strong, and we are looking forward to helping existing and prospective clients alike take advantage of the new features and functions to achieve their next level of operational efficiency.”  
The leading system of its type around the world, Provantis is a fully integrated software suite for organizations and universities engaged in non-clinical evaluation studies. From single-users to large multi-site laboratories, Provantis streamlines processes and workflows with straightforward, intuitive functionality for simple and complex studies within GLP or non-GLP environments. Provantis applications can be purchased and installed on-site or clients can enter into a subscription and access Provantis over the Internet via Instem’s professionally managed cloud platforms that are run from centralized state-of-the-art data centers.  
Anyone interested in learning more about this latest release of Provantis is encouraged to contact Instem at info@instem.com.   
About Instem   
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Instem Helping to Educate the Quality Assurance Community on SEND  
Instem to co-present at Research Quality Association’s North American Regional Forum  
CONSHOHOCKEN, PA – March 17, 2017 - - Instem, a leading provider of IT solutions to the global early development healthcare market, is pleased to announce they will be co-presenting on CDISC’s Standard for Exchange of Nonclinical Data (SEND) at the Research Quality Association’s (RQA) North American Regional Forum.  
Taking place Tuesday, March 21st at GlaxoSmithKline in Mississauga, Ontario, attendees to the session will learn about:  
  
An introductory overview of SEND  
Considerations when preparing for SEND, including how and where Quality Assurance should be involved  
Challenges that organizations go through when they are starting with SEND, both from a data perspective as well as a process perspective  
The importance for sponsors to perform a SEND review even if their SEND conversions are being handled by a CRO  
Specific examples of what QA departments are doing to successfully implement SEND  
  
“I am thrilled to co-present this session on the impact of SEND on the QA community. This forum is the perfect environment to continue Instem’s commitment to educate and prepare CROs and Sponsors for SEND,” said Donna Danduone, Senior Director, Outsourcing Services at Instem.  
For more information on this session, or Instem’s submit™ platform, the most widely adopted SEND software and outsourced study services in 15 countries, email info@instem.com.   
About the Research Quality Association  
The RQA is an association dedicated to providing status and visibility for those concerned with the quality of research and development within the pharmaceutical, agrochemical, chemical and medical devices industries.   
  
 Since its inception in 1977, the RQA has grown and developed to reflect regulatory changes, the impact of regulatory inspection and the changing structure and needs of industry. For more information on the RQA, visit www.therqa.com.   
About Instem  
Instem is a leading supplier of IT applications and services to the early development healthcare market delivering compelling solutions for data collection, analysis and regulatory submissions management. Instem solutions are in use by customers worldwide, meeting the rapidly expanding needs of life science and healthcare organizations for data-driven decision making leading to safer, more effective products.  
Instem’s portfolio of software solutions and consulting services increases client productivity by enhancing product development processes while offering the unique ability to generate new knowledge through the extraction and harmonization of actionable scientific information.  
Instem supports over 500 clients through offices in the United States, United Kingdom, France, Japan, China and India.  
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NCDSER Purchases Instem's Provantis Preclinical Software Suite  
Leading China CRO Selects Provantis Integrated Software Solution for Shanghai Headquarters  
CONSHOHOCKEN, PA – (Business Wire) - July 16 2014 - - Instem, a leading provider of IT solutions to the global early development healthcare market, is pleased to announce that the National Shanghai Center for Drug Safety Evaluation and Research (NCDSER), also known as Shanghai InnoStar Bio-Tech Co. Ltd., has purchased the Provantis® preclinical software suite to automate laboratory processes at their R&D facility in the Zhangjiang Hi-Tech Park, Pudong, Shanghai, China.   
Founded in 1993, NCDSER is one of China’s leading CROs and enjoys a prestigious reputation within the region. NCDSER is SFDA, FDA and OECD GLP certified and has submitted numerous high quality safety evaluation studies and IND packages to both the Chinese and US FDA. NCDSER has recently undergone an impressive expansion program, adding increased laboratory space and additional animal rooms at their Shanghai facility.  
Key Facts  
  
NCDSER to implement Provantis 9, the latest version of Instem’s preclinical software solution suite  
Comprehensive suite of Provantis modules to be deployed including General Toxicology, Reproductive Toxicology, Pathology and Clinical Pathology  
Provantis to replace a combination of in-house developed applications and legacy systems to streamline processes   
Contract awarded following a detailed competitive evaluation; Provantis recognized as the overwhelming standard within China and the leading solution around the world   
NCDSER to use the SaaS delivery model from Instem’s Shanghai-based data center, adding another large and prestigious laboratory to Instem’s established hosting data center client roster   
5-year agreement with on-line deployment starting in 2014  
A range of professional services purchased to facilitate quicker implementation and faster return on investment  
  
Professor Jing Ma, Executive Director at NCDSER said “We are extremely pleased to be deploying Provantis at our Shanghai facility. We recognize that Instem and Provantis have fast become the gold standard within China and we look forward to joining the expanding Provantis user community within China and across the globe.”   
Neil Donaldson, VP Sales Europe & Asia, Instem commented “We are delighted to welcome NCDSER as our latest client. NCDSER is recognized as a center of excellence within the region and we are honored that they have chosen Instem to support them in their growth plans. We look forward to a long and successful partnership.”   
About NCDSER  
Founded in 1993, National Shanghai Center for Drug Safety Evaluation and Research (NCDSER), also known as Shanghai InnoStar Bio-Tech Co. Ltd., is a leading preclinical CRO in China. As the first CFDA-certified GLP laboratory and the most comprehensive and experienced Chinese toxicology CRO, NCDSER has submitted numerous high quality safety evaluation studies and IND packages to both CFDA and US FDA. Since being certified by CFDA in 2003, NCDSER has evaluated a total of 506 compounds including 417 small molecules, 72 biologics and 17 TCMs. NCDSER is experienced in designing studies following the guidelines of different international regulatory authorities including FDA, OECD and CFDA.  
NCDSER serves 300+ clients across North America, Europe and Asia  
To learn more about NCDSER please visit http://www.innostarsh.com/enabout.asp  
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SRI International Chooses Instem's SEND Solutions  
SRI International Deploying Submit Software Using SaaS  
CONSHOHOCKEN, PA - (BUSINESS WIRE) – September 1, 2015 - -Instem, a leading provider of IT solutions to the global early development healthcare market, announced today that SRI International (SRI) has purchased a comprehensive suite of software solutions to support CDISC’s Standard for Exchange of Nonclinical Data (SEND).   
In December 2014, the FDA issued the final Guidance for Standardized Study Data for providing regulatory submissions in electronic format. The introduction of SEND for both regulatory submission and the electronic exchange of toxicology data is having a significant impact on the industry, with many organizations increasingly turning to Instem to help them become SEND-enabled.   
Key Facts  
  
SRI International to deploy submit™, a suite of integrated tools and services for the creation and management of SEND datasets and associated documents.  
SRI International’s deployment to include the SENDView application to enable simplified review of SEND datasets.  
SRI International to access submit and SENDView using Instem’s SaaS delivery model.   
  
Mike Harwood, Senior Vice President, Instem, commented “SRI is a diverse and dynamic organization, and we are pleased to strengthen our relationship with them. Instem has the largest community of SEND clients in the world, supported by the industry’s leading SEND experts. We are delighted to welcome SRI to this established and rapidly growing community.”   
Instem has been extensively involved in the creation and development of SEND since its inception, working closely with SEND pilot organizations, the FDA and industry to help define the standard and align it with industry practices. As a result of this detailed involvement, Instem developed the first adopted set of complete SEND management tools in the market, with Instem SEND solutions now licensed across 12 countries at over 34 sites.   
About SRI International  
SRI International creates world-changing solutions to make people safer, healthier, and more productive. SRI, a research center headquartered in Menlo Park, California, works primarily in advanced technology and systems, biosciences, computing, and education. SRI brings its innovations to the marketplace through technology licensing, spin-off ventures and new product solutions.   
About Instem  
Instem is a leading supplier of IT applications to the early development healthcare market delivering compelling solutions for data collection, management and analysis across the R&D continuum. Instem applications are in use by customers worldwide, meeting the rapidly expanding needs of life science and healthcare organizations for data-driven decision making, leading to safer, more effective products.  
Instem’s portfolio of software solutions increases client productivity by automating study-related processes while offering the unique ability to generate new knowledge through the extraction and harmonization of actionable scientific information.  
Instem supports over 400 clients through full service offices in the United States, United Kingdom and China with additional locations in Japan and India.  
Meeting clients at the intersection of investment & return™.  
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Instem at PHUSE EU Connect 2023  
Instem Clinical Trial Acceleration & Transparency, Booth 20  
Stop by booth #20 to learn more about Instem’s powerful software solutions & services.   
Accel a turnkey cloud based statistical computing environment pre-loaded with all the tools, applications and licenses your biometric team needs to efficiently share data, programs, and analysis. And it’s all validated and ready for use within 1 week, removing any disruption to your teams’ workflow.   
Aspire is a clinical analysis framework that’s flexible clinical components allow data scientists to focus on the managing of the data by automating mundane tasks which also allows a fit-for-purpose workflow and is configured on an extendable cloud architecture.   
Blur is the industry leading anonymization and quantifiable risk measurement tool. It was built in collaboration with pharma sponsors and has a user-centric design with Natural Language Processing (NLP) capabilities.  
Instem are proud to Sponsor and host the Speed Networking Session on Sunday Evening   
When: Sunday 5th November 17.00-18.30  
Where: Hall 3 Come by Hall 3 at 5pm and meet professionals from industry. Speed networking, sponsored by Instem is a great way to learn more and interact with peers. The right conversation at the right time can enhance the entire conference experience.   
  
Instem Event Schedule  
Instem Presentations and Workshops  
Monday 6th November  
14:00-14:30, Hall 6a - Presentation TT04: Navigating R Package Management in a Validated Environment: Maintaining and Implementing the Latest R Packages with Different Versions of R. Rakesh Gotiwale, Senior Consultant, Instem  
Tuesday 7th November   
11:40-12:00, Hall 10A - Presentation DS03: The Digital Protocol Is Just the Beginning. Or Is It? Thierry Philippe, Principal Business Consultant, Instem  
13:30-15:30, Professional Development Workshop - Exploring Neurodiversity: Impacts, Experiences and Best Practices within our Industry. Jenni Dootson, Global Learning, Culture & Development Director, Instem   
13:30-14:00, Hall 10B - Presentation DH05: A Data Lake is Not a CDR and a CDR is Not a Data Lake: Understanding the Differences and the Value of Each. Chris Decker, VP CTA Solutions, Instem  
14:00-14:30, Hall 7 - Presentation SD06: Leveraging the Cloud to Transform Your SCE. Alastair Scarlett, Senior Consultant, Instem   
16:00-17:30, Hall 9 - People Leadership & Management Interactive Session - Building a Diverse and Successful Strengths Based Team in Today’s New World. Chris Decker, VP CTA Solutions, Instem  
Wednesday 8th November   
12:00-12:30, Hall 6a - Presentation RE07: Building an Integrated Preclinical and Clinical Data Platform to Enable Rapid Translational Data Review. Brenda Finney, VP Translational Science, Instem   
  
We are also pleased to be presenting at the Poster Session on Tuesday 7th November, 17:30-18:30, Hall 3   
‘Where are you on the blob tree?’ Presented by Flo Ratcliffe, Project Manager, Instem  
This poster will explore techniques and tools used to aid team health and monitor project teams in a work-from-home world, such as The Blob Tree, Clifton Strengths, and more. It will also examine the link between team health and communication frequency between Project Management and the team(s) within Agile management.   
  
   
  
  
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Instem Announces Details of 2015 International Conference  
Conference Features Presentations, Interactive Breakouts and Workshops; Connecting with Clients from Around the Globe  
CONSHOHOCKEN, PA - (BUSINESS WIRE) – July 28, 2015 - -Instem, a leading provider of IT solutions to the global early development healthcare market, announced today that the 2015 Instem International Conference (IIC) will take place at the Hilton Penn’s Landing Hotel, Philadelphia on October 6th & 7th.  
The IIC is a key component of Instem’s Customer Involvement Program (CIP), providing opportunities for Instem clients across the globe to hear the latest news on product strategy, gain in-depth knowledge of Instem’s products and services, help shape and influence product development and become more engaged with key industry initiatives such as SEND. The IIC also provides excellent networking opportunities, enabling delegates to connect with their industry peers and key members of the Instem team, sharing best practice and learning opportunities.   
The 2015 conference will offer delegates 2 full days of platform presentations, interactive breakout sessions, 1:1 Advice Clinics and Group Workshops with Instem Specialists, as well as a lively networking and social program. The agenda features key speakers from Instem and industry who will address a range of topics including Transformational IT projects, Preparing For & Implementing SEND, Software System Validation, Leveraging Online Platforms and Future Technologies. The Philadelphia conference follows on from two highly successful user meetings held in China and Japan earlier in the year, as well as an ongoing series of Special Interest Group meetings for Instem’s large and growing global SEND client community.   
Gary Mitchell, VP Global Marketing, Instem said “The IIC is an extremely popular component of our Customer Involvement Program, delivering demonstrable added value to our global clients of all sizes. We also are excited to announce that this year, for clients who are unable to travel to Philadelphia, we will be offering Virtual IIC passes, giving clients the opportunity to join sessions via live streaming right from their desktop. This is proving to be very popular and early registrations are extremely encouraging.”  
For further details about the IIC please contact iic@instem.com  
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NCSED Chooses Instem's Integrated Software Suite for Preclinical Studies in China  
Provantis® Preclinical Software Solution Chosen for Deployment within China at Government Owned Laboratory  
CONSHOHOCKEN, PA - (BUSINESS WIRE) –December 8, 2011 - - Instem, a leading provider of early development software applications, announced today that China’s National Center for Safety Evaluation of Drugs (NCSED) has selected Instem’s Provantis® software solution suite to automate their preclinical study processes.  
The NCSED, a subsidiary of the Chinese State Food & Drug Administration (SFDA), manages and sponsors government and commercial contract research studies throughout the PRC (Peoples Republic of China). The NCSED additionally plays a vital role in the education and training of Good Laboratory Practice (GLP) inspectors and in developing and enforcing Chinese drug safety assessment regulations.  
Key Facts  
  
Integrated General Toxicology, Clinical Pathology and Pathology modules to be deployed at the Beijing facility  
Competitive evaluation conducted; Provantis recognized as the overwhelming standard in western facilities and as the leading solution within the PRC  
Provantis offering NCSED compliance to national and western standards, dual language operation and proven protocol-driven automation   
Comprehensive package of implementation services purchased including project management, installation, training and validation  
NCSED to be supported from Instem’s full service office in Zhangjiang Hi-Tech Park, Shanghai, China   
  
“We are delighted to welcome NCSED as our newest client within China” comments Neil Donaldson, VP Operations EU & Asia. “NCSED is one of China’s leading laboratories and given their specific responsibilities within China’s regulatory framework, we are honored that they have chosen Instem’s Provantis solution to automate their research laboratory.”  
Mr Baowen Li, NCSED Deputy Director said “Using Instem’s Provantis data management solution will support NCSED in our mission to become a world-leading GLP laboratory. We are looking forward to working closely with Instem and to deploying more of their services and solutions in the future.”   
As the first western toxicology/pathology software supplier to enter the Chinese market, Instem officially deployed its first China-based system in one of the largest and most advanced vivariums during 2006. Acknowledging analyst projections that the PRC is growing to become the second largest pharmaceutical market in the world, Instem established a full-service office in Shanghai, recruited local staff and has localized the Provantis product suite into Mandarin Chinese. Instem is supporting international organizations and domestic laboratories exclusively serving the PRC.  
About NCSED  
The NCSED is located in Hong Da Zhong Lu A8 of the Beijing Economic-Technological Development Area and has a total area of 7104.9 square meters. The NCSED is attached to the National Institute for Food and Drug Control (NIFDC), the State Food and Drug Administration (SFDA) of the People's Republic of China. Its main business is the safety evaluation in the non-clinical study of drugs.  
The center can carry out the following types of studies; Single and repeated dose Toxicity, Reproductive and Developmental, Genotoxicity, Carcinogenicity, Local Toxicity, Immunogenicity, Safety Pharmacology and Toxicokinetic Studies.  
About Instem  
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Tripod China Chooses Provantis Preclinical Software Suite for Nanjing Facility  
Chinese CRO Purchases Provantis SaaS to Increase Efficiencies, Further Enhance Quality and Automate Processes at R&D Facility in Nanjing.  
CONSHOHOCKEN, PA – (Business Wire) –May 8 2015 - - Instem, a leading provider of IT solutions to the global early development healthcare market, is pleased to announce that Jiangsu Tripod Preclinical Research Laboratories Inc. (Tripod) has purchased the integrated Provantis preclinical software solution suite to automate processes at its Nanjing facility.  
Founded in April 2008, Tripod is a nonclinical Contract Research Organization providing a wide range of high quality studies including Bioanalysis/DMPK/TK, general toxicity, safety pharmacology, reproductive toxicity, Geno toxicity, carcinogenicity studies and clinical pathology and histo-pathology tests.   
Tripod’s investment in Provantis will deliver increased efficiencies in the collection, storage and reporting of key research data and will further improve service levels to sponsors.   
Key Facts  
  
Tripod to implement Provantis 9, the latest version of Instem’s preclinical software solution suite  
Comprehensive suite of Provantis modules to be deployed including General Toxicology, Tables & Statistics, Protocol & Report Assembly, Dispense, Pathology, Clinical Pathology and Data Import  
Contract awarded following a detailed competitive evaluation; Provantis recognized as the overwhelming standard within China and the leading solution around the world   
Tripod to use the SaaS delivery model from Instem’s Shanghai-based data center, adding yet another laboratory to Instem’s established and rapidly growing hosting data center client roster   
A range of professional services purchased to facilitate quick implementation and a rapid return on investment  
  
Neil Donaldson, VP Sales Europe & Asia, Instem, commented “Tripod is a well-established CRO with exciting growth plans and we are honored that they have chosen Instem and Provantis to help them further improve the level of service to their sponsors and support them in their objective of becoming a world-class non-clinical research organization.”   
Instem’s Provantis solution was the first western toxicology/pathology software to enter into the Chinese market, deploying its initial system in one of the largest and most advanced vivariums during 2006. As the Chinese preclinical market continues to grow, Instem is leading the market with Instem solutions deployed at more sites within the region than any competing product.   
Instem has an established full-service office in Shanghai and supports organizations serving the PRC through traditional on-site systems as well as through their SaaS delivery model from a secure, professionally managed data center based in Shanghai.   
About Tripod  
Located in Nanjing, the 2nd largest metropolitan in the Yangtse River Delta of China, Tripod takes great advantages of local industrial, cultural and educational resources. Strictly following OECD, FDA, SFDA,GLP regulations and AAALAC animal welfare requirements, Tripod is able to provide accurate, reliable and high quality nonclinical research services for global pharmaceutical companies, drug R&D enterprises and institutes. The core strength of Tripod is its intensively and extensively experienced professionals and management team. Tripod aims to become a world-class non-clinical contract research organization in the near future.  
For further information about Tripod please visit http://www.tprglp.com/english/index.asp  
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Instem and AstraZeneca Presenting at the British Society of Toxicological Pathology Annual Meeting  
Instem and AstraZeneca to present “Cardiovascular Drug Toxicities Associated With Pharmacological Activity; Data Harmonization Makes The 'Known' Visible”  
CONSHOHOCKEN, PA – November 11, 2013 - -Instem, a leading provider of IT solutions to the global early development healthcare market, is pleased to announce that Dr. Jane Reed, Director of Safety Intelligence at Instem, will be co-presenting a poster at the British Society of Toxicological Pathology (BSTP) 28th Annual Scientific Meeting in Cheshire, UK.   
The poster presentation, “Cardiovascular Drug Toxicities Associated With Pharmacological Activity; Data Harmonization Makes The “Known” Visible” has been developed in conjunction with AstraZeneca scientists from Sweden and the UK. The poster will discuss how data from Instem’s Safety Intelligence Program™ (SIP) has been combined with target profiles of drugs to identify associations between pharmacological activities and cardiac events.   
The 28th Annual BSTP meeting is being held jointly with the Safety Pharmacology Society (SPS) and is sponsored by the Health and Environmental Sciences Institute (HESI). The theme of the meeting is “Integrated Cardiovascular Safety Risk Assessment for New Candidate Drugs from Functional and Pathological Data” The meeting is being held at AstraZeneca’s Alderley Park site, Cheshire, UK on November 14th & 15th.  
The poster will be on display in the BSTP Exhibit Hall throughout the meeting. Instem will also be exhibiting at booth # 4, where delegates will have the opportunity to participate in a free SIP taster session. Delegates are invited to submit their cardiovascular safety question and Instem will provide a free output of the SIP ToxPath Knowledgebase to provide them with an answer.   
At the BSTP booth, Instem will also be showcasing their market-leading Provantis® Pathology solution for the collection, processing and reporting of data for gross and histopathology.  
The BSTP is a non-profit organization that seeks to advance pathology for the public benefit in all its aspects pertaining to the effects of extraneous substances and environmental agents to which man or other species are exposed through design or adventitiously. Additionally it seeks to foster training and advance education in toxicological pathology by providing continuing professional development seminars and educational training modules.  
About Instem  
Instem is a leading supplier of IT applications to the early development healthcare market, delivering compelling solutions for data collection, management and analysis across the R&D continuum. Instem applications are in use by customers worldwide, meeting the rapidly expanding needs of life science and healthcare organizations for data-driven decision making leading to safer, more effective products.  
Instem’s portfolio of software solutions increases client productivity by automating study-related processes while offering the unique ability to generate new knowledge through the extraction and harmonization of actionable scientific information.  
Instem supports over 400 clients through full service offices in the United States, United Kingdom and China with additional locations in India and a full service distributor based in Japan.  
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Biotoxtech, South Korea To Deploy Comprehensive Suite of Preclinical Study Management and SEND Software Solutions from Instem  
   
  
  
  
  
  
  
  
  
  
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Biotoxtech, South Korea to Deploy Comprehensive Suite of Preclinical Study Management and SEND Software Solutions from Instem  
Instem Technology Selected to Streamline Preclinical Operations, Improve Productivity and Ensure SEND Compliance at South Korea’s Largest Preclinical R&D Facility   
CONSHOHOCKEN, PA – Business Wire, June 3, 2020 - Instem, a leading provider of IT solutions to the global life sciences market, announced today that South Korean Contract Research Organization (CRO), Biotoxtech Co., Ltd. (Biotoxtech) has purchased a comprehensive package of preclinical data collection, analysis and regulatory submissions management solutions to automate and optimize study related processes at its R&D facility in South Korea’s North Chungcheong Province.   
Founded in August 2000, Biotoxtech boasts the largest R&D facility within South Korea and was the first CRO in the region to achieve GLP, AAALAC, Japan PMDA and US FDA certification. Biotoxtech performs around 800 experiments a year for its domestic and international clients; its extensive range of services includes Toxicology, Reproductive & Developmental, Ecotoxicological, Genetic Toxicology and Safety Pharmacology studies, as well as Pharmacokinetics testing and Biological Sample Analysis.  
Biotoxtech sought to replace numerous disparate in-house and paper-based systems to harmonize preclinical data collection, management and reporting, streamline laboratory processes and meet growing client demand for SEND (Standard for Exchange of Nonclinical Data). Instem was selected following a comprehensive competitive vendor evaluation process that included detailed planning and discovery sessions, product demonstrations, portfolio review sessions and onsite visits to Instem offices in the UK and China.  
This deal includes software and services from across Instem’s solution portfolio including Provantis®, the leading solution for preclinical study management, submit™, the most widely adopted software suite for creating, visualizing and managing SEND data, and Cyto Study Manager, for the management of genetic toxicology assays.   
Key Facts  
  
Biotoxtech has purchased an extensive suite of Provantis modules including Inlife Toxicology, Pathology, Clinical Pathology, Dispense, Reproductive Toxicology, Report Assembly and Toxicology Resource Planning (TRP™)  
Biotoxtech to deploy Instem’s submit™ software solution for the creation and management of SEND compliant datasets   
Instem to assist Biotoxtech to reduce the amount of paper-based data used within their laboratory through the deployment of Instem’s Logbook technology  
Biotoxtech to harness the power of the Provantis Academy e-learning platform and a range of professional services, facilitating quick implementation and a rapid return on investment   
Biotoxtech has selected Cyto Study Manager to streamline their genetic toxicology study workflows into one comprehensive system. Cyto Study Manager will enable Biotoxtech to integrate genetox data acquisition, auditing, reporting, historical control data and study management into a single system, streamlining genetic toxicology operations, reducing costs, increasing efficiencies and improving regulatory compliance.   
  
Dr. Jong-Koo Kang, CEO, Biotoxtech said “Our investment in Instem’s market leading solutions will deliver wide reaching, transformational benefits for our organization and our clients. We recognized that a deployment of this size will require a partner, not simply a vendor. Our combined commitment to this valuable project will vastly enrich our research processes and ensure even higher levels of service and faster response times for our clients.”   
Jon Sparkes, Senior Director Sales, Europe & Asia, Instem, commented, “We are delighted to welcome Biotoxtech to our user community and are looking forward to delivering tangible business impact for them as their premier preclinical technology partner”.  
About Biotoxtech  
Established in August 2000, Biotoxtech Co., Ltd. (Biotoxtech) is a non-clinical Contract Research Organization based in Chungcheongbuk-do, South Korea.  
Biotoxtech serves domestic and international clients and has submitted hundreds of documents to numerous international regulatory agencies including within the US, Japan and Europe for new compounds, as well as performing the most GLP certified non-clinical GLP studies in Korea.  
Biotoxtech is the only CRO to be KOSDAQ listed in Korea and was the first organization in Asia to receive Full AAALAC Accreditation. Furthermore, Biotoxtech has received Korea’s first accreditations in safety pharmacology and alternatives to animal testing. In January 2015, Biotoxtech was the first domestic private non-clinical testing institution to receive GLP accreditation from the US FDA.   
Biotoxtech established a joint venture company, SCAS-BTT Bioanalysis Co., Ltd. (SBB), with Japan's Sumika Chemical Analysis Service to support the toxicokinetics/ pharmacokinetics sector.  
For further information visit http://eng.biotoxtech.com/  
About Instem  
Instem is a global provider of leading software solutions and services that are helping over 500 clients bring their life enhancing products to market faster. We enable clients in the life sciences to more efficiently collect, analyze, report and submit high quality regulatory data, while maintaining compliance for their products around the world.   
Instem solutions are in use by customers worldwide, meeting the rapidly expanding needs of life science and healthcare organizations for data-driven decision making, leading to safer, more effective products.  
Instem supports its global roster of clients through offices in the United States, United Kingdom, France, Japan, China and India.   
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Industry Experts Join Instem; New Jersey Office Opens  
Instem to Accelerate Penetration of New Solutions Throughout Preclinical Market  
CONSHOHOCKEN, PA - (BUSINESS WIRE) - January 5, 2010 - - Instem, a leading provider of early drug development software solutions, announced today that two Preclinical industry experts are joining the company and will be based out of a new Instem office in Bridgewater, New Jersey.   
Jennifer Feldmann, formerly President of Xybion® will take on the newly created position of Vice President of Business Development when she joins Instem on February 1st 2010, and will report directly to Phil Reason, Instem’s Chief Executive. Donna Danduone, formerly Xybion’s Professional Services Director and Quality Manager, has already taken on the role of Senior Consultant with Instem, having joined the company December 1st 2009.  
Phil Reason commented, “I’m absolutely delighted about Donna and Jennifer joining us. Each of them brings a unique set of skills from their many years at Xybion that dovetails perfectly with our ongoing initiatives for continuous innovation. Both Jennifer and Donna will be helping advance key strategic projects such as Instem business intelligence and data exchange solutions that are valuable to all drug development companies, no matter whose data collection software they use. “   
Instem’s New Jersey office is located near several major Pharmaceutical clients and builds upon the successes of 2009 which included Instem adding 13 new customers and opening a full service office in Shanghai, China.  
Jennifer said “I’ve long believed that a winning company in this industry will provide a solution that allows effective use of the enormous volume of data generated during drug development. While there are many good reasons for a company to retain specialized scientific data collection systems, a single solution for aggregation, exchange, and analysis of data is the key to the future. Instem has clearly been at the forefront in these areas and this is a fantastic opportunity to use my industry experience and relationships to promote this vision. I’m very pleased to be joining Instem’s exceptional team.”  
Additionally, as clients make the transition from competitive Preclinical data acquisition solutions, particularly from Xybion, Jennifer and Donna will be very helpful to quickly highlight many of the value-added features and functions included within the Instem product suite.  
Donna stated “In the current economic climate it’s very reassuring to join a company that is growing so successfully and continuing to invest heavily in its product development, sales, marketing and service delivery teams. I’m relishing the opportunity to be involved with the client selection and implementation of Instem’s Provantis® solutions, and am particularly excited to be part of a focused team introducing Instem’s newer solutions. I have worked closely with Jennifer for 12 years and was very excited to hear that she will also be joining Instem.”   
About Provantis®  
Provantis is a modern, fully integrated software system for single users and global organizations engaged in preclinical evaluation studies. Orchestrating every facet of preclinical drug safety assessment, Provantis streamlines processes and workflows with straightforward, intuitive functionality for simple or complex studies within a GLP or non-GLP environment, on-site or over the Web.  
About Instem  
Instem is a leading supplier of IT applications to the early development healthcare market, delivering compelling solutions for data collection, management and analysis across the R&D continuum. Instem applications are in use by customers worldwide, meeting the rapidly expanding needs of life science and healthcare organizations for data-driven decision making leading to safer, more effective products.  
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Instem to Showcase Enhanced Provantis Pathology Solution at Upcoming STP Symposium  
Powerful study management updates provide cutting-edge digital pathology capabilities.  
PHILADELPHIA, PA – (BUSINESS WIRE) – June 13, 2024 – Instem, a leading provider of IT solutions and services to the global life sciences market, announced today that it will be showcasing its enhanced Provantis® Pathology solution at this year’s Society of Toxicologic Pathology (STP) Symposium June 16-19, in Baltimore, MD.   
A cornerstone of Provantis, the leading software solution for managing preclinical tox/path studies, Provantis Pathology is used by organizations across the globe, from single user remote Pathologists to multi-site laboratories. The latest additions to this solution support greater web-based functionality, significant digital pathology integration, and enhanced read-across capabilities with a dynamic histopathology matrix.   
Key highlights include:  
  
Web Histopathology matrix - Improved look and feel UI design hosted in a web-based application giving pathologists:  
   
Faster guided data entry  
Improved application performance  
Spotlighter™ – A web-based software solution for historical data management, enabling users to store, retrieve, and evaluate histopathology data across studies.  
Digital pathology – Synchronized with a digital pathology platform, pathologists can navigate between Histopathology data entry and the corresponding digital image(s).  
  
A key part of Instem’s enhanced pathology offering includes the introduction of a partnership/integration with Pathcore® and their secure, cost-effective, and scalable digital pathology software for image management.   
Phil Ledsome, Preclinical Product Director at Instem said “Pathcore’s easily accessible and reliable image management system PathcoreFlow™ is a powerful complement to the Provantis Study Management platform, and we are thrilled to have a seamless API with their system.”  
“We encourage attendees to visit booth #200 to see firsthand how the latest version of Provantis Pathology empowers Pathologists with the most efficient way to read, analyze, and report their studies” comments Carlos Frade, VP Market Development at Instem.  
Not attending this year’s STP Symposium? Learn how Instem’s Provantis solution can support your Pathologists by simply downloading the fact sheet or contacting info@instem.com.   
About Instem  
A global provider of leading software solutions, technology enabled outsourced services and powerful scientific insights, Instem is helping clients to bring their life enhancing products to market faster.  
We enable organizations in the life sciences to more efficiently collect, report and submit high quality regulatory data, while offering them the unique ability to generate new knowledge through the extraction and harmonization of actionable scientific information.  
Every day, across the entire drug development value chain, Instem solutions are meeting the rapidly expanding needs of life science organizations for data-driven decision making, leading to safer, more effective products.  
Instem supports its global roster of clients through offices in the United States, United Kingdom, France, Japan, China, and India.  
About Pathcore  
Pathcore® is dedicated to advancing digital pathology through innovative software solutions that empower organizations with the tools they need to implement digital transformations. For over two decades, our co-founders have led and developed widely used platforms including PathcoreFlow™, the Sedeen Viewer™, and PathcoreScholar™.  
   
 Our applications support a wide range of clients in more than 68 countries and 2000 organizations, making data easily accessible and driving the adoption of digital pathology.   
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Noble Life Sciences Selects Comprehensive Suite of Preclinical Software Solutions from Instem   
US Contract Research Organization Deploys Provantis Preclinical Software Solution to Automate Study Processes  
CONSHOHOCKEN, PA – Business Wire, June 6, 2018 - -Instem, a leading provider of IT solutions to the global life sciences market, is pleased to announce that Noble Life Sciences, Inc. (Noble) has purchased a comprehensive package of preclinical software solutions, including Provantis®, the market leading preclinical data management system.  
Noble is a full-service preclinical contract research organization offering standard GLP and non-GLP services, including safety and efficacy testing, for the development of drugs, vaccines and medical devices.   
Provantis will replace existing manual processes at Noble’s state of the art, 24,000 square feet AAALAC accredited facility in Maryland, delivering increased efficiencies in the collection, storage and reporting of preclinical data, as well as ensuring GLP and regulatory compliance.  
Additionally, Noble has purchased ACIS™, Instem’s Animal Care Information System, which will enable them to more efficiently manage the requisition, procurement and reporting of animal usage within their vivarium, and Logbook™, Instem’s ELN solution, which will allow Noble to vastly reduce the number of paper forms used across their laboratory.  
Key Facts  
  
Noble to deploy the Provantis preclinical software solution suite to automate study processes  
Client to implement ACIS, Instem’s Animal Care Information System, to deliver a complete animal management solution  
Noble deploying the Logbook ELN solution to reduce paper forms and provide a single, searchable, secure repository for their data   
Contract awarded following a rigorous competitive evaluation; Instem recognized as the leading organization in the field of preclinical IT solutions   
Instem solutions to replace existing manual processes at Noble’s facility  
Client to access Instem solutions via the SaaS delivery model, benefitting from lower infrastructure and support costs, together with flexibility and scalability to support further growth   
Noble has purchased a range of implementation services to ensure rapid deployment and quicker Return on Investment   
  
Srujana Cherukuri, Ph.D., Chief Executive Officer, Noble said “During our review of the available solutions on the market, it was evident that Instem is the clear leader in the area of preclinical IT solutions. Our investment in Instem solutions will enable us to deliver increased efficiencies, which will ensure even better quality of service and quicker response times for our clients.”   
Gregor Grant, Executive Vice President, Instem, commented, “We are delighted to welcome Noble to our growing client community and look forward to supporting them in their mission to assist their clients in conducting exceptional quality research to advance human health.”   
About Noble Life Sciences, Inc.  
Noble Life Sciences is a full-service preclinical contract research organization offering standard GLP and non-GLP services, including safety and efficacy testing, for the development of drugs, vaccines, and medical devices.   
Noble’s services also include the development of disease and animal models, the production of GLP and non-GLP custom polyclonal antibodies, the derivation and maintenance of animal breeding colonies, and animal housing and husbandry.   
Noble has more than 15 years’ experience contracting with vaccine, medical device and drug manufacturers to conduct GLP submissions. Examples include single and repeat dose toxicity, local tolerance, efficacy and safety, reproductive and developmental toxicity, bio distribution, and ocular and skin irritation evaluations.   
For further information please visit http://www.noblelifesci.com/  
About Instem  
Instem is a global provider of leading software solutions and services that are helping over 500 clients bring their life enhancing products to market faster. We enable clients in the life sciences to more efficiently collect, analyze, report and submit high quality regulatory data, while maintaining compliance for their products around the world.   
Instem solutions are in use by customers worldwide, meeting the rapidly expanding needs of life science and healthcare organizations for data-driven decision making, leading to safer, more effective products.  
Instem supports its global roster of clients through offices in the United States, United Kingdom, France, Japan, China and India.   
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Leading Chinese Research Institute Purchases Provantis Preclinical Software Solution for Shanghai Headquarters  
  
  
  
  
  
  
  
  
  
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Leading Chinese Research Institute Purchases Provantis Preclinical Software Solution for Shanghai Headquarters  
Provantis Chosen to Increase Efficiencies at Shanghai-based Research Facility  
CONSHOHOCKEN, PA – (Business Wire) –November 6 2014 - - Instem, a leading provider of IT solutions to the global early development healthcare market, is pleased to announce that the Shanghai Institute of Planned Parenthood Research (National Evaluation Centre for the Toxicology of Fertility Regulating Drugs) ( SIPPR-NTC) has purchased the Provantis Reproductive Toxicology software solution to automate processes at its Shanghai facility.   
Founded in 1978, SIPPR-NTC is recognized as a center of excellence in the area of reproductive health and is one of the major collaborating centers of the World Health Organization’s HRP program. HRP is the main instrument within the United Nations system for research in human reproduction, bringing together policy-makers, scientists, health care providers, clinicians, consumers and community representatives to identify and address priorities for research to improve reproductive health.   
SIPPR-NTC’s investment in Provantis will further streamline its research processes and will deliver increased efficiencies in the collection, storage and reporting of key research data.   
Key Facts  
  
Provantis Reproductive Toxicology module purchased by SIPPR-NTC for their Shanghai facility  
Contract awarded following a formal competitive tender; Provantis recognized as the overwhelming standard within China and the leading solution around the world  
Instem to implement a full turnkey solution, including hardware and software deployment  
SIPPR has purchased a range of professional services to facilitate quicker implementation and faster return on investment  
  
Dr. Zu-Yue Sun, Director, SIPPR-NTC, said “We are delighted to be deploying Instem’s world-leading Provantis software solution at our Shanghai facility. SIPPR-NTC has exciting growth plans for the future and we see our partnership with Instem and our investment in Provantis as a key component of our growth strategy.”  
Neil Donaldson, VP Sales Europe & Asia, Instem commented “We are extremely pleased to welcome SIPPR-NTC to our Provantis user community. SIPPR-NTC is recognized as a leading organization within their field and it is a great honor that they have chosen Instem to support them in their growth plans.”  
  
About SIPPR-NTC  
SIPPR-NTC is a principal member of the Shanghai Life Science Research Center, a national resource institute for fertility regulating studies, and one of the largest World Health Organization collaborating centers in the Asia Pacific region. With continuous support from the Government, World Health Organization, and UNFPA, SIPPR has developed into a comprehensive research center at a national level, as well as an international collaborating resource for human reproductive health. SIPPR has successfully conducted many key national projects and international research programs.  
To learn more about SIPPR please visit www.sippr.org.cn   
www.ntc-who.org  
  
About Instem   
Instem is a leading supplier of IT applications to the early development healthcare market delivering compelling solutions for data collection, management and analysis across the R&D continuum. Instem applications are in use by customers worldwide, meeting the rapidly expanding needs of life science and healthcare organizations for data-driven decision making leading to safer, more effective products.  
Instem’s portfolio of software solutions increases client productivity by automating study-related processes while offering the unique ability to generate new knowledge through the extraction and harmonization of actionable scientific information.  
Instem supports over 400 clients through full service offices in the United States, United Kingdom and China with additional locations in India and a full service distributor based in Japan.  
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Instem Exhibiting and Presenting at Society of Toxicology Meeting  
Instem Showcasing its Preclinical Solutions and Outsourced Services While Holding Educational Presentations Covering SEND and Target Safety Assessment  
CONSHOHOCKEN, PA - March 7, 2018 - - Instem, a leading provider of IT solutions to the global life sciences market, is pleased to announce it will be once again exhibiting at the Society of Toxicology Annual Meeting and ToxExpo at the Henry B. Gonzalez Convention Center in San Antonio, Texas March 11-15th.  
The largest event of its kind, the Society of Toxicology Annual Meeting and ToxExpo attracts nearly 7,000 attendees from more than 50 countries and features over 330 exhibitors. The meeting and exhibition offers stimulating lectures and presentations on scientific breakthroughs, important education and professional training opportunities.   
Attendees of this year’s exhibition can stop by one of Instem’s stands to hear about the latest capabilities of Instem’s market-leading preclinical software and outsourced services. Visitors can also join one of Instem’s Exhibitor Hosted Presentations.  
Visit Instem at stand #1223 to learn more about:  
  
Instem’s submit™-for-SEND software and outsourced study services, the most widely adopted in the industry. Come hear about the latest updates, including:  
  
SEND Explorer® for advanced SEND data visualization & analysis; offering a new range of features and capabilities such as a new Study Overview Page for capturing better insights.  
SENDTrial™; enabling clients to reduce the time required for trial design creation by up to 80%.  
Hear about the steady stream of clients that are turning to Instem as their partial or full exclusive SEND outsourcing partner.  
  
Provantis® for preclinical study data management; the #1 SaaS software solution that keeps you focused on your science, not your software. Online clients also have full access to the Provantis Academy of eLearning; stop by and let us demonstrate how we can make you even better at what you do.   
KnowledgeScan™; Learn how our technology-driven services are helping clients reduce the time & costs of target safety assessment by up to 50%.   
NOTOCORD-hem™;The leading solution for the acquisition, display and analysis of physiological signals. We are also introducing NOTOCORD-sense™, our new Cloud-based collaboration platform for the analysis and sharing of all experimental data, enabling clients to easily monitor, acquire and analyze data from anywhere in the world.   
  
Visit Instem at stand #730 to learn more about:  
  
Comet Assay IV - the market leading live video imaging system for accurate and reproducible slide comet scoring. Clients can score a comet slide in two minutes and it is the most efficient system on the market. Be sure to ask for a demo and a free trial!  
Cyto Study Manager - integrating genetox data acquisition, auditing, reporting and study management into a single system. Reduce costs while increasing efficiencies and improving regulatory compliance, all within one intuitive system.   
  
Instem Presentations – no advanced registration required:  
Solving Target Safety Assessment Challenges  
 Tuesday, March 13th  
 12 noon – 1pm  
 Room 217D  
 Complimentary lunch will be served, plus a prize draw!  
Session overview:  
 Companies are under enormous pressure to quickly produce high-quality target risk assessments to make drug development decisions. KnowledgeScan™ Target Safety Assessment (TSA) is revolutionizing this area. Hear how Instem clients are improving quality, reducing costs, getting faster results and gaining value by engaging in TSA projects with Instem.   
Ensuring SEND Success Beyond Regulatory Compliance  
 Wednesday March 14th  
 4:30pm – 5:30pm  
 Room 217A  
 Complimentary drinks and appetizers will be served, plus a prize draw!  
Session Overview:  
 SEND - is it simply a standard, or are there more commercial factors that organizations are overlooking? Join us for this informative session where we will be discussing how to exploit the standard beyond simply being compliant. During this time attendees will also receive the latest SEND updates.  
More information about all of Instem’s market leading SEND software and outsourcing services can be found at www.instem.com/solutions   
About Instem  
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Battelle Places Order with Instem for Provantis Preclinical and submit-SEND Software Solutions  
  
  
  
  
  
  
  
  
  
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Battelle Places Order with Instem for Provantis Preclinical and submit-SEND Software Solutions  
Instem Solutions to Automate Full Range of R&D Processes  
CONSHOHOCKEN, PA - (BUSINESS WIRE) – July 19, 2011 - -Instem, a leading provider of early development software applications, announced today that Battelle has purchased its Provantis® and submit™ preclinical software solutions to automate processes within their GLP compliant preclinical facilities.  
Battelle is the world’s largest independent research and development organization. Battelle’s health and life science capabilities support development, delivery, testing, and evaluation of innovative solutions for the biotech, pharmaceutical, and agrochemical industries and government agencies.   
Provantis is a modern, fully integrated software system for single users and global organizations engaged in   
 preclinical evaluation studies. Orchestrating every facet of preclinical drug safety assessment, Provantis streamlines processes and workflows with straightforward, intuitive functionality for simple or complex studies within a GLP or non-GLP environment, on-site or over the Web.  
Part of the Centrus™ solution suite, Instem’s submit™ software supports the Standard for Exchange of Nonclinical Data (SEND) initiative. Submit is the only fully integrated solution in production today for companies using SEND for the exchange, review and submission of research data. Converting data from any source system into SEND files, submit allows sponsors, CRO’s and regulators to share, visualize and analyze study data more efficiently.  
“Knowing the active role Battelle plays in conducting studies for a variety of clients, we are truly honored to welcome them as a new client,” said, John Anderson-Carter, VP North American Sales at Instem.   
About Battelle  
As the world’s largest, independent research and development organization, Battelle provides innovative solutions to the world’s most pressing needs through its four global businesses: Laboratory Management; National Security; Health and Life Sciences; and Energy, Environment and Material Sciences. It advances scientific discovery and application by conducting $6.5 billion in global R&D annually through contract research, laboratory management and technology commercialization. Headquartered in Columbus, Ohio, Battelle oversees 22,000 employees in more than 130 locations worldwide, including seven national laboratories which Battelle manages or co-manages for the U.S. Department of Energy and the U.S. Department of Homeland Security and a nuclear energy lab in the United Kingdom.   
  
 Battelle also is one of the nation’s leading charitable trusts focusing on societal and economic impact and actively supporting and promoting science, technology, engineering and mathematics (STEM) education.  
Learn more at www.battelle.org  
About Instem  
Instem is a leading supplier of IT applications to the early development healthcare market, delivering compelling solutions for data collection, management and analysis across the R&D continuum. Instem applications are in use by customers worldwide, meeting the rapidly expanding needs of life science and healthcare organizations for data-driven decision making leading to safer, more effective products.  
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Alizée Pathology Deploying Provantis Preclinical Software  
Maryland based Pathology Consultancy to Deploy Instem's Provantis Pathology Software Solution to Automate Laboratory Processes  
CONSHOHOCKEN, PA - (BUSINESS WIRE) – December 8, 2014 - -Instem, a leading provider of IT solutions to the global early development healthcare market, announced today that Alizée Pathology LLC (Alizée) has purchased the Provantis® Pathology software solution following a detailed competitive evaluation.   
Alizée is a dedicated, independent Pathology consultancy business, providing histopathological services to organizations conducting studies in the preclinical stage of product development. Alizée specializes in Histology, Pathology, Tissue Cross-reactivity, Immunochemistry and also offers a range of specialty services including support for medical device studies, surgical and orthopedic models, and many animal models of human diseases such as wound healing, arthritis and diabetes. Specific technical services include high resolution radiography and contact microradiography, plastic processing and morphometry and pathology support by vastly experienced ACVP certified pathologists.   
Provantis will replace in-house and paper-based systems to automate processes at Alizée’s Maryland laboratory.  
Alizée will be using Instem’s SaaS (Software-as-a-Service) model to access Provantis, offering simpler, more cost effective ways to provide software functionality, maintenance and support over the Internet. Instem’s professionally managed cloud platforms are run from a centralized state-of-the-art data center, which is being used by clients running GLP and non-GLP studies around the world.   
Key Facts   
  
Alizée purchases Provantis Pathology solution to automate processes at Maryland facility   
Alizée to use Instem’s SaaS delivery model   
Contract awarded following a detailed competitive evaluation   
Alizée also deploying Provantis Protocol & Report Assembly module to further enhance the quality of their reporting services   
  
Dr. Serge Rousselle, Principal Pathologist and Founding Partner at Alizée said “We are extremely excited that a group our size can tap into the benefits that Provantis provides. As part of our purchasing process, we undertook a thorough evaluation of the available solutions on the market and we were very impressed with the simple and straightforward functionality, flexibility and scalability that Provantis has to offer.”  
Ed Lorenti, VP Global Sales, Instem commented “We are delighted to welcome Alizée to the Provantis Pathology community. Our Pathology solution is in use by organizations across the globe, from single user remote Pathologists to multi-site laboratories and we are proud to add Alizée to our growing client roster.”  
  
About Alizée  
Alizée Pathology provides histopathological services to clients conducting studies in the preclinical stage of product development. Alizée offers high-quality Pathology Reports providing:  
  
Compliance with Good Laboratory Practice (GLP) federal regulations and other regulations.  
Customized digital images and annotated images.  
Sophisticated morphometry methods  
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Publication support  
  
Alizée also offers a wide variety of services including Precision Embedding and Staining of Tissue, Immunohistochemistry Staining and Method Development, Morphometry, Radiography and Microradiography, Protocol and Study Design Assistance, Necropsy Supervision, Specialty Tissue Trimming and Tissue Cross-Reactivity Studies.  
To learn more about Alizée please visit www.alizeepathology.com  
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Pharmaceutical Organization Selects Provantis Preclinical Software Suite for German R&D Center  
International Pharmaceutical Organization Deploying Provantis to Support Growth in GLP Studies  
CONSHOHOCKEN, PA - (BUSINESS WIRE) – December 1, 2015 - -Instem, a leading provider of IT solutions to the global early development healthcare market, announced today that an international research-based pharmaceutical company has purchased the Provantis® preclinical software solution suite to automate laboratory processes at its R&D Center in Germany.   
The company specializes in Pain Relief Therapies and has a long track record of delivering innovative pain treatments and state-of-the-art technologies to patients. Its purchase of Provantis will deliver increased efficiencies in the collection, storage and reporting of preclinical data and will support its recent growth in GLP studies.   
Key Facts  
  
Client to deploy the Provantis General Toxicology & Pathology modules  
Provantis to replace existing manual processes  
Client to utilize the integrated Data Import module to seamlessly import data from a wide variety of sources   
Instem’s Rapid Deployment Method being deployed to facilitate quick implementation and a rapid return on investment  
  
Gregor Grant, Senior Vice President, Instem, commented “We are delighted to welcome another client to the ever-growing Provantis user community. This latest client is actually a small laboratory within a much larger, international organization and it is great to see them harness the power of Provantis.”  
About Instem  
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Beijing Union Purchases Instem's Preclinical Software Solution  
Chinese Contract Research Organization selects Provantis integrated preclinical software solution to automate study processes  
CONSHOHOCKEN, PA - (BUSINESS WIRE) - January 31, 2012 - - Instem, a leading provider of early development software applications, announced today that Beijing Union – Genius Pharmaceutical Technology Ltd (Beijing Union) has purchased the Provantis preclinical software solution following a comprehensive competitive evaluation of domestic and western solutions on the market.  
   
Beijing Union, located in the Beijing Economic Technological Development Area, was established in 2002 as a commercial offshoot of the Chinese Academy of Medical Sciences and Peking Union Medical College. The company carries out a range of new drug safety evaluation studies in compliance with Good Laboratory Practices (GLPs), including acute, chronic and carcinogenicity studies, genetic toxicity, reproductive toxicity, safety pharmacology, local toxicity, immunotoxicity, dermal toxicity testing and toxicokinetics studies.  
Key Facts  
  
Integrated Reproductive and Inlife Toxicology modules purchased for implementation at Beijing facility  
Competitive evaluation conducted; Instem selected for local presence within the region combined with global market leadership  
Implementation begins immediately; project underway   
Provantis offers Beijing Union compliance to national and western standards and dual language operation   
Beijing Union to be supported from Instem’s full service office in Zhangjiang Hi-Tech Park, Shanghai   
  
Dr. Aiping Wang, Director, Beijing Union commented “We were looking for a world class solution that would help us to further improve the quality of our study processes and deliver demonstrable efficiency improvements. I am pleased to say that following a thorough review of local and Western software products on the market we are confident that Instem and Provantis are the right choices. We are looking forward to building a long and successful partnership with Instem for the future.”  
Neil Donaldson, VP of European & Asian Operations, Instem said “We are delighted to welcome Beijing Union to our growing client base within China and are looking forward to working closely with them so they can quickly realize the benefits of Provantis.”   
As the first western toxicology/pathology software supplier to enter the Chinese market, Instem officially deployed its first China-based system in one of the largest and most advanced vivariums during 2006. Acknowledging analyst projections that the People’s Republic of China (PRC) is growing to become the second largest pharmaceutical market in the world, Instem established a full-service office in Shanghai, recruited local staff and has localized the Provantis product suite into Mandarin Chinese. Instem is supporting international organizations and domestic laboratories exclusively serving the PRC.  
  
About Beijing Union  
Beijing Union-Genius Pharmaceutical Technology Ltd (New Drug Safety Evaluation Centre in CAMS & PUMC) is recognized as a contract research organization (CRO) engaged in the safety evaluation of services, certified by SFDA GLP, US AAALAC, ISO9001:2008, China Metrology Accreditation, UKAS and ANAB. It mainly carries out a range of safety evaluation studies for new drugs, new chemistry, chemicals and pesticides in compliance with Good Laboratory Practices (GLP), including single dose toxicity (rodents and non-rodents), repeated dose toxicity (rodents and non-rodents), reproductive toxicity, genetic toxicity (Ames, micronucleus, chromosomal aberrations), carcinogenicity, local toxicity, immunogenicity, safety pharmacology and toxicokinetics studies.   
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Instem Receives Award from National Institute of Environmental Health Sciences  
Provantis Preclinical Software Chosen for National Toxicology Program  
CONSHOHOCKEN, PA - (BUSINESS WIRE) - March 4, 2013 - - Instem, a leading provider of IT solutions to the global early development healthcare market, announced today that The National Institute of Environmental Health Sciences (NIEHS), part of the National Institutes of Health (NIH), has purchased the Provantis® preclinical software suite to support National Toxicology Program studies. These Reproductive, Immunotox, Neurobehavioral, Sensitization and Carcinogenicity studies are primarily carried out at contractor laboratory sites throughout the United States.  
The National Toxicology Program (NTP) is an interagency program established in 1978 to coordinate toxicology research and development across the Department of Health and Human Services. The program was also created to strengthen the science base in toxicology, develop and validate improved testing methods and provide information about potentially toxic chemicals to health regulatory and research agencies, scientific and medical communities, and the public.  
 Headquartered at NIEHS, the NTP is managed by the NIEHS and supported by the United States Food and Drug Administration and the Centers for Disease Control and Prevention.  
Key Facts  
  
Provantis modules purchased by NIEHS include General Toxicology, Reproductive Toxicology, Pathology, Tables & Statistics, Protocol & Report Assembly, and Data Import  
NIEHS to implement Provantis 9; the latest version of Instem’s preclinical software suite   
Instem SaaS model to provide on-demand Internet-based access to NIEHS and member sites   
Value of year-1 base award to Instem, funded completely by the federal government, is $869,886; with potential to extend and expand agreement up to a further 9 years, giving possible total 10-year contract value of between $6,185,633 -$7,619,981  
NIEHS agreement also includes ability to expand program to larger number of additional contractor laboratory sites across the United States which could result in further substantial award revenue  
  
Phil Reason, President & CEO Instem commented, “This is a very proud moment for Instem. Such a significant contract with the NIEHS, won through a competitive tendering process, is not only a fantastic endorsement of Instem’s innovative Study Workflow & Automation software suite but also of our strategy to support collaborative working practices. The accessibility of Provantis data by a diverse NTP community via our SaaS delivery model will also enable the NIEHS to meet a key goal of combining study information with a broader set of biology information to improve scientific insights.”  
This project has been funded in whole or in part with Federal funds from the National Institute of Environmental Health Sciences, National Institutes of Health, Department of Health and Human Services, under Contract No. HHSN27320130004C.   
About NIEHS  
The NIEHS supports research to understand the effects of the environment on human health and is part of the National Institutes of Health (NIH). Its mission is to reduce the burden of human illness and disability by understanding how the environment influences the development and progression of human disease.  
 For more information on environmental health topics, visit www.niehs.nih.gov.  
The NIH — The Nation's Medical Research Agency — includes 27 Institutes and Centers and is a component of the U.S. Department of Health and Human Services.   
 It is the primary federal agency for conducting and supporting basic, clinical and translational medical research, and it investigates the causes, treatments, and cures for both common and rare diseases. For more information about NIH and its programs, visit www.nih.gov.  
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Pharmaron Selects Instem's Submit™ Software Suite for Complete SEND Management  
Leading Chinese CRO at the Forefront of SEND Compliance in China  
CONSHOHOCKEN, PA - August 16, 2016 - -Instem, a leading provider of IT solutions to the global early development healthcare market, announced today that Chinese Contract Research Organization, Pharmaron, has purchased its full submit™ software solution suite to automate the creation and management of nonclinical data in accordance with CDISC’s Standard for Exchange of Nonclinical Data (SEND).  
Founded in 2003, Pharmaron has over 10 years’ experience at the forefront of cutting edge research and development, and has been playing an important role in accelerating the drug discovery and development process for its partners by providing high quality of drug R&D services.   
Pharmaron is proud to be recognized as one of China’s market leaders in the field of drug research and development services, and has invested in Instem’s submit™ solution suite to further strengthen its market leading position, particularly in the safety assessment area and to become one of the first CROs in the region to offer industry-leading SEND capabilities to its clients.   
Key Facts  
  
Pharmaron has purchased the full submit™ software platform, a suite of integrated tools for the creation and management of SEND datasets and associated documents   
In addition, Pharmaron has selected Instem’s SENDView™ application to simplify the QC review and exploration of SEND datasets  
This investment follows the recent procurement of additional Provantis® user licenses and the Provantis Reproductive Toxicology module, demonstrating strong commitment to the Instem preclinical solution portfolio  
  
Speaking on the recent purchases, Allison Perkins, Executive Director of Business Development at Pharmaron, said: “Over the past 10 years, Instem has helped us to remain at the forefront of the research & development sector by supplying robust, reliable, innovative software solutions and services. Our recent submit™ purchase, will strengthen our market-leading position, enabling us to provide consistent, accurate, high quality SEND datasets to our clients.”  
Elaborating on the deal, Neil Donaldson, Vice President of Global Sales for Europe & Asia at Instem, commented: “Pharmaron were our first client in China, and we are deeply grateful for their continued support of and faith in our products. With the purchase of submit™, as well as the additional SENDView™ application, we are looking to help them retain their position as a market leader in their sector, as well as increase the productivity and efficiency of their service”.  
About Pharmaron  
Pharmaron is a private, premier R&D service provider for the life science industry. Founded in 2003, Pharmaron has invested in its people and facilities, and established a broad spectrum of drug R&D service capabilities, ranging from synthetic and medicinal chemistry, biology, DMPK, pharmacology, safety assessment, radiochemistry and radiolabeled metabolism to chemical & pharmaceutical development. With about 4,000 employees and operations in China, the U.S. and the U.K., Pharmaron has an excellent track record in the delivery of R&D solutions to its partners in North America, Europe, Japan and China. For more information, please visit:  
www.pharmaron.com  
About Instem   
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Instem University e-Learning Platform Announced; Provantis Preclinical Academy First to Launch  
On-Demand Education for New and Existing Clients Offers More Effective Ways for Users to Maximize Instem Software Solutions  
CONSHOHOCKEN, PA – December 6, 2016 - Instem, a leading provider of IT solutions to the global life sciences market, announced it will be launching the Instem University, an online learning platform for its global customer base.  
The Instem University is a sophisticated, easy to use, intuitive web based solution that is available on-demand whenever a client needs it. The platform meets the needs of all users, from super users through to those staff who may only use Instem solutions infrequently.   
Instem’s entire approach for the project is based upon the single objective of making it easier for clients to use Instem software solutions so that users can better perform their jobs.  
Offered through flexible and cost effective subscription plans, each of Instem’s core solution suites will have a dedicated online Academy within the Instem University environment, delivering targeted content for the end-user, based on their area of application.  
“The introduction of Instem University and its dedicated Academies represents a further step in our efforts to become a value-added extension of our clients’ business, ensuring they receive the highest amount of value from our software solutions,” comments Gary Mitchell, VP Global Marketing.  
The launch of the Instem University takes Instem’s educational services to the next level, delivering targeted learning, certifications, training records and more. It offers clients even more ways to become proficient on Instem solutions; facilitating increased efficiency and effectiveness and fostering a culture of continuous learning.  
Provantis Academy First to Launch  
Instem’s most widely deployed software suite, Provantis®, will be first to launch its new e-Learning initiative, and will be available to all of its users beginning in version 10.  
To mark the launch of the Provantis Academy, Instem will be hosting two live Webcasts beginning on December 13th. These presentations will provide a guided tour of the online Academy and will be showcasing the specific benefits it will deliver to users.   
The Provantis Academy will provide a more effective, lower cost way for users to learn and retain information. The flexible subscription plans include direct, live access to Instem’s team of educational industry experts and on-demand support.   
The interactive online courses have been developed by Instem’s Education Services experts and industry application specialists. Reviewed and tested by users, the courses contain self-paced, on-demand training exercises, user guides and support materials, as well as online tests to evaluate understanding.  
“Instem University provides users with a personalized approach to learning, giving them access to the training they need anywhere, at any time. All of our Academy modules are self-paced and can be revisited as often as they are needed,” states Penny Stockley, Instem Product Director.   
Special Introductory incentives are being offered during 2016 and into early 2017.  
Instem plans to launch the ALPHADAS® Academy, a dedicated e-learning platform for users of its early phase clinical trial EDC system during January, with additional academies being introduced throughout 2017.  
About Instem   
Instem is a leading supplier of IT applications and services to the early development healthcare market delivering compelling solutions for data collection, analysis and regulatory submissions management. Instem solutions are in use by customers worldwide, meeting the rapidly expanding needs of life science and healthcare organizations for data-driven decision making leading to safer, more effective products.  
Instem’s portfolio of software solutions and consulting services increases client productivity by enhancing product development processes while offering the unique ability to generate new knowledge through the extraction and harmonization of actionable scientific information.  
Instem supports over 500 clients through offices in the United States, United Kingdom, France, Japan, China and India.  
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Instem Announces Transfer of ToxHub Platform and launch of Centrus®  
New powerful technology and data sharing suite provides a range of translational science solutions  
PHILADELPHIA, PA – May 15, 2023 Instem, a leading provider of IT solutions to the global life sciences market, announced today that it has been granted exclusive rights to transition the ToxHub Platform (the “Platform”) from eTRANSAFE.  
The Platform has been designed to speed up the development of medicines and will be commercialized by Instem following integration into the Company's unique in silico suite, which it has rebranded as Centrus®.  
ToxHub will sit alongside the Company’s existing, data sharing, predictive modelling and insight generation solutions; areas where Instem already processes complex data using advanced technologies such as artificial intelligence (“AI”) and natural language processing.   
The Company has also received the first Software-as-a-Service (“SaaS”) subscription order for the Platform from Bayer AG, one of 13 international life sciences companies involved in the eTRANSAFE consortium www.eTRANSAFE.eu (the “Consortium”). Bayer AG’s Head of Investigational Toxicology commented: “ToxHub, a powerful suite of predictive tools and visualization software for translational data analyses, offers a valuable and innovative addition to enhance safety assessment for our drug development programs.”   
Building on Strong Foundations  
 The Consortium commenced work in 2017 and spent over five years and c.€41m specifying, designing and developing the Platform, with funding from the Innovative Medicines Initiative (IMI), Europe’s largest public-private initiative aiming to speed up the development of better and safer medicines for patients. Recognizing the accelerated investment that Instem will be making to commercialize the Platform and the commitment to continue to work with several of the key technology partners in the Consortium, there is no initial capital outlay for the Company associated with the transition of the Platform.  
Grant funding was provided to eTRANSAFE by the IMI2 Joint Undertaking, which receives support from the European Union and the European Federation of Pharmaceutical Industries and Associations (EFPIA). A key objective of the Consortium, and a significant justification for funding, was to reduce the number of animals used in the development of new drugs and chemicals.  
Centrus, a powerful technology and data sharing suite, provides a range of translational science solutions designed to strengthen translation of data and insight between the discovery, nonclinical and clinical phases of research and development, increasing confidence, efficiency and velocity, materially reducing the cost of life sciences R&D and helping Instem’s clients bring their life changing products to market faster.  
The Consortium members have addressed the technically and operationally challenging aspiration to share much of their proprietary historical data for mutual benefit, while also enabling them to securely incorporate their still private data into the system. The Consortium members had already contributed data from approximately 10,000 non-clinical studies and a small number of clinical studies, creating a significant repository of valuable data, most of which had not previously been shared. Having received the Bayer AG contract, approximately 1,000 of their non-clinical studies are now available in Centrus. As other Consortium members place Centrus subscription orders with Instem, their data will be added into the Platform. The Company will also provide a service to continually add studies from new and existing subscribers.   
Growth Opportunity  
 As the eTRANSAFE project approached the end of its IMI2 grant funding, it was proposed that Instem assumes ownership of and commercialises the ToxHub platform, integrating it with Instem’s existing in silico solution portfolio, to create compelling new capabilities, expand the user-base and ensure continuity in the exceptional data collaboration and innovation achieved already by the Consortium. Already a long-term supplier to all 13 pharmaceutical and chemical companies in the Consortium, Instem was quickly recognized as an obvious, trustworthy custodian for the valuable data, and a company capable of establishing a secure, global collaborative translational science platform.  
Modelling, simulation and data exploration solutions, frequently incorporating artificial intelligence capabilities, are the fastest growing areas of software investment in life sciences R&D. With a current total addressable market of over £600m, a serviceable addressable market of c.£150m and multiple opportunities to grow its new Centrus solution suite and market share in a rapidly evolving environment, Instem believes it is well positioned to accelerate growth organically and acquisitively.   
In addition to the IP ownership of core elements of the Platform, the Company will also benefit from access to open-source technology and the perpetual right to use data from many of the studies that have been contributed already by the Consortium.  
Strengthening the Whole Portfolio  
 The addition of the Platform, technology and data will complement Instem’s existing in silico solutions andthe proven mechanism for data sharing is expected to accelerate the potential for additional data sharing from Instem’s workflow software solutions, which have been used over several decades to collect and analyse data from many thousands of non-clinical and clinical studies.   
Centrus utilises US Food & Drug Administration mandated standards SEND (Standard for the Exchange of Nonclinical Data) and clinical equivalent SDTM (Study Data Tabulation Model) as preferred formats to ingest new data. Instem’s deep understanding of, and its market leading technology solutions that create and use, SEND and SDTM, makes the transition of our customers’ operational data into Centrus a logical progression and opportunity to unlock further value from their investments.  
With the recent growth of Instem’s portfolio, the breadth of customer data that the Company now works with stretches from the earliest days of drug discovery to the latest stages of Clinical development. This unparalleled reach is now matched with a Centrus platform that offers customers a single repository from which to unlock new knowledge through the application and deployment of cutting-edge algorithms that draw on this unique, enterprise-wide resource.  
Positioned for Growth   
 In the near term, the Company will invest in onboarding the Platform, ramping up the commercial and technical teams, establishing the technology environment and continuing the highest priority functional enhancements. To facilitate this, there will be a reallocation of internal resource to reflect the increasing emphasis on data, AI and insight generation.  
Centrus will further build out and then accelerate the Company’s in silico presence from its current base, with management focused on increasing exposure to this segment of the market, which provides higher margin opportunities and increased revenue visibility. This will enable the Company to establish a blended growth strategy, building on the relationships and fundamentals of its established business.  
Dr Thomas Steger-Hartman, Head of Investigational Toxicology and Vice President at Bayer AG commented: “ToxHub, now part of Centrus, is a unique platform for accessing and analysing our own nonclinical data head-to-head with unpublished data from other pharmaceutical companies. The incorporation of clinical databases makes Centrus the first tool to approach translational questions in a seamless way.”  
Phil Reason, Instem CEO, commented: “We are delighted that our long-standing history as a market leading technology provider and trusted partner to most of the world’s leading life sciences R&D organizations has enabled us to take ownership of ToxHub. We will benefit from over €40m spent on the Platform by eTRANSAFE since 2017 and their substantial data contributions. The Consortium members (and wider industry) will benefit from our accelerated investment in the commercialisation of the platform, integration into our new Centrus in silico solution suite and an ever-expanding repository of usable data.  
“We have had tremendous support from the Instem team, clients and investors over the last 10 years as we have grown our solution portfolio, domain expertise and client base organically and acquisitively. We have been resolute in our belief in the potential to leverage our access to and understanding of large volumes of complex chemistry and biology data from early discovery to late-stage clinical trials to radically reduce the cost and time of drug development and we believe the launch of Centrus provides a transformational growth opportunity for Instem.  
“Instem’s capabilities, client necessity, emerging technology and regulatory authority acceptance are coinciding to enable rapidly developing industry collaboration and innovation. This has the potential to deliver new life changing products at unprecedented pace to address unmet societal needs. A large repository of current and historical data together with a broad suite of SaaS solutions and the potential to leverage these assets through a rich set of technology enabled services will ensure that we remain a key player in a rapidly developing new era for life sciences R&D. It is hugely exciting and rewarding to be intimately involved in this work and we look forward to sharing further progress as additional clients deploy our current and expanding Centrus in silico solutions.”  
About Instem  
A global provider of leading software solutions and scientific insight services, Instem is helping clients bring their life enhancing products to market faster.  
We enable organizations in the life sciences to more efficiently collect, report and submit high quality regulatory data, while offering them the unique ability to generate new knowledge through the extraction and harmonization of actionable scientific information.  
Across the entire drug development value chain, every day Instem solutions are meeting the rapidly expanding needs of life science organizations for data-driven decision making, leading to safer, more effective products.  
Instem supports its global roster of clients through offices in the United States, United Kingdom, France, Switzerland, Japan, China, and India.  
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About eTRANSAFE  
The “Enhancing TRANslational SAFEty Assessment through Integrative Knowledge Management (eTRANSAFE)” project develops an integrative data infrastructure and innovative computational methods and tools that aim to drastically improve the feasibility and reliability of translational safety assessment during the drug development process. This infrastructure will be underpinned by development of open standards and robust policies widely accepted by stakeholders, including regulatory agencies and international organisations.  
The eTRANSAFE is a 5.5-year project, started on 1st September of 2017, funded by the Innovative Medicines Initiative 2 Joint Undertaking (IMI 2) together with the pharmaceutical industry, that aims to develop an advanced data integration infrastructure together with innovative computational methods to improve the security in drug development process.   
This announcement contains inside information for the purposes of the retained UK version of the EU Market Abuse Regulation (EU) 596/2014 ("UK MAR").   
  
  
  
  
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Instem Coronavirus (COVID-19) Response  
24 March 2020  
We would like to provide an update on Instem’s response to the escalating coronavirus (COVID-19) situation and, particularly to:  
  
Emphasize that the safety of our staff, their families, the communities in which we operate, and our customers are our first priority  
Reassure you of our ability to continue to provide the services and support that are vital to many businesses engaged in the essential area of life sciences development and regulatory approval  
Inform you that we may have the potential to provide additional help should your own staff or partners be temporarily unavailable  
Acknowledge that we may need to work closely with clients as they reorganize or reschedule activities to help address the crisis, or to simply deal with its business consequences.  
  
With staff and customers in China, and directly in Wuhan, Instem’s Business Continuity team was quickly engaged. Our first priority was to address personal safety and then to ensure business continuity for both Instem and our clients. Our Business Continuity team has continued to spearhead our response as the crisis has escalated and spread worldwide.  
Like most businesses, we have been closely following and implementing the advice of agencies, such as the World Health Organization and US Centers for Disease Control & Prevention, and quickly introduced international, and then domestic, travel bans, as well as policies to increase hygiene and social distancing. We required staff with even mild illnesses to stay at, or work from home, and so far, have no known, or suspected staff coronavirus infections.   
While these measures have had some impact on client-related site work, we have worked collaboratively with our customers to find ways to complete much of this work remotely. In some cases, this is increasing efficiency as we save on the time and expense of international travel. We hope to see some enduring benefits as we, and our clients, realize quite how much can be done in this way.  
Instem is fortunate to have invested heavily over the last 5 years in technology that supports our widely dispersed workforce and the many staff that already work entirely, or frequently, from home. Our GxP regulatory framework, certification to quality standard ISO 9001 and information security management standard ISO 27001, all require us to have a risk management and business continuity mindset embedded in the organization. We also reflect these requirements with the operational partners on whom we rely, and they have confirmed their ability to continue to support Instem and our clients during this crisis.  
While our COVID-19 response is primarily operational, we, and our clients, can take some comfort from Instem’s current financial position, our high levels of recurring revenue and the visibility and financial regulation afforded by our public company status.  
We have quickly, but carefully, moved to a position where over 95% of our staff are now working from home, keeping ahead of those locations where governmental mandatory “work from home” and/or “shelter at home” is now in place. Should we need to attend our offices in exceptional circumstances, we believe we will likely retain that right as a business that is supporting critical, life enhancing/sustaining scientific research and development. For example, while not needing to visit one of our offices, our global SEND outsourced services team worked over the last weekend to generate a SEND submission for a potential COVID-19 related therapy.  
While most of our staff are working equally efficiently remotely, we are addressing situations where staff need to balance looking after home bound children/dependents and those areas where external network connectivity is being challenged by entire regions that are restricted to home working and schooling.  
While some clients are utilizing Instem’s service capacity at pre-coronavirus levels, we are seeing some project delays, which open the potential opportunity to provide additional, highly skilled Instem capacity should you need it. We are also prepared to reprioritize longer-term investment initiatives to free up resources, in the event that our clients need to direct additional coronavirus or other critical R&D activities to the expert Instem team.  
You will no doubt be aware of our significant capabilities in the area of in-silico R&D, both organically and through the November 2019 acquisition of Leadscope Inc. We recognize that in-silico R&D may offer benefits in speed and practicality during these exceptional times. Please do not hesitate to talk to Instem if you think we may be able to help.  
We remain committed to the safety and success of our community of clients and will continue to update this page with any material developments.  
Read our April 20th Update: Instem Provides Free SEND Services to COVID-19 Related Research & Development  
  
  
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Mitsubishi Chemical Medience Corporation Switches to Provantis®  
Japanese CRO selects Instem's Provantis solution for their Kashima and Kumamoto Facilities  
CONSHOHOCKEN, PA - (BUSINESS WIRE) - March 8, 2010 - - Instem, a leading provider of early drug development software solutions, announced today that Mitsubishi Chemical Medience Corporation (MCM) has purchased the Provantis preclinical software solution.   
Following an extensive competitive evaluation MCM decided to replace its existing data collection systems with the fully integrated Provantis solution to manage Preclinical study processes at their research facilities in Kashima and Kumamoto, Japan.   
MCM is one of Japan’s largest CROs. They have purchased a wide range of Provantis modules for over 200 users across the 2 sites, including General Toxicology, Clinical Pathology, Pathology, Reproductive Toxicology and Instem’s unique reporting solution – Protocol & Report Assembly.  
MCM has also purchased a range of Professional Services to enable them to get quickly up to speed with the Provantis solution and Instem will be working hand in hand with their Japanese distributor CTCLS to ensure that MCM get quick return from their investment in Provantis. CTCLS is one of Japan’s leading providers of integrated R&D support systems for the life sciences and they support Instem solutions through their full service office in Tokyo.   
Provantis was chosen after a detailed competitive evaluation and will replace 2 separate systems that are currently in place at MCM.   
Dr. Hideaki Hiratsuka, General Manager of MCM’s Safety Assessment Department commented “As part of our company’s expansion plans and our drive to reduce operational costs and further streamline our processes we were looking for a unified system that we could deploy at multiple locations. We were extremely impressed with the capabilities of the Provantis solution.”  
Provantis is a modern, fully integrated software system for single users and global organizations engaged in non-clinical evaluation studies. Orchestrating every facet of preclinical drug safety assessment, Provantis streamlines processes and workflows with straightforward, intuitive functionality for simple or complex studies within a GLP or non-GLP environment   
“Instem’s vast experience of working with the US regulators and Part 11 Compliance of its Provantis solution was also a key factor in MCM’s decision to purchase Provantis” said Shigeharu Yamashita, GxP Business Group Manager at CTCLS. “Increasingly Japanese preclinical software organizations such as MCM are performing FDA regulated studies and they are demanding solutions that meet FDA regulatory requirements.”   
Neil Donaldson, Instem’s VP Operations EU & Asia said “We are delighted to welcome MCM as our latest Japanese customer. This is an extremely exciting time for Instem and our clients in the Asia-Pacific region. We have a rapidly expanding client base, and, with the recent opening of our full service office in Shanghai, China and our established partnership with CTCLS in Japan we are fully committed to supporting our clients in this region.”   
MCM are planning to go live with Provantis for their GLP studies during 2011.  
About Mitsubishi Chemical Medience Corporation  
Mitsubishi Chemical Medience Corporation (MCM) is one of Japan’s leading Contract Research Organisations. Headquartered in Tokyo, MCM employs just under 4,000 staff. MCM’s primary business areas are the development, sale, export and import of in vitro diagnostic reagents and instruments, Clinical Testing, Preventative Medical Services, Drug Development Support Services and Food Sanitation and Hygiene Analysis.  
About CTCLS  
As a unique member of Itochu Techno-Solutions Corporation, CTCLS has evolved into one of Japan's leading solution providers, specializing in the integration of R&D support systems for life science companies.  
With incomparable end-to-end solution capability, CTCLS works with pharmaceutical, chemical and food manufacturers, as well as universities and public offices. CTCLS offers a wide-range of products and services that cover every stage of R&D activities.   
About Instem  
Instem is a leading supplier of IT applications to the early development healthcare market, delivering compelling solutions for data collection, management and analysis across the R&D continuum. Instem applications are in use by customers worldwide, meeting the rapidly expanding needs of life science and healthcare organizations for data-driven decision making leading to safer, more effective products.  
Instem’s portfolio of software solutions increases client productivity by automating study-related processes while offering the unique ability to generate new knowledge through the extraction and harmonization of actionable scientific information.  
Instem supports over 400 clients through full service offices in the United States, United Kingdom and China with additional locations in India and a full service distributor based in Japan.  
Meeting clients at the intersection of investment & return™.  
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NOTOCORD Celebrates Key Achievements and Milestone Anniversary  
Instem Reports Key Accomplishments for Safety Pharmacology Solutions Business Following First Year as Part of Instem Group   
CONSHOHOCKEN, PA, December 12, 2017 - Instem, a leading provider of IT solutions to the global life sciences market, is pleased to report a number of key accomplishments and achievements for its NOTOCORD Safety Pharmacology solutions business since becoming part of the Instem Group last year.  
NOTOCORD was acquired by Instem in September 2016 to support Instem’s mission to further consolidate and harmonize key application areas that are helping customers streamline their research and development processes. Based in Paris, France, with a presence in the United States, NOTOCORD provides software solutions for data acquisition and analysis in preclinical studies and is a recognized leader in cardiovascular, respiratory, electrophysiology and nervous system research areas. NOTOCORD solutions are used by pharmaceutical companies, contract research laboratories, hospitals and academic research centers around the world.  
Instem is pleased to report that the NOTOCORD staff and solution portfolio have now been fully integrated into the Instem organization and recognizes a number of key accomplishments during the year including:  
  
The release of NOTOCORD-hem™ Version 4.3.0.75. NOTOCORD-hem, NOTOCORD’S flagship product, is an advanced software platform for the acquisition, display and analysis of physiological signals, with a focus on the areas of Cardiovascular, Respiratory and Nervous System research. This latest release offers users further improved GLP compliance and is compatible with DSI Hardware Configuration 1.8 and Stellar Telemetry implantable devices.   
The development of an Open Strategy for NOTOCORD-hem, which will continue to connect NOTOCORD-hem to an increasing number of 3rd party signal acquisition, hardware and telemetry devices.  
Enhanced SEND capabilities – As recognized leaders in the SEND arena, Instem is fully poised to support its Safety Pharmacology client base as they prepare for SEND. Whether study data resides in an Instem/NOTOCORD solution, or is stored within an alternative software platform, Instem has open industry partnerships in place to provide clients with complete FDA SEND Compliance.   
New Product Development – The development of NOTOCORD-sense®, a new cutting edge, Cloud-based collaboration platform for the analysis and sharing of Experimental data.  
A successful 2-day User Group Meeting held in Paris in January 2017.   
  
To celebrate this special anniversary, Instem is offering NOTOCORD clients a range of special incentives that are available through the end of 2017 including:  
  
Discounts on additional NOTOCORD-hem licenses  
Discounts on SEND-related solutions & services  
Deferred payment options   
Discounts and partial software credits for future product offerings including NOTOCORD-sense and submit™ for SEND.   
  
About Instem  
Instem is a global provider of leading software solutions and services that are helping over 500 clients bring their life enhancing products to market faster. We enable clients in the life sciences to more efficiently collect, analyze, report and submit high quality regulatory data, while maintaining compliance for their products around the world.   
Instem solutions are in use by customers worldwide, meeting the rapidly expanding needs of life science and healthcare organizations for data-driven decision making, leading to safer, more effective products.  
Instem supports its global roster of clients through offices in the United States, United Kingdom, France, Japan, China and India.   
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Instem International Conference Series Deemed a Success by Clients  
Delivering Value to Clients at Meetings in US, UK, Japan & China  
CONSHOHOCKEN, PA - November 14, 2012 - - Instem, a leading provider of IT solutions to the global early development healthcare market, is pleased to announce that its 2012 Instem International Conference (IIC) series has been a great success, enabling Instem to connect with over 100 clients across the globe.  
The IIC forms part of Instem's Customer Involvement Program (CIP). It offers delegates an excellent opportunity to help shape Instem's solution roadmap, see new solutions under development and hear the latest news regarding product strategy. The IIC also provides excellent networking opportunities, enabling delegates to connect with their industry peers and key members of the Instem team, sharing best practice and learning opportunities.  
During the month of October a series of regional IIC meetings took place across the globe in Manchester, UK, Philadelphia, USA and Shanghai, China. Each meeting featured a range of platform presentations and breakout sessions centering on the 2012 conference theme - Value. Efficiency. Success. During the first week of November the final meeting took place in Osaka, Japan, hosted by CTC, Instem’s Japanese distributor.   
IIC Meetings included several sessions on Provantis 9, the latest release of Instem’s preclinical study management solution. This included sessions on Provantis 9 functionality, planning for upgrades, reviewing alternative workflow processes and exploring how new validation processes can help Instem clients go live with the latest version faster. In addition, a New Product Showcase generated a great deal of interest and enthusiasm among the delegates, featuring Instem's newest value add solutions - the Provantis Portal, Logbook and SENDView™. Delegates were also given a valuable insight into how its Bioinformatics applications can assist them in extracting more value from their study data; in particular a demonstration of the Safety Intelligence Program (SIP) was well received.   
Gary Mitchell, VP Global Marketing, Instem said "It was exciting to meet with so many of our users across our IIC conference series. In addition to the official program sessions, many clients also took advantage of the opportunity to schedule one-on-one meetings to advance items of interest or to utilize the presence of Instem staff to give an update on their plans and aspirations. Overall, delegate feedback was very positive, indicating that delegates had got real value from the event and were now looking forward to taking the key messages back to their respective companies and building upon the knowledge and new insight they had gained. It is also extremely pleasing to see that 100% of delegates who completed our post event survey said that they would recommend the IIC to their colleagues."  
About Instem  
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Instem’s portfolio of software solutions increases client productivity by automating study-related processes while offering the unique ability to generate new knowledge through the extraction and harmonization of actionable scientific information.  
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Instem Announces Expanded Capabilities and Increased Market Demand for Cyto Study Manager Software   
Instem Welcomes New Clients and Delivers Enhanced Functionality for Leading Genetox Solution  
CONSHOHOCKEN, PA – Business Wire, July 10, 2018 - - Instem, a leading provider of IT solutions to the global life sciences market, is pleased to announce continued demand for its unique Cyto Study Manager (CSM) genetic toxicology software solution.  
CSM integrates data acquisition, auditing, reporting and study management processes into a single intuitive system that greatly improves efficiencies, while ensuring data integrity during genetic toxicology studies. CSM includes modules for the comet assay, micronucleus, chromosome aberrations as well as a revolutionary customizable module.  
Demand for CSM continues to grow and many leading R&D organizations including Roche, Charles River Laboratories, Merck & Co., Sanofi, Boehringer Ingelheim and, most recently, Integrated Laboratory Systems, have selected CSM to help them streamline genetic toxicology study workflows, reduce costs, increase efficiencies and improve regulatory compliance.  
Building on this continued success, Instem has made further significant investments in the CSM solution. Extensive reporting capabilities enable clients to create customized reports in seconds, complete with data tables, statistics and graphs. Instem now provides CSM validation packs, onsite assistance and implementation support services, which are all enabling clients to get into live use quicker and with less effort than ever before.  
Gregor Grant, Executive Vice President Preclinical Solutions, Instem, said “It is extremely exciting to see the CSM community continuing to grow and our clients are telling us that CSM delivers dramatic efficiency gains within their genetic toxicology operations. Our recent investments in the product have revolutionized the creation of genetox reports, introduced new custom reporting capabilities, and now, by supporting specialty assays, CSM continues to handle all genetox study workflows and experiments.”   
For further information about Cyto Study Manager download the fact sheet or read the case study.   
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WIL Research Partners with Instem for Global Harmonization Project   
Instem Chosen by International Contract Research Organization to Deploy Multi-site Global Solution  
CONSHOHOCKEN, PA - (BUSINESS WIRE) – December 18, 2014 - -Instem, a leading provider of IT solutions to the global early development healthcare market, announced today that WIL Research has placed an expanded order for the deployment of a comprehensive solution to optimize study-related processes at all WIL Research worldwide sites.   
Following the recent completion of a thorough vendor evaluation, Instem was chosen by WIL Research for its market leadership position, global support capabilities, product functionality and strong endorsements from existing Instem clients.  
Following an announcement earlier this year about the project, WIL Research has now turned to Instem for an expanded role in their multi-year global harmonization project as they look to provide a consistent experience for their clients around the world.  
“Instem’s solution will provide exactly what we need; harmonized data collection, integrated scheduling, cutting edge SEND management tools and support for our global reporting to enable improved decision making across all of our departments,” comments David Spaight, CEO at WIL Research. “I’m confident that our expanded technology investment will enrich our research processes, help develop better controls and provide excellent experiences for every one of our clients, while expanding our capabilities for continued growth.”  
WIL Research has approximately 1,300 staff and 63,000 square meters of laboratory space around the world. Their facilities offer a blend of technical and regulatory expertise in discovery support, product safety toxicological research, metabolism, bioanalytical chemistry, analytical chemistry, formulation and regulatory services.   
“We are looking forward to delivering tangible business impact for WIL Research as their premier preclinical technology partner through this transformational program,” states Gregor Grant, Senior Vice President at Instem. “We are impressed by WIL’s commitment to create more value for their clients through these enhancements and as the leading provider of SEND solutions, with more than 30 licensed sites in 11 countries, we are especially encouraged to see WIL supporting a critical FDA-adopted CDISC standard in preclinical.”  
The WIL Research program has been developed to harmonize global systems and processes that will effectively create a single hosted environment providing better efficiencies with more controls for them and their clients. Instem will additionally be assisting WIL Research reduce the amount of paper-based data, and using Instem’s powerful 21 CFR part 11 compliant Logbook™ ELN technology, WIL Research will be moving toward paperless processes which will further drive increases in productivity and quality.   
WIL Research will be using Instem’s hosting services, globally. Instem’s professionally managed hosted platforms are run from centralized state-of-the-art data centers, which are being used by clients running GLP and non-GLP studies around the world.   
About WIL Research   
WIL Research is an interdisciplinary non-clinical contract research organization providing product safety, toxicological assessment research, bioanalytical, regulatory compliance / registration, formulation and manufacturing services to the international pharmaceutical, biotechnology, veterinary, industrial and agricultural chemical industries.  
Find out more about WIL Research at www.wilresearch.com  
About Instem   
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Instem Co-Presenting at 52nd Annual Meeting of the Society of Toxicology  
CONSHOHOCKEN, PA - February 28, 2013 - - Instem, a leading provider of IT solutions to the global early development healthcare market, announced today that Jane Reed, Director Safety Intelligence Program will be part of a platform presentation at this year’s Society of Toxicology annual meeting in San Antonio, Texas.  
The talk, entitled Cheminformatics Analysis of Compound-Cytochrome P450 Interaction Profiles is being given by Prof. Denis Fourches in the “Bioinformatics: Pathways, Profiles, and Predictions” session, on March 12th from 1:30PM to 4:15PM.   
Participating institutions include the Laboratory for Molecular Modeling, University of North Carolina at Chapel Hill, Chapel Hill, NC, United States and The Hebrew University of Jerusalem, Jerusalem, Israel.  
The research uses compound-protein interaction data from Instem’s SIP ToxPath knowledgebase, combined with two public domain data sets, to assess chemical concordance across five key cytochrome P450 enzymes involved in drug metabolism.   
The cytochrome P450 family of enzymes (CYPs) are the major enzymes involved in drug metabolism, and CYP-drug interactions are a key source of adverse drug interactions, since changes in CYP enzyme activity affect the metabolism and clearance of various drugs. A good understanding of the potential CYP interactions for a new compound is an essential part of the early drug development investigation, and predictive approaches are valuable across many areas of pharmacology and toxicology, in drug development, preclinical toxicity studies, clinical trials, environmental exposures and risk assessment.   
Using cheminformatics approaches, we have been able to reveal the chemical concordance across the five key enzymes (illustrating the singularity of CYP1A2 and the similarities between CYP2C9 and CYP2C19); identify new compounds both potent and selective for a particular CYP; and develop robust QSAR models to enable prediction of CYP interaction profiles for novel compounds. Such predictive models are a key resource in early drug development for assessing the metabolic profile and toxicity of a novel compound.  
Instem’s exhibit at the Society of Toxicology’s ToxExpo is located at space #1137.  
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Instem Showcasing SEND at Annual Meeting of the American College of Toxicology  
Instem Collaborates on SEND Poster Presentation While Promoting Expanded Services   
CONSHOHOCKEN, PA - - November 4, 2015 - - Instem, a leading provider of IT solutions to the global early development healthcare market, is pleased to announce its support and involvement at the 36th Annual Meeting of the American College of Toxicology November 8-11, 2015. Instem will be exhibiting at the event and has also co-authored a poster presentation with industry peers from Accenture, Bristol-Myers Squibb, Merck, Pfizer, Eli Lilly and Company, and Charles River Laboratories.  
The poster, SEND Nonclinical Data Submissions: Topics to Focus on Now, discusses key topics that the industry is currently focusing on to comply with the SEND (Standard for Exchange of Nonclinical Data) standard. The poster will highlight important considerations for managing data that makes use of multiple versions of the standard; verifying the quality and completeness of SEND datasets; best practices for presenting metadata with submissions; addressing specific sections of the non-binding Technical Conformance Guide; dataset challenges recognized by nonclinical FDA reviewers to-date and understanding the full value of the Study Data Reviewers Guide.  
“Our primary focus at this meeting is to continue to educate and prepare the industry for SEND,” said Jennifer Feldmann, Vice President, SEND Product Strategy, Instem. “Instem’s SEND solutions have been chosen by over 30 client sites across 13 countries and we are looking forward to this meeting to share our best practices to help guide both Sponsors & CROs.”  
Instem will be located at booth # 217, showcasing submit™, its market leading platform of integrated tools and services for the creation and management of SEND datasets. Instem staff will be on hand to discuss its expanded set of SEND Management Services, which are supporting clients at every stage of SEND Readiness.   
Instem will also be available to discuss the latest features and functions of its market-leading preclinical study management solution, Provantis.   
The 36th Annual Meeting of the American Society of Toxicology will take place at the Red Rock Resort in Summerlin, NV with over 800 delegates expected from countries around the world and over 70 exhibiting companies.   
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CiToxLAB Implements Provantis 9 and submit-SEND Solutions  
International CRO CiToxLAB to Further Improve Reporting Quality and Response Times to Sponsors  
CONSHOHOCKEN, PA - (BUSINESS WIRE) – March 16, 2015 - -Instem, a leading provider of IT solutions to the global early development healthcare market, announced today that CiToxLAB is deploying an extensive package of Instem software solutions to optimize its preclinical workflows and to support CDISC’s Standard for Exchange of Nonclinical Data (SEND).  
CiToxLAB provides a comprehensive range of preclinical and specialty services from 5 facilities in France, Canada, Denmark and Hungary. Together with its partners, CiToxLAB also provides clinical bioanalysis (Atlanbio), embryonic stem cell biomarker discovery and customized preclinical efficacy model services (Stemina).  
CiToxLAB has recently completed an upgrade to Provantis 9, the latest version of Instem’s world-leading preclinical software solution at its facility in Hungary, with the sites in Canada, Denmark and France all poised to go live this year.  
CiToxLAB comprehensively evaluated Provantis as they looked to provide an integrated data capture system at each of their sites. This included a requirement for a solution that could convert data from any source system into SEND files and allow sponsors and regulators to share, visualize and analyze study data more efficiently. Instem was chosen for its global market leadership, stability and regional support center.   
“We are happy to announce that we have chosen to grow our relationship with Instem with what is a valuable set of solutions,” comments Dr. Jean-Francois Le Bigot, President and CEO of CiToxLAB. “This type of innovation, combined with our immediate gains of heightened efficiency, allows us to respond even faster to our clients, with quality results.”  
Following issuance by the FDA of the long awaited final Guidance for Standardized Study Data for providing regulatory submissions in electronic format in December of 2014, CiToxLAB will implement Instem’s submit™ solution suite at all of its facilities, starting with France and Denmark. Submit™ enables clients to create and manage SEND study datasets throughout their lifecycle and allows sponsors, CROs and regulators to share, visualize and analyze study data more efficiently. Using the submit™ solution suite and aided by Instem, CiToxLAB is able to provide study data in SEND format to its clients, and through its example will help the continued adoption of SEND outside of North America.   
“It is encouraging to see organizations within Europe continue to embrace SEND following last year’s mandate by FDA,” states Gary Mitchell, VP Global Marketing, Instem “We are seeing a marked increase in the demand for Instem’s submit-SEND solution suite and proudly support more than 30 licensed sites across 11 countries.”   
In a further commitment to delivering added value to its clients, CiToxLAB is in the process of deploying the Provantis Portal™ Remote Study Monitoring solution. The Provantis Portal will allow CiToxLAB’s clients to log in to a secure website using any standard browser to view data from their on-going studies. This will make it easier for clients, particularly international organizations, to monitor their studies remotely, allowing efficient and timely access to study data as well as streamlining communications internally and with CiToxLAB.   
About CiToxLAB   
CiToxLAB provides a broad range of GLP and non-GLP preclinical services backed by over 45 years of experience to help their clients meet the demands of today’s complex global marketplace. With five facilities located in France (Evreux, Saint-Nazaire), Canada (Montreal), Denmark (Copenhagen) and Hungary (Veszprem), the CiToxLAB group offers a comprehensive range of preclinical services to meet the needs of pharmaceutical, biotechnology and chemical companies worldwide.  
CiToxLAB carries out studies in general, reproductive and developmental toxicology, carcinogenicity, immunology, safety pharmacology, DMPK and bioanalysis. The group has unique expertise in areas such as toxicology and reproductive toxicology in NHPs and minipigs, inhalation toxicology, radiation studies, and environmental studies (ecotoxicology and those related to REACH regulations).  
Through its partnership with Atlanbio, CiToxLAB also provides clinical bioanalysis and biomarkers services.   
To learn more about CiToxLAB, visit www.citoxlab.com  
CiToxLAB: Safety and Health Research Laboratories  
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Instem's SEND Solution Showcasing at Japanese Society of Toxicology Meeting  
Instem and Partner CTCLS to Co-exhibit at the 41st Annual Meeting of the JSOT; Kobe, Japan.  
CONSHOHOCKEN, PA - - July 2, 2014 - - Instem, a leading provider of IT solutions to the global early development healthcare market, announced today that it will be co-exhibiting with partner, CTCLS at the Japanese Society of Toxicology (JSOT) Annual meeting July 2nd – 4th in Kobe, Japan.  
Following the release of the US Food and Drug Administration’s draft guidance for electronic submissions earlier this year, Instem’s presence at JSOT will focus on helping organizations learn more about CDISC’s Standard for Exchange of Nonclinical Data (SEND) and how both sponsors and CRO’s can prepare for and leverage the standard with industry leading software tools.  
JSOT delegates will be able to learn about SEND and view demonstrations ofInstem’s market-leading submit™ software solution suite, which enables organizations to convert data from any source system into SEND files while allowing sponsors, CRO’s and regulators to share, visualize and analyze study data more efficiently.  
Neil Donaldson, Instem’s Vice President of Sales, Europe and Asia, commented, “I am pleased to be joining CTCLS at JSOT to reinforce Instem’s commitment to SEND and help our industry colleagues in Japan further embrace the standard. We have seen an increase in the global demand for our SEND solutions and services in 2014 and our presence at this meeting supports Instem’s role as the leading provider.”  
Attendees may visit Instem and CTCLS at booth #34 at JSOT, July 2-4th at the Kobe Convention Center. Also featured at the booth will be Instem’s market-leading Provantis® software solution, the fully integrated system for organizations and universities engaged in non-clinical evaluation studies.  
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Biopharmaceutical Organization Selects Provantis® Pathology to Optimize Histopathology Reviews  
Massachusetts Based Biopharmaceutical Company Automates Histopathology Processes   
CONSHOHOCKEN, PA – June 9, 2016 - Instem, a leading provider of IT solutions to the global early development healthcare market, announced today that a US-based biopharmaceutical company has purchased Provantis® Pathology to provide storage for tissue imaging samples, along with analysis, review and reporting of histopathology data.  
The client specializes in the development of a new generation of highly selective and potent kinase therapies to dramatically improve the lives of patients with genomically defined diseases. Their investment in Provantis Pathology will enable them to further streamline the Histopathology review process, eliminating the use of high maintenance spreadsheets for data management and tracking.  
Key Facts  
  
Biopharma client to implement Provantis Pathology to support histopathology processes  
Client will be able to produce tabulated study-based data, while referencing an integrated decision tree for sophisticated statistical analysis and reporting  
Tailored implementation and training plan deployed to ensure maximum return on investment   
  
Gary Mitchell, Vice President of Marketing at Instem, said, “We are delighted to welcome this latest client to our user community. They represent a growing number of small teams that are gaining immediate value in their data collection, processing and reporting activities by implementing Provantis.”  
Provantis Pathology is a fully integrated and scalable software solution used by organizations around the globe, helping single user remote Pathologists or global, multi-site customers collect, process and report gross and histopathology data faster and more accuractely. A comprehensive and intuitive system, Provantis Pathology is in use by leading research and development organizations across the life sciences spectrum.  
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Instem at ACT Annual Meeting, 2023  
Instem, Booth 212  
Discover our innovative Study Management, Regulatory & In Silico Solutions   
Provantis®  
 As the #1 preclinical software suite for organizations engaged in non-clinical evaluation studies, Provantis streamlines processes and workflows with straightforward, intuitive functionality for simple and complex studies within both GLP and non-GLP environments.  
 Learn more about our new standalone modules within our Pathology suite, including modules for Tissues Processing, Image Management, and Spotlighter™ , our historical data solution that helps you find the hidden value in your reference data.  
SEND Solutions  
 The most comprehensive and widely deployed set of software (submit™) and services (SEND Advantage™) supporting the creation and management of SEND datasets. Stop by our booth to learn more about our two NEW software solutions, DefineNow™ for the creation and editing of define.xml files and GuidePro™, Instem’s Study Data Reviewer’s Guide generator.  
Genetic Toxicology  
 Image analysis and data management solutions helping users better collect, manage, review and extract data while transitioning information into insight, utilizing our Comet Assay IV and Cyto Study Manager tools. Also, don’t miss the opportunity to learn more about our new Transgenic Rodent Assay module!  
(NEW) Advance™ Weight of Evidence Assessments: Instem’s latest In Silico service which is re-imagining the way organizations perform carcinogenicity assessments via the 6 Weight of Evidence (WoE) factors under the ICH S1B guideline.  
KnowledgeScan™ Target Safety Assessment (TSA) Service: Delivering comprehensive TSAs for clients around the world, enabling them to make faster, better-informed decisions on their drug targets.  
Watch the KnowledgeScan Explainer video   
Leadscope Model Applier™: Advanced informatics and prediction technology, together with comprehensive database solutions that are helping organizations effectively unlock valuable knowledge contained in both public and proprietary sources of research data. Ask about our new module Leadscope N-nitrosamine CPCA.  
Predict™ In Silico Toxicology service: A leading edge, technology-enabled service that delivers a combination of powerful computation models with expert scientific review, to help clients predict chemical safety more quickly, efficiently and comprehensively.  
Centrus®: An innovative technology platform that delivers a combination of pioneering, well-integrated computing modules, along with a comprehensive catalogue of non-clinical and clinical data.  
If you would like to schedule a discussion with us during ACT contact us at info@instem.com indicating your area of interest.  
  
Instem Event Schedule  
Tuesday, November 14  
Exhibitor Hosted Event: Using Translational Science Tools to Support an Integrated Weight of Evidence Approach: Case Study on ICH S1B Carcinogenicity Assessment.  
Tuesday, November 14, 12:00 PM - 12:55 PM (EST), Room E5  
We will present the latest intelligence surrounding translational safety assessment, including an illustration of the recently revised ICH S1B guideline. A demonstration of how clinical and preclinical data, together with evidence from literature and database searches, can be collated and reviewed in a defined workflow, then extrapolated to gain scientific insight.  
Presented by: Frances Hall, PhD, Senior Director, In Silico Solutions, Instem and Brenda Finney, PhD, Vice President, In Silico & Translational Science, Instem   
Lunch will be provided  
Wednesday, November 15  
Symposium Gold Sponsor of ACT Session number S15, Managing Nitrosamine Impurities in Pharmaceuticals: 2023 Update  
Wednesday, November 15, 9 AM - 12.00 PM (EST)  
Symposium Presentation: Factors Influencing the Potency of N-Nitrosamines: Reviewing the Carcinogenic Potency Categorization Approach  
Presented by: Kevin Cross, PhD, VP of Regulatory Science   
  
We are also pleased to be involved in the following posters:   
Abstract Title: Translational and in silico assessment of liver injury for 4-hydroxy-2,6-dichlorodiphenylamine.  
Presenting Author: Brenda Finney, PhD, Vice President, In Silico & Translational Science, Instem  
Poster Session Date and Time: Monday, November 13, 5.00 PM – 6.30 PM (EST)  
Abstract Title: Standardized Target Carcinogenicity Assessment (TCA) Enables ICH S1B-based Regulatory Decisions   
Presenting Author: Frances Hall, PhD, Senior Director, In Silico Solutions, Instem  
Poster Session Date and Time: Monday, November 13, 5.00 PM – 6.30 PM (EST)  
Poster Number: 205   
  
Instem are participating in the ACT ToxHunt game so stop by our booth 212 to scan a QR code that will earn you points.  
  
  
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Jiangsu Provincial Institute of Materia Medica Selects Provantis Preclinical SaaS Solution  
Provantis to Increase Efficiencies and Further Improve Study Data Quality at Nanjing Research Facility  
CONSHOHOCKEN, PA – Business Wire, June 4, 2019 - Instem, a leading provider of IT solutions to the global life sciences market, announced today that Jiangsu Provincial Institute of Materia Medica (JPIMM), has purchased the Provantis® preclinical SaaS solution suite to manage preclinical processes at its research facility in Nanjing.  
JPIMM, part of Nanjing Tech University, conducts a wide range of study types including general toxicology, reproductive toxicology, genetic toxicology and carcinogenic studies. The institute, one of the first laboratories in China to be awarded GLP certification, has won more than 50 research awards and obtained 34 patents for inventions.   
Provantis will replace JPIMM’s existing manual processes to deliver increased efficiencies in the collection, storage and reporting of preclinical data, as well as delivering further improvements in data quality and traceability.  
Key Facts  
  
JPIMM to deploy an extensive suite of modules including General Toxicology, Pathology, Clinical Pathology, and Tables & Statistics  
JPIMM to access Provantis via the SaaS delivery model, benefiting from a reduced IT footprint and lower support costs, together with the flexibility and scalability to support further growth on-demand   
Contract awarded following a detailed competitive evaluation; Provantis recognized as the global market leader and the gold standard within China  
JPIMM has also purchased a range of professional services to facilitate quick implementation and a rapid return on investment   
  
Dr. Jing Liu, Deputy Director of Jiangsu Provincial Institute of Materia Medica and Director of Jiangsu Center for Safety Evaluation of Drugs said “During our search for a preclinical data management solution it was vital for us to choose not only a proven, robust and comprehensive product, but also a vendor with the knowledge, experience and capabilities to support our future growth and our aspirations to increase our client base internationally. As the global market leader and the gold standard within China, we are confident that Instem and Provantis can help us achieve these goals.”  
Jon Sparkes, Senior Director Sales, Europe & Asia, Instem, commented, “We are delighted to welcome JPIMM as our newest client within China and look forward to developing a long and fruitful relationship with them. We are particularly excited to see JPIMM join our growing roster of SaaS clients that have secure and immediate access to the latest versions of our products over the Web.”   
Instem has an established full-service office in Shanghai and supports organizations through traditional on-site deployment , as well as through its SaaS delivery model from a secure, professionally managed data center based in Shanghai.  
About Jiangsu Provincial Institute of Materia Medica (JPIMM)  
JPIMM, part of Nanjing Tech University, consists of four professional research offices (the medical chemistry research office, the natural drug research office, the pharmacology and toxicity research office, and the pharmaceutical preparation and quality research room) as well as an experimental animal quality check station. JPIMM was one of the first laboratories in China to achieve GLP accreditation.  
JPIMM has won more than 50 research awards (1 international award, 5 national awards, 26 provincial-level and ministry-level awards) and has obtained 34 patents for inventions. The institute has conducted academic exchanges with the USA, the UK, France, Japan and some South-east Asian countries and established research partnerships with WTO, IOCD, TAMU Institute of Ophthalmology and Pharmacology, US Bausch & Lomb, and HK Fugao Pharmaceutical Co. Ltd.   
For further information visit http://jsyws.njtech.edu.cn/  
About Instem  
Instem is a global provider of leading software solutions and services that are helping over 500 clients bring their life enhancing products to market faster. We enable clients in the life sciences to more efficiently collect, analyze, report and submit high quality regulatory data, while maintaining compliance for their products around the world.   
Instem solutions are in use by customers worldwide, meeting the rapidly expanding needs of life science and healthcare organizations for data-driven decision making, leading to safer, more effective products.  
Instem supports its global roster of clients through offices in the United States, United Kingdom, France, Japan, China and India.   
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Instem Sponsors Prominent India Conference and Showcases Preclinical Software Solutions  
Instem Supports the 6th Conference of the Society of Toxicologic Pathology – India  
CONSHOHOCKEN, PA – October 17, 2016 - - Instem, a leading provider of IT solutions to the global early development healthcare market, is pleased to announce its support of the 6th Conference of the Society of Toxicologic Pathology – India (STP-I), taking place at the Westin Pune Koregaon Park, Pune, from October 21-23, 2016.  
Visitors to the conference will learn about:  
  
Submit™ - the most widely deployed set of SEND tools and outsourced services, adopted at over 45 sites across 15 countries   
Provantis® - the undisputed leading solution for preclinical study management  
KnowledgeScan™ - Target Safety Assessment Service for investigating safety concerns in drug development   
  
“As India-based pharmaceutical and contract research organizations continue to contribute exponentially to the global pharmaceutical market, Instem is pleased to offer its ongoing support to events such as STP-I.” said Neil Donaldson, Instem VP Global Sales, Europe & Asia.  
As interest in FDA submissions has grown within the Indian market, Instem continues to support this demand through the submit™ solution of SEND management tools and services.  
Instem entered the early drug development market in India in 2005 with its first customer, Advinus Therapeutics, to help them enhance client services, attract western business and support Good Laboratory Practices. During 2012, Instem further demonstrated its commitment to the region through the establishment of an office in Pune. Since then, the Pune office footprint has doubled in size and resources have trebled.   
About Instem   
Instem is a leading supplier of IT applications and services to the early development healthcare market delivering compelling solutions for data collection, analysis and regulatory submissions management. Instem solutions are in use by customers worldwide, meeting the rapidlyexpanding needs of life science and healthcare organizations for data-driven decision making leading to safer, more effective products.  
Instem’s portfolio of software solutions and consulting services increases client productivity by enhancing product development processes while offering the unique ability to generate new knowledge through the extraction and harmonization of actionable scientific information.  
Instem supports over 500 clients through offices in the United States, United Kingdom, France, Japan, China and India.  
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Instem Announces New Software Solution to Support Updated Nitrosamines Guidance  
New Software Module Introduced to Support the Latest Regulatory-approved Carcinogenic Potency Categorization Approach (CPCA)   
PHILADELPHIA, PA - September 28, 2023 - Instem a leading provider of IT solutions and services to the global life sciences market, has announced its latest module offering as part of the Leadscope Model Applier™ computational toxicology software solution.  
The US Food and Drug Administration (FDA), the European Medicines Agency (EMA), and Health Canada have recently released a major update on N-nitrosamine impurities in human medicinal products including a new approach to determining Acceptable Intake (AI) limits for N-nitrosamines. The new option is referred to as the Carcinogenic Potency Categorization Approach (CPCA) which is a decision tree that assigns an N-nitrosamine impurity to one of five potency categories based on its chemical environment. This information is used to assign an AI limit based on the potency category resulting from the nitrosamine structure.   
Instem’s new Leadscope Model Applier N-Nitrosamine CPCA module will provide a seamless solution for rapidly generating the CPCA potency categories and its associated AI limits based on this latest guidance. Alongside this, the module will automatically and consistently calculate the potency category and associated AI limits in seconds without the need to manually process the detailed and complex chemistry rules, and rapidly generate reports aligned with regulatory expectations.  
For further information about the new CPCA module please email insilico@instem.com   
About Instem  
A global provider of leading software solutions and scientific insight services, Instem is helping clients bring their life enhancing products to market faster.  
From concepts to cures, we enable organizations in the life sciences to more efficiently collect, report and submit high quality regulatory data, while offering them the unique ability to generate new knowledge through the extraction and harmonization of actionable scientific information.  
Across the entire drug development value chain, every day Instem solutions are meeting the rapidly expanding needs of life science organizations for data-driven decision making, leading to safer, more effective products.  
Instem supports its global roster of clients through offices in the United States, United Kingdom, France, Switzerland, Japan, China, and India.  
Instem’s in silico solutions enable organizations around the world to effectively unlock valuable knowledge contained in both public and proprietary sources of research data. Clients can also access well over 600,000 toxicology studies for more than 200,000 chemicals, enabling fast, accurate, defendable and regulatory-accepted predictions.  
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Instem Conference Series Delivers Value To Users Across The Globe  
Instem Connects With Clients at Meetings in Europe, North America, China and Japan  
CONSHOHOCKEN, PA – December 11, 2013 - -Instem, a leading provider of IT solutions to the global early development healthcare market, is pleased to announce that its 2013 Instem International Conference Series (IIC) has been deemed another great success by clients.  
The IIC is a key component of Instem's Customer Involvement Program (CIP), offering delegates an excellent opportunity to help shape Instem's solution roadmap, see new solutions under development and hear the latest news regarding product strategy. The IIC also provides excellent networking opportunities, enabling delegates to connect with their industry peers and key members of the Instem team, sharing best practice and learning opportunities.   
During October a series of regional IIC meetings took place across the globe in Cheshire, UK, Philadelphia, USA and Beijing, China, with the final meeting taking place in November in Tokyo, Japan, hosted by CTC, Instem’s Japanese distributor.  
The IIC meetings included a range of presentations delivered by members of the Instem team and client speakers from Astellas Pharma Inc., AstraZeneca, Bristol-Myers Squibb, MPI Research, Shanghai Institute of Materia Medica and WIL Research. The keynote address, delivered by David Cook, Associate Director Global Safety Assessment, AstraZeneca, discussed the benefits of collecting, analyzing and sharing data across the R&D continuum to deliver improved drug safety, a theme which underpinned many of the conference presentations.   
SEND (Standard for Exchange of Nonclinical Data) was a hot topic at all 4 meetings and delegates appreciated the opportunity to learn more about this important standard and Instem’s range of widely deployed SEND solutions including submit™ and SENDView™. Delegates also had the opportunity to take part in a range of Spotlight Sessions – interactive breakout sessions featuring a range of solutions from Instem’s Study Workflow & Automation and Data Integration & Bioinformatics solution suites. In addition, the IIC offered plenty of networking opportunities as well as 1:1’s and Q&A sessions with Instem’s team of experts.   
Julie Jones, Marketing Manager, Instem said "It was fantastic to connect with so many of our clients from across the globe. The IIC provides a great opportunity for us to further cement and strengthen our client relationships and it was pleasing to see such high levels of positive interaction and great customer feedback across the conference series.”  
About Instem  
Instem is a leading supplier of IT applications to the early development healthcare market, delivering compelling solutions for data collection, management and analysis across the R&D continuum. Instem applications are in use by customers worldwide, meeting the rapidly expanding needs of life science and healthcare organizations for data-driven decision making leading to safer, more effective products.  
Instem’s portfolio of software solutions increases client productivity by automating study-related processes while offering the unique ability to generate new knowledge through the extraction and harmonization of actionable scientific information.  
Instem supports over 400 clients through full service offices in the United States, United Kingdom and China with additional locations in India and a full service distributor based in Japan.  
Meeting clients at the intersection of investment & return™.  
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Integrated Laboratory Systems Subscribes to Provantis® Online  
Provantis Preclinical Solution Chosen to Accelerate Study Volume While Reducing Costs  
CONSHOHOCKEN, PA - (BUSINESS WIRE) - March 5, 2010 - - Instem, a leading provider of early drug development software solutions, announced today that Integrated Laboratory Systems (ILS) has subscribed to Provantis Online, enhancing their existing software systems.  
Headquartered in Research Triangle Park, North Carolina, ILS is a multidisciplinary research organization providing comprehensive support to federal and commercial clients in the environmental and health sciences.  
After reviewing all commercial alternatives within the preclinical IT market, ILS chose Provantis as the most comprehensive solution to fully automate their toxicology data acquisition, analysis and reporting processes. By using Provantis, they will be able to reduce costs, execute more studies and deliver increased value in shorter timeframes to their sponsors.  
  
 “Instem’s hosted solution is a true turn-key system, so the time required by our staff to get their system validated and into production is significantly reduced,” comments Brad Blackard, COO at ILS. “We felt that using Provantis over the Web provided the best fit for our business model and allowed our limited IT resources to be leveraged more efficiently.”  
Using Instem’s hosted remote delivery model offers simpler, more cost effective ways to provide software functionality, maintenance, and support over the Internet. ILS will have complete in-application access to their data just as if their software was deployed on-site, yet they no longer require additional hardware or dedicated resources. Removing the need for on-site software ensures clients like ILS can access the latest major releases of Provantis without the delays and costs traditionally involved with site-based installations.   
Instem’s turn-key subscription includes all 3rd party licenses such as Oracle, Outlook and SAS, along with training, maintenance, unlimited help desk support and Instem’s Validation Pack.  
Since 2005, Instem has utilized a military-grade data center based in the US, which is being used by clients running GLP and non-GLP studies.   
ILS will additionally be taking advantage of Instem’s Specialized Solution services, a more tailored approach to deployment, offering dedicated client specialists and extended customer care. This program features the Continuous Learning Model, where clients stay closely connected for one year following their first study using Provantis, with on-demand access to industry specialists to assist with new study designs, refresher learning or anything else needed to optimize their use of Instem solutions.  
Provantis is a modern, fully integrated software system for single users and global organizations engaged in preclinical evaluation studies. Orchestrating every facet of preclinical drug safety assessment, Provantis streamlines processes and workflows with straightforward, intuitive functionality for simple or complex studies within a GLP or non-GLP environment, on-site or over the Web.  
Instem & ILS welcomes anyone wanting more information to visit them at this year’s 49th annual ToxExpo in Salt Lake City, Utah at booths 1201 & 2118.  
  
About ILS   
For 25 years ILS has provided research and testing services to clients in the federal, pharmaceutical, biotechnology, chemical and medical device industries.  
 ILS provides customized solutions in the toxicology, pathology, histology, genetic toxicology, molecular biology as well as environmental and information science fields. By their contributions to these endeavors, ILS is helping to improve the quality of environmental and human health and is making the world a better and safer place for everyone.  
 To learn more about ILS and the services they provide, please visit www.ils-inc.com.  
About Instem  
Instem is a leading supplier of IT applications to the early development healthcare market, delivering compelling solutions for data collection, management and analysis across the R&D continuum. Instem applications are in use by customers worldwide, meeting the rapidly expanding needs of life science and healthcare organizations for data-driven decision making leading to safer, more effective products.  
Instem’s portfolio of software solutions increases client productivity by automating study-related processes while offering the unique ability to generate new knowledge through the extraction and harmonization of actionable scientific information.  
Instem supports over 400 clients through full service offices in the United States, United Kingdom and China with additional locations in India and a full service distributor based in Japan.  
Meeting clients at the intersection of investment & return™.  
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SNBL USA Purchases Provantis Preclinical Solution Suite; 500 Users to be Deployed  
  
  
  
  
  
  
  
  
  
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SNBL USA Purchases Provantis Preclinical Solution Suite; 500 Users to be Deployed  
Provantis to Assist SNBL in Delivering the Exceptional Customer Experience  
CONSHOHOCKEN, PA - (BUSINESS WIRE) – February 10, 2011 - - Instem, a leading provider of early development software applications, announced today that SNBL USA has placed an order for 500 users of its Provantis® preclinical software solution suite. SNBL USA will be using the integrated Provantis solution suite to offer their biotechnology and pharmaceutical clients’ unparalleled quality in both science and service.  
Based in Everett, Washington, SNBL USA is one of the nation’s leading contract research organizations (CROs) uniquely positioned to provide a broad range of preclinical study services in support of the drug development process.  
SNBL USA will be accessing every module of the integrated Provantis solution suite, including Instem’s Dispense™ solution for test item control and its latest Data Import module, enabling SNBL USA to seamlessly pull a broad range of external information into Provantis such as Estrous Cycle and Bone Assessment data.  
SNBL USA’s evaluation began with Instem’s Toxicology Resource Planning (TRP™) solution. Deployed as an integrated module within the Provantis suite or a stand-alone solution, TRP enables scheduling of studies, resources, equipment, animals and facilities to improve study throughput and increase up-time with less administration. Using TRP, SNBL USA will be able to initiate projects more quickly, generate more value from physical assets, and know the status of studies at all times while keeping their plans consistent across all of their facilities.   
“Once we saw how comprehensive and effective their TRP solution would be for us, we expanded our evaluation to include Instem’s entire Provantis solution suite,” comments Dr. Darren Warren, SNBL USA Safety Assessment Director. “Provantis exceeded our expectations and it became clear that we needed to replace our existing software with a single integrated solution that could bring more value to our organization.”   
“In addition to modern integrated solutions, we’re finding that clients want to be supported by full-service partners that are cost effective extensions of their business, working with them to achieve a common objective,” comments John Anderson-Carter, VP Sales at Instem. “Our Provantis solution will give the technological edge SNBL USA is looking for, and our people will ensure they are empowered by it, not constrained. Provantis is here to help clients with 5 users or 500, to be more productive while staying focused on their science.”   
About Provantis®  
Provantis is a modern, fully integrated software system for single users and global organizations engaged in preclinical evaluation studies. Orchestrating every facet of preclinical drug safety assessment, Provantis streamlines processes and workflows with straightforward, intuitive functionality for simple or complex studies within a GLP or non-GLP environment, on-site or over the Web.   
About SNBL USA, Ltd.  
Headquartered in Everett, WA, SNBL USA, Ltd. is a preclinical CRO that specializes in nonhuman primate (NHP) and small animal research. Study programs range from regulatory toxicology to customized study designs and disease models. Specialized programs include reproductive toxicology, safety pharmacology, immunotoxicology and carcinogenicity.   
Through a commitment to investment and excellence, SNBL USA strives to offer the biotechnology and pharmaceutical industries unparalleled quality in both science and service. For additional information call 425.407.0121 or visit www.snblusa.com.  
SNBL USA is a wholly-owned subsidiary of Shin Nippon Biomedical Laboratories, Ltd. (SNBL), one of the largest CROs in Japan. Established in 1957, SNBL currently employs approximately 2,000 team members worldwide and provides full service drug development capabilities ranging from preclinical through clinical services.   
About Instem  
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ChemOn Selects Instem to Help Automate Preclinical Processes and Meet Growing Demand for SEND  
  
South Korean Contract Research Organization to Deploy Provantis® for Preclinical Data Management and Submit™ Software for SEND Management  
CONSHOHOCKEN, PA (BUSINESS WIRE) July 10, 2017 - Instem, a leading provider of IT solutions to the global early development healthcare market, announced today that Chemon Inc. (Chemon) has purchased a comprehensive package of preclinical data collection, analysis and regulatory submissions management solutions to automate and optimize study related processes at its Non-Clinical Research Laboratory in Yongin, South Korea.   
Founded in 2000, Chemon is a privately owned, non-clinical Contract Research Organization (CRO), headquartered in Suwon, offering a wide range of testing services including toxicity and efficacy, pharmacokinetics and in vitro pharmacology.  
Following a detailed competitive evaluation, Chemon selected the Provantis® preclinical data management solution to automate preclinical study processes and deliver increased efficiencies in the collection, storage and reporting of preclinical data. Chemon will also be deploying Instem’s submit™ software suite for the creation and management of SEND (Standard for Exchange of Nonclinical Data) compliant datasets. Chemon will access Instem’s solutions via the SaaS delivery model, giving them cost-effective access to software functionality, maintenance and support.   
Key Facts  
  
Comprehensive suite of Provantis modules to be deployed including General Toxicology, Clinical Pathology, Reproductive Toxicology, Pathology and Tables & Statistics  
Provantis to replace existing manual processes and legacy systems  
Chemon to implement the complete submit software suite for the creation and management of SEND datasets   
Chemon also deploying SENDView™, an Instem tool for simplified QC review of SEND datasets  
Chemon to harness the power of the Instem University e-learning platform, enabling users to quickly become proficient in Instem solutions.  
  
Dr. Si-Whan Song, CEO, Chemon said “Instem is widely recognized as the leading organization in the field of preclinical IT solutions and we look forward to quickly realizing the benefits of our Provantis and submit-for-SEND deployments. These investments will enable us to take our service to the next level, delivering faster response times and improved data quality to our sponsors. Our submit purchase will further strengthen our competitive position, enabling us to provide consistent, accurate, high quality SEND datasets to our clients.”   
Neil Donaldson, VP Sales Europe & Asia, Instem, commented “We are delighted and honored to welcome Chemon to our client community. As a leading voice for the creation of a more connected ecosystem in the life sciences industry, it is pleasing for us to see organizations such as Chemon turning to Instem to deploy cohesive, state-of-the-art technology solutions that remove process barriers and help create heightened efficiencies for them and their clients.”   
About Chemon Inc.  
Chemon Inc. is a privately owned, non-clinical Contract Research Organization (CRO), which was founded in 2000. Chemon Inc. is headquartered in Suwon, South Korea and also has a state of the art, GLP and AAALAC certified research laboratory in Yongin.  
Chemon Inc. offers a wide range of testing services including toxicity and efficacy, pharmacokinetics and in vitro pharmacology.   
For further information please visit http://chemon.co.kr/eng/index.php  
About Instem  
Instem is a global provider of leading software solutions and services that are helping over 500 clients bring their life enhancing products to market faster. We enable clients in the life sciences to more efficiently collect, analyze, report and submit high quality regulatory data, while maintaining compliance for their products around the world.   
Instem’s portfolio of software solutions and consulting services increases client productivity by enhancing product development and management processes, while offering the unique ability to generate new knowledge through the extraction and harmonization of actionable scientific information.  
Instem solutions are in use by customers worldwide, meeting the rapidly expanding needs of life science and healthcare organizations for data-driven decision making leading to safer, more effective products.  
Instem supports its global clients through offices in the United States, United Kingdom, France, Japan, China and India.  
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Instem and Apelon Extend Partnership for Patient-Focused Clinical Decision Support  
Instem Solutions Deployed to Help Manage Electronic Medical Data  
CONSHOHOCKEN, PA - (BUSINESS WIRE) - March 29, 2012 - - Instem, a leading provider of IT solutions to the global early development healthcare market, and Apelon, an international provider of terminology and data interoperability solutions, today announced a further partnership to deploy advanced technology for patient-focused clinical decision support.  
Apelon and Instem Scientific (formerly known as BioWisdom) have worked together in previous partnerships, combining Instem’s suite of taxonomic and semantic products and services with Apelon’s vocabulary creation expertise to deliver unique solutions for pharmaceutical R&D and the wider healthcare IT market.   
Instem Scientific has helped clients around the world navigate the complex scientific and commercial issues involved in developing successful healthcare products. Acquired by Instem in early 2011, BioWisdom is now an integrated business unit operating as ‘Instem Scientific’.   
Most recently, the companies worked together for a large U.S. federal agency to apply novel state-of-the-art language and terminology processing algorithms and processes to extract knowledge from semi-structured text documents. The project demonstrated how a low-cost starting point for knowledge extraction can effectively be achieved. Instem and Apelon generated a large number of actionable, encoded assertions from the source documents, which were curated by expert reviewers to produce a high-quality knowledge base.   
The novel Instem technology leverages advanced deterministic algorithms underpinned by a large biomedical ontology, covering all of the key concepts relevant to the healthcare industry. This approach proved singularly adept at discovering a broad range of actionable knowledge. After expert curation and review, the knowledge base is encoded in SNOMED CT (Systematized Nomenclature of Medicine--Clinical Terms) and other controlled vocabularies and used for applications ranging from point-of-care decision support to epidemiologic surveillance and research hypothesis testing.   
Instem’s approach provides a valuable tool to help manage the explosion of electronic medical data, which promises better, more efficient care. This project suggests that in order to answer a broad range of hypothetical questions based on free text information, knowledge extraction solutions require substantial complementary infrastructure, including visualization tools such as Instem’s OmniViz™, and a lifecycle approach to data management such as Apelon’s Terminology Asset Management(sm) services.  
This blend of Instem technology and Apelon’s scientific management services will allow pharmaceutical organizations around the world to improve care and bottom line profitability through better extraction of data that was previously inaccessible.  
"Over the past twenty years we have had the privilege of working on many federal agency informatics projects, traditionally one of most significant venues for testing emerging healthcare information-related processes at scale" said Stephen Coady, Apelon’s President and CEO. "Because work for government organizations is in the public domain, the insights and expertise this work has provided are available for all to consider. We welcome opportunities to share our experience."  
“Our work on this project has demonstrated how Instem technology developed for pre-clinical knowledge discovery can be used to build patient-focused clinical decision support,” comments Dr. Gordon Baxter, Instem Chief Scientific Officer. “Making existing data more visible and usable has long been a key aspect of our work and we are delighted to be partnering with Apelon again in such an important area.”   
About Apelon  
Apelon is an international clinical informatics company focusing on data standardization and interoperability. Apelon helps leading healthcare enterprises, life sciences organizations and government agencies improve the quality, comparability and accessibility of their information. Apelon offers solutions and professional services for terminology development, management, mapping and deployment.   
For more information, please visit www.Apelon.com.  
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Instem Genetox Solution Supports Development of Bioartificial Human Skin Models  
Phenion Scientists Deploy Comet Assay IV To Accurately Measure DNA Damage in Phenion Full Thickness Skin Models  
CONSHOHOCKEN, PA - Jan 30, 2018 - Instem, a leading provider of IT solutions to the global life sciences market, is pleased to announce that Phenion, an expert in 3D skin model technology, has deployed the Comet Assay IV live video imaging system to analyze DNA damage in Phenion Full Thickness Skin Models that have been subjected to the 3D Skin Comet assay.   
Originally developed by Perceptive Instruments, and now part of the Instem solution portfolio, Comet Assay IV is a live video imaging system for fast, accurate and reproducible comet slide scoring. Comet Assay IV's unique single-click scoring method and instant live video technology make it the most efficient and easy-to-use system available for measuring DNA damage using single cell gel electrophoresis.   
Comet Assay IV has been successfully deployed in the validation study of the 3D Skin Comet Assay. This assay, built on Phenion Full-Thickness Skin Models, has shown excellent toxicological predictivity during its validation by five US and European laboratories. The assay detects structural DNA damages and other lesions, which may give rise to gene mutations and the method is well-suited to supplement existing in vitro test batteries and to follow-up initial positive findings. The 3D Skin Comet Assay has already successfully supported safety assessments of hair dye ingredients, and scientists envision that the method will be adopted into an OECD test guideline for its global use in safety assessment of chemicals, e. g. in the framework of REACH.   
About Phenion  
Phenion, with its expertise in skin physiology, markets in vitro testing tools for safety assessment and basic research in dermatology and cosmetic science. Phenion products include the human Phenion Full-Thickness Skin Model and the Phenion Full-Thickness AGED Skin Model. These tissues are exclusively populated with primary human cells, thus perfectly mimicking human skin in diverse dimensions, such as histological architecture and a wide spectrum of physiological skin parameters. After having used the innovative skin models for its own research purposes for many years, the organization has decided to take the next step and grant unlimited access to the Phenion products, thus making them available for other companies, organizations and research institutes.   
For more information, please visit: www.phenion.com   
About Instem  
Instem is a global provider of leading software solutions and services that are helping over 500 clients bring their life enhancing products to market faster. We enable clients in the life sciences to more efficiently collect, analyze, report and submit high quality regulatory data, while maintaining compliance for their products around the world.   
Instem solutions are in use by customers worldwide, meeting the rapidly expanding needs of life science and healthcare organizations for data-driven decision making, leading to safer, more effective products.  
Instem supports its global roster of clients through offices in the United States, United Kingdom, France, Japan, China and India.   
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Instem Exhibiting at Genetic Toxicology Association Annual Meeting, Newark, Delaware  
  
  
  
  
  
  
  
  
  
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Instem Exhibiting at Genetic Toxicology Association Annual Meeting, Newark, Delaware  
Instem's Perceptive Instruments Group to Showcase Leading GeneTox Solutions  
CONSHOHOCKEN, PA– May 8, 2017 - - Instem, a leading provider of IT solutions to the global early development healthcare market, is pleased to announce that Perceptive Instruments, an Instem company, will be exhibiting at the Annual Genetic Toxicology Association (GTA) Scientific Meeting May 11-12, Newark, Delaware.  
Visitors to the booth will learn how organizations across the globe are using its solutions to improve the integration between data acquisition, auditing and reporting for regulatory genetox assays. Solutions on display include:  
  
Comet Assay IV - the market leading live video imaging system for fast, accurate and reproducible slide comet scoring   
Sorcerer Colony Counter – instant, automatic plate counting for GLP laboratories  
Ames Study Manager – plate counting, data management and reporting for the Ames test  
Cyto Study Manager - Data acquisition, integration and reporting for genetic toxicology assays, including modules for the comet assay, micronucleus test and chromosome aberrations.   
  
The Genetic Toxicology Association was founded in 1975 to promote the development of the science of genetic toxicology and to foster the exchange and dissemination of information concerning the field. Its Annual Scientific meetings take place every spring at the Clayton Hall Conference Center on the Campus of the University of Delaware in Newark.  
About Instem  
Instem is a leading supplier of IT applications and services to the early development healthcare market delivering compelling solutions for data collection, analysis and regulatory submissions management. Instem solutions are in use by customers worldwide, meeting the rapidly expanding needs of life science and healthcare organizations for data-driven decision making leading to safer, more effective products.  
Instem’s portfolio of software solutions and consulting services increases client productivity by enhancing product development processes while offering the unique ability to generate new knowledge through the extraction and harmonization of actionable scientific information.  
Instem supports over 500 clients through offices in the United States, United Kingdom, France, Japan, China and India.  
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Instem to Showcase Deep RIM Capabilities at DIA’s Upcoming RSIDM Exhibition   
Instem to Present Single-Place-of-Truth™ Approach for Regulatory Affairs Professionals  
CONSHOHOCKEN, PA – February 7, 2019 - - Instem, a leading provider of IT solutions to the global life sciences market, will be showcasing its comprehensive Regulatory Information Management (RIM) capabilities at DIA’s Regulatory Submissions, Information, and Document Management (RSIDM) show February 11-13, 2019 in Bethesda, MD.  
Instem’s Samarind RMS suite is a fully integrated software solution that has been purpose-built to mirror the processes associated with acquiring and maintaining product licenses across the world. The benchmark for RIM, Samarind RMS provides a flexible and smarter way to manage Medical Product Information, allowing unlimited reuse of data for current and future product license applications. This concept has proven to streamline workflows, shorten internal review cycles, improve collaboration and maintain best-in-class data quality for the Drug Safety, Generics and Medical Device communities.   
“We encourage attendees to stop by booth #104 and learn how our pragmatic approach to systems design and implementation enables our customers to manage their licenses smoothly and efficiently, safe in the knowledge that our Single-Place-of-Truth™ approach for regulatory affairs professionals delivers a complete end-to-end solution,” comments Olaf Schoepke, PhD, Vice President Regulatory Solutions at Instem.  
Not attending this year’s RSIDM event? No worries – you can learn how our Single-Place-of-Truth™ approach can bring value to your organization, regardless of size, location or number of licenses by simply downloading our fact sheet or contacting us.   
About Instem  
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Instem Launches In Silico Toxicology Service  
Technology-enabled service delivers fast, efficient, comprehensive in silico toxicology predictions  
CONSHOHOCKEN, PA – Business Wire, December 10, 2020 - Instem, a leading provider of IT solutions to the global life sciences market, announced today that it has launched the Predict™ In Silico Toxicology service. Predict™ is a leading edge, technology-enabled service that delivers a combination of powerful computation models with expert scientific review, to help clients predict chemical safety more quickly, efficiently and comprehensively.  
The new service leverages Instem’s expertise in delivering technology-enabled services with computational solutions developed by Leadscope, an Instem company, who are leaders in the area of In Silico Toxicology. Known for their advanced informatics and prediction technology, together with comprehensive database solutions, Leadscope helps organizations around the world effectively unlock valuable knowledge contained in both public and proprietary sources of research data. Clients searching Leadscope’s toxicity databases can access well over 500,000 toxicology studies for more than 200,000 chemicals, enabling fast, accurate, defendable and regulatory-accepted predictions.   
The new Predict™ In Silico Tox service builds on the power of these world-leading computational models and databases, combining them with expert scientific review, to deliver comprehensive, unbiased, high quality, regulatory-accepted assessments of chemical safety.  
The Predict™ service is delivered by an experienced team, in conjunction with external consultants, who have a deep understanding of applicable guidelines and regulatory agencies’ processes, as well as extensive experience in computational methodologies, toxicology, and chemistry. All assessments and expert reviews are based on a documented standard operating procedure and leverage an infrastructure that ensures the latest information is being used, including historical databases of toxicity studies. The new service supports a variety of applications including the ICH M7 pharmaceutical impurities guideline, assessment of extractables and leachables, and classification and labelling.   
Dr. Glenn Myatt, Instem’s Vice President of Informatics said, “We are extremely excited to launch our new Predict™ service, and we are encouraged to see our clients realizing immediate value from our service.” Dr. Myatt added “Ideal for organizations of all sizes, Predict™ has been designed to meet the needs of small and medium sized organizations that may not have the necessary team to perform an expert review, by providing a complete (Q)SAR solution to satisfy regulatory requirements. For larger organizations with in-house expertise and technology, Predict™ offers an additional option to complement their in-house capabilities or to assist during times of peak demand.”   
To learn more about Predict™ download the fact sheet.  
About Instem - From Concepts to Cures.  
A global provider of leading software solutions and scientific insight services, Instem is helping clients bring their life enhancing products to market faster. We enable organizations in the life sciences to more efficiently collect, report and submit high quality regulatory data, while offering them the unique ability to generate new knowledge through the extraction and harmonization of actionable scientific information.   
Across the entire drug development value chain, every day Instem solutions are meeting the rapidly expanding needs of life science organizations for data-driven decision making, leading to safer, more effective products.  
Instem supports its global roster of clients through offices in the United States, United Kingdom, France, Japan, China and India  
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Instem to Present at 6th Annual AsiaTox Conference, Sendai, Japan  
  
  
  
  
  
  
  
  
  
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Instem to Present at 6th Annual AsiaTox Conference, Sendai, Japan  
Instem Presenting on Acceptance Status and Future Deployment Plan of SEND Format by FDA  
CONSHOHOCKEN, PA - July 12th , 2012 - - Instem, a leading provider of IT solutions to the global early development healthcare market, is pleased to announce that Instem Consultant, Jonathan Sparkes will be presenting at AsiaTox VI, the 6th International Congress of the Asian Society of Toxicology, taking place in Sendai, Japan, from July 17th-20th.  
The presentation will outline the current acceptance status and future deployment plan of the SEND (Standard for Exchange of Nonclinical Data) format by the FDA and will also look at how the SEND initiative facilitates data cooperation between pharmaceutical organizations and contract research laboratories (CROs).   
FDA reviewers continue to receive mostly paper or electronic paper (PDF) submissions. Manually entering this data for further analysis is seen as time consuming and inefficient, taking time away from the primary mission of reviewing the content of submissions to asses and ensure the safety of the drug that is being tested. The SEND format enables more efficient review of nonclinical data, offering improved data quality, accessibility and predictability.  
Using data in SEND format, industry can help improve the safety review process while streamlining the flow of data from collection through submission and facilitate data interchange within their organizations and with external study partners.  
“I am delighted to have been invited to speak on this topic,” commented Mr. Sparkes, “Instem has been a leading participant in the SEND initiative from the outset and it is a subject that is being keenly watched by research organizations throughout the Asia Pacific region.”   
To help see the standard propagated throughout pharmaceutical companies and CROs worldwide, Instem has been providing education and outreach to promote SEND while demonstrating its own technology solution suite – submit™. Industry is now actively embracing the SEND solution and Instem clients are utilising submit™ to create and manage their SEND study datasets.   
AsiaTox VI takes place in conjunction with the 39th Annual Meeting of the Japanese Society of Toxicology and the focus of this year’s conference is Risks versus Benefits of Organic Chemicals, Drugs, Metals and Natural Products.  
Instem will also have an exhibitor presence at the conference, where they will be sharing a booth with CTCLS, their Japanese distributor. CTCLS is one of Japan’s leading providers of integrated R&D support systems for the life sciences, supporting Instem’s solutions through their full service offices in Tokyo and Osaka.   
About Instem  
Instem is a leading supplier of IT applications to the early development healthcare market, delivering compelling solutions for data collection, management and analysis across the R&D continuum. Instem applications are in use by customers worldwide, meeting the rapidly expanding needs of life science and healthcare organizations for data-driven decision making leading to safer, more effective products.  
Instem’s portfolio of software solutions increases client productivity by automating study-related processes while offering the unique ability to generate new knowledge through the extraction and harmonization of actionable scientific information.  
Instem supports over 400 clients through full service offices in the United States, United Kingdom and China with additional locations in India and a full service distributor based in Japan.  
Meeting clients at the intersection of investment & return™.  
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The Jackson Laboratory Consolidates IT Systems; Selects Instem Preclinical Solutions  
Provantis Preclinical SaaS with Resource Planning Product Selected for Rapid Deployment at Sacramento Facility  
CONSHOHOCKEN, PA - (BUSINESS WIRE) – August 31, 2011 - - Instem, a leading provider of early development software applications, announced today that The Jackson Laboratory has purchased Instem’s Provantis Preclinical solution, including its comprehensive resource planning product, TRP™.  
Founded in 1929 as a cancer research facility, The Jackson Laboratory (Jackson) is an independent, nonprofit organization conducting research in the area of cancers, neurobiology, metabolic diseases, immunology, developmental and reproductive biology, and computational biology and bioinformatics. Their mission is to discover the genetic basis for preventing, treating and curing human disease, and to enable research for the global biomedical community.   
Key Facts  
  
Instem integrated General Toxicology, Pathology and Formulation modules with Toxicology Resource Planning (TRP) product, deploying at Jackson site in Sacramento, California   
TRP will enable Jackson to schedule studies, resources, equipment, animals and facilities to improve study throughput and increase up-time with less administration  
Jackson will be using SaaS delivery model from Instem’s US-based data center  
Project includes integration of Jackson’s existing ERP system and replaces numerous custom-built applications  
Instem providing dedicated on-site resources to support rapid deployment  
  
“We are seeing organizations of all sizes wanting to consolidate their systems to help integrate and streamline processes and in many cases reduce costs,” comments John Anderson-Carter, VP North American Sales at Instem. “More than ever, who they choose as their primary solutions provider is of critical importance. Instem’s stability and global market leadership was clearly a differentiator for Jackson, and we are eager to support their mission of advancing human health.”  
Jackson additionally provides scientific resources, techniques and data to the global research community and has accumulated much recognition in their work. Twenty-two Nobel Prizes connected to Jackson research, resources and education programs have been awarded from 1960 to 2009. Jackson additionally breeds and manages colonies of mice, supplying other research institutions and scientists nearly 3 million JAX mice in over 50 countries each year.   
About The Jackson Laboratory  
The Jackson Laboratory is a nonprofit biomedical research institution and National Cancer Institute-designated Cancer Center based in Bar Harbor, Maine, with a facility in Sacramento, Calif. Its mission is to discover the genetic basis for preventing, treating and curing human diseases, and to enable research and education for the global biomedical community.  
More information can be found at www.jax.org.  
About Instem  
Instem is a leading supplier of IT applications to the early development healthcare market delivering compelling solutions for data collection, management and analysis across the R&D continuum. Instem applications are in use by customers worldwide, meeting the rapidly expanding needs of life science and healthcare organizations for data-driven decision making, leading to safer, more effective products.  
Instem’s portfolio of software solutions increases client productivity by automating study-related processes while offering the unique ability to generate new knowledge through the extraction and harmonization of actionable scientific information.  
Instem supports over 400 clients through full service offices in the United States, United Kingdom and China with additional locations in Japan and India.  
Meeting clients at the intersection of investment & return™.  
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Instem Acquires Market Leader d-wise to Further Accelerate Life Science Development   
Instem’s Acquisition of Leading Clinical Trial Technology and Consulting Provider d-wise Represents Substantial Advancement of its Mission  
PHILADELPHIA, PA – (BUSINESS WIRE) – March 22, 2021 - Instem, a leading provider of IT solutions and services to the global life sciences market, announced today that it has acquired clinical trial technology and consulting leader d-wise, Inc. (d-wise) as part of its mission to enable clients to bring their life enhancing products to market faster. The further consolidation of key application areas will help customers streamline and accelerate their research and development processes, while access to a broader range of data from across the R&D continuum will increase the power of future in silico modelling and prediction solutions.  
Founded in 2003, d-wise are well respected clinical trial technology domain experts who advise on and build clinical trial analysis and data anonymization solutions, leveraging open-source and cloud technologies. For 19 of the top 20 global pharmaceutical companies, d-wise has made a significant impact in creating operational and clinical data efficiencies that have accelerated clinical trial analysis and regulatory submissions. d-wise supports its global customer community through its U.S. headquarters based in Research Triangle Park, North Carolina, along with an office location in Manchester, United Kingdom.   
Instem sees the acquisition of d-wise as an integral part of its transformational growth strategy, extending its ability to further deliver solutions that meet the rapidly expanding needs of life science organizations for faster data-driven decision making, leading to safer, more effective products.  
“More than a growth-based acquisition, this can truly help transform the industry landscape,” states Phil Reason, CEO at Instem. “Our combined capabilities will help us meet the demand from our clients to create a more connected ecosystem across the life sciences in the global effort to bring life enhancing products to market faster. And, behind all of the technology, is a highly talented, experienced and motivated d-wise team who shares our mission and values. They are widely trusted industry thought leaders and practitioners, committed to delivering an exceptional client experience.”   
Reason continues, “the d-wise organization is well known for its drive to transform the life sciences through open and flexible access to data. They act as strategic advisors to many of Instem’s existing clients and are one of the leading IT solution engineering and integration partners in the market today. We are extremely excited about future opportunities to leverage wider areas of data and knowledge, backed by leading technologies and services, to maximize client value in ways we and the industry have only dreamed of in the past.”   
John Leveille, CEO at d-wise comments, “Our mission has always been to help our clients navigate technology change in pursuit of human health and wellbeing. Today is a watershed moment in our journey, as we take d-wise products and services to the next level and achieve even greater reach and impact. We are excited to be part of Instem, a growing global organization of over 400 professionals with a shared purpose of helping our clients in their life changing missions.”  
Leveille continues, “Instem’s reputation is stellar and we share many of the same core values which will enable a solid cultural fit. Being part of a large, publicly traded organization will enable us to more rapidly develop and introduce new innovative products and services. By providing solutions across a wide area of the life science R&D continuum, I’m certain that as part of Instem we will accelerate clinical development timelines and have an even broader impact on human health and wellbeing.”   
“Better Together”  
 A key internal theme of the acquisition, the combined strength of Instem & d-wise positions the group as the foremost authority and driving force in generating, analyzing and leveraging data from Discovery through late-stage Clinical Trials. Instem and d-wise will be poised to deliver unique value to clients as one, unified technology-driven powerhouse.  
The d-wise team and its solutions will create a new business unit at Instem known as Clinical Trial Acceleration Solutions. Additionally, Instem reports that planning has begun to develop innovation teams that will be exclusively focused on leveraging the combined capabilities to further expand areas of application as they look to connect and leverage data across a wider area.  
More about d-wise solutions, now part of Instem  
 d-wise offers technology products and services to biometric and transparency leaders, helping clients understand the technology options available to connect and automate systems and workflows. Designed to always meet individual client needs, d-wise solutions provide validated pathways for cloud adoption and open-source clinical analysis.   
d-wise Clinical Trial Acceleration   
 d-wise provides strategy, services and products that leverage open source and public cloud for biometrics, data science and submissions. With domain expertise in R&D product development, IT systems architecture, and change management, d-wise is the preferred advisor and technology implementation partner of controlled clinical analytics environments to some of the world’s most prominent pharmaceutical organizations.  
d-wise Clinical Trial Transparency   
 d-wise transparency software and services empower sponsors to meet EMA Policy 0070 and Health Canada’s Public Release of Clinical Information and support industry wide sharing initiatives. Built in collaboration with industry leaders, d-wise offers Blur™, the #1 clinical anonymization software solution that automates anonymization of both document and data through Natural Language Processing. Available as a SaaS technology solution, or as an outsourced service, d-wise enables sponsors to share anonymized data and documents efficiently, helping to drive medical innovation.   
About Instem   
A global provider of leading software solutions and scientific insight services, Instem is helping clients bring their life enhancing products to market faster.   
From Concepts to Cures, we enable organizations in the life sciences to more efficiently collect, report and submit high quality regulatory data, while offering them the unique ability to generate new knowledge through the extraction and harmonization of actionable scientific information.  
Across the entire drug development value chain, every day Instem solutions are meeting the rapidly expanding needs of life science organizations for data-driven decision making, leading to safer, more effective products.  
Instem supports its global roster of clients through offices in the United States, United Kingdom, France, Japan, China, and India.  
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Instem at ICT 2022  
Helping our clients bring their life enhancing products to market faster  
Please stop by one of our booths to learn more about Instem’s powerful software solutions & services  
Preclinical Solutions - Booth #18  
Learn how Instem’s preclinical solutions keep our clients focused on their science, not their software.  
  
Provantis® is the #1 online solution for managing preclinical studies.   
Learn about submit™, the most widely adopted modular software suite for creating, reviewing and managing SEND data or ask our SEND experts about our new SEND Advantage services.   
Our Genetic Tox Solutions are in a class of their own, featuring Comet Assay IV and Cyto Study Manager.  
  
In Silico Solutions - Booth #19  
Learn how our software and outsourced services enable researchers to generate new scientific insights through the identification, extraction and analysis of data to create actionable information.   
  
KnowledgeScan™ Target Safety Assessment (TSA) Service: Delivering comprehensive TSAs for clients around the world, enabling them to make faster, better-informed decisions on their drug targets.  
Leadscope Model Applier: Easy-to-use software to apply prediction models, perform an expert review, and create reports.  
Genetic Toxicity (Q)SARs: Complete solutions for the computational assessment of genetic toxicity, including statistical-based and expert rule-based models.  
Predict™: A leading edge, technology-enabled service that delivers a combination of powerful computation models with expert scientific review, to help clients predict chemical safety more quickly, efficiently, and comprehensively.  
Poster Presentations:   
P21-01 – Poster Viewing II (PV02), Tuesday 20 September  
 Challenges and Practical Examples in Creation of SEND Data for Developmental and Reproductive Toxicity Studies   
 Co-authored: Showa University School of Medicine, G-SEND (Global SEND Alliance), Ina Research Inc., Instem  
Poster Viewing 1, Monday, September 19th, 2022, 1.00pm-2.00pm / e-poster number is LP-119  
EMA-Mutamind: Which properties determine the mutagenicity of API- derived nitrosamines?  
Presenter: Kevin Cross, VP Product Development, Instem Co-authored by; A. Bassan, I. Brandsma, S. Chang, M. Christmann, M.A. Djuari, U. Deppenmeier, L. Elenschneider, J. Fahrer, R. Frötschl, G. Johnson, B. Haas, T. Hansen, A. Londenberg, T. Osterlund, M. Schulz, M. Vogel, C. Ziemann and S.E. Escher  
   
  
  
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Instem Awarded EU Horizon 2020 Research Grant  
Instem Company NOTOCORD Secures Portion of €4m Grant as Member of Exclusive Scientific Consortium Helping to Make Medications Safer  
CONSHOHOCKEN, PA – (BUSINESS WIRE) - July 1, 2019 - Instem, a leading provider of IT solutions to the global life sciences market, is pleased to announce that NOTOCORD®, an Instem Company, has been awarded a European Commission Horizon 2020: Research & Innovation Program grant.  
As part of an industry and academic consortium of 10 beneficiaries, NOTOCORD will be collaborating on a 3-year research program entitled, INSPIRE: INnovation in Safety Pharmacology for Integrated cardiovascular safety assessment to REduce adverse events and late stage drug attrition. INSPIRE will lead to safer medications with fewer cardiovascular adverse events.  
INSPIRE aims to build on recent technological advances to improve risk prediction in safety pharmacology. With the involvement of leading pharmaceutical companies, universities, software and hardware suppliers, the research will translate into products and services for improved assessment of drug-induced cardiovascular toxicity and, ultimately, safer medicines for patients.  
INSPIRE also aims to train the next generation of safety pharmacology scientists to have a broad range of in-depth scientific knowledge and an ability to adapt to a dynamic and ever-changing industry. In support of this, the grant will enable NOTOCORD to fund and supervise two PhD early stage research projects. The research projects involve NOTOCORD-Sense™, a unique cloud-based collaboration platform offering powerful capabilities for secure data sharing which will be used to prototype and deploy new analysis modules.   
NOTOCORD’s Operations Manager & Product Director, Sylvain Bernasconi, PhD commented, “Being involved in the INSPIRE programme is a fantastic opportunity for us to work with top researchers in developing new methodologies to help reduce drug safety risks. We are eager to start working with them on the numerous projects involved in this exciting research program.”  
 This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 858070.  
Instem’s NOTOCORD group provides software solutions for data acquisition and analysis in preclinical studies and is a recognized leader in cardiovascular, respiratory, electrophysiology and nervous system research areas. NOTOCORD solutions are used by pharmaceutical companies, contract research laboratories, hospitals and academic research centers around the world.  
About Instem  
Instem is a global provider of leading software solutions and services that are helping over 500 clients bring their life enhancing products to market faster. We enable clients in the life sciences to more efficiently collect, analyze, report and submit high quality regulatory data, while maintaining compliance for their products around the world.   
Instem solutions are in use by customers worldwide, meeting the rapidly expanding needs of life science and healthcare organizations for data-driven decision making, leading to safer, more effective products.  
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Instem Presenting and Exhibiting at the American College of Toxicology Meeting, Florida  
Instem to Present Latest Trends in Target Safety Assessment and Showcase Leading Preclinical Solutions and Outsourced Services   
CONSHOHOCKEN, PA – October 22, 2018 - - Instem, a leading provider of IT solutions to the global life sciences market, is pleased to announce it will once again exhibit at the American College of Toxicology (ACT) Annual Meeting, taking place November 4–7, at Palm Beach County Convention Center, West Palm Beach, Florida.   
Conference delegates can also join Instem’s Chief Scientific Officer, Dr. Gordon Smith Baxter, for an Exhibitor Hosted Presentation titled “Solving Target Safety Assessment Challenges”.   
Visitors to Instem’s booth #217 can learn more about:   
  
Submit™ for SEND Management- the most widely adopted suite of software and outsourced study services deployed at over 80 client sites in 15 countries. Stop by and learn how to Submit with confidence™. Download a case study ahead of the event.  
Provantis® - the leading SaaS solution for preclinical study management, serving single users to multi-site clients. Provantis users also have access to the Provantis Academy, an intuitive, online learning solution. Visit us for a demonstration! Learn how clients have reduced preclinical time from hours to minutes, download the case study.   
KnowledgeScan™ - Using a combination of artificial intelligence and human expertise KnowledgeScan is a unique technology-enabled service that is setting new standards in Target Safety Assessment (TSA). Customers can make faster, better informed decisions on their drug targets as a result of high-quality, unbiased and evidence-based TSAs. Download the fact sheet.  
  
Instem will also be holding the following Exhibitor Hosted Presentation:  
Solving Target Safety Assessment Challenges   
Wednesday, November 7  
12:00 Noon–12:55 PM  
Room 1D  
Presented by: Dr. Gordon Smith Baxter, Chief Scientific Officer, Instem   
Companies are under enormous pressure to quickly produce high-quality target risk assessments to make drug development decisions. During this session, we will look at current industry trends and how augmented intelligence, coupled with data mining technologies, are enhancing this area.   
No advance registration is required. For more information about the session email tsa@instem.com or speak to Instem’s booth team throughout the exhibition at booth # 217  
The ACT Annual Meeting is designed by and for members, with the goal of providing excellent quality scientific and regulatory content that is directly applicable to the practice of toxicology.   
The 39th Annual Meeting will include a wide-ranging scientific program, offering a unique opportunity for toxicologists preparing for the challenges and decisions that will affect public health and safety in years to come. For further information about ACT and their annual meeting visit https://www.actox.org/am/am2018/index.asp  
About Instem  
Instem is a global provider of leading software solutions and services that are helping over 500 clients bring their life enhancing products to market faster. We enable clients in the life sciences to more efficiently collect, analyze, report and submit high quality regulatory data, while maintaining compliance for their products around the world.   
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vivoPharm Selects Provantis® to Automate GLP Research for Australian Market  
CRO Leverages Provantis to Tap into Australia's Unmet Need for Local GLP Compliant Services   
CONSHOHOCKEN, PA – October 27, 2016 - Instem, a leading provider of IT solutions to the global early development healthcare market, announced today that vivoPharm Asia/Pacific, an Australian based contract research laboratory, has purchased Instem’s Provantis® preclinical data management solution. The purchase was made to support the company’s Melbourne, Australia team in their GLP (Good Laboratory Practices) research, enabling them to automate and streamline processes and improve data integrity, while maintaining GLP compliance. In addition, by harnessing Instem’s SaaS deployment model, vivoPharm will benefit from lower infrastructure and support costs, together with the flexibility and scalability to meet changing business demands.   
vivoPharm offers a unique, proprietary suite of services and bioanalytical technology for the biotechnology and pharmaceutical industry. The company specializes in conducting studies tailored to guide drug development, starting from compound libraries and ending with a comprehensive set of in vitro and in vivo data and reports, as needed for Investigational New Drug Applications (IND) filings.  
Key Facts  
  
vivoPharm conducted a competitive evaluation and selected Provantis for its ease of use and robust functionality   
Under a three-year agreement, vivoPharm will be utilizing Provantis Pathology, General Toxicology, Clinical Pathology and Data Import modules.  
vivoPharm is maintaining an aggressive implementation schedule and leveraging Instem’s SaaS deployment option to more rapidly meet the growing demands of the Australian market  
Provantis replaces labor intensive manual processes and an internally developed solution  
  
Dr. Ralf Brandt (PhD), CEO and managing director, vivoPharm, commented, “The purchase of Provantis aligns with our comprehensive strategy to address the outsourcing needs of the burgeoning Australian and global market. We are the market leaders because we optimize our services and leverage technology to gain efficiency and improve data integrity for our customers. Provantis will help us to do both of these things as we continue to tackle the growing need for GLP compliant services in the Australian biopharmaceutical market.”   
Neil Donaldson, Instem’s vice president of sales for Europe & Asia, added, “vivoPharm is an innovative and agile team. Their selection of Provantis illustrates their eagerness to maintain market leadership in this arena and reflects their deep understanding of the GLP compliance needs of their customers.”   
Provantis is a fully integrated Windows-based solution suite designed to streamline activities supporting non-clinical evaluation studies in both GLP and non-GLP environments. A comprehensive and intuitive system, Provantis is in use by leading research and development organizations across the life sciences spectrum.  
About vivoPharm  
vivoPharm provides proprietary preclinical services with focus on Oncology, offering integrated service in different disease areas to the biotechnology and pharmaceutical industries. vivoPharm is leading in orthotopic and metastases tumor models and offers whole body imaging. Furthermore, vivoPharm provides all services including toxicology testing and bioanalytical analysis to GLP. vivoPharm’s team of highly trained specialists provides advice and optimized study design to its clients. vivoPharm specializes in conducting studies tailored to guide drug development, starting from compound libraries and ending with a comprehensive set of in vitro and in vivo data and reports, as needed for Investigational New Drug Applications (IND) filing. vivoPharm operations follow strict quality control methods and meet the highest industrial standards, acknowledged by customers worldwide.   
For further information please visit www.vivopharm.com  
About Instem   
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Instem’s portfolio of software solutions and consulting services increases client productivity by enhancing product development processes while offering the unique ability to generate new knowledge through the extraction and harmonization of actionable scientific information.  
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Shanghai Institute of Materia Medica Selects Instem’s Genetic Toxicology and ReproTox Solutions to Support Growth  
  
  
  
  
  
  
  
  
  
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Shanghai Institute of Materia Medica Selects Instem’s Genetic Toxicology and ReproTox Solutions to Support Growth  
Shanghai-Based Drug Development Institute Purchases Expanded Package of Instem Solutions to Support Increasing Demand for Genetic Toxicology and ReproTox Services  
CONSHOHOCKEN, PA - (BUSINESS WIRE) – July 21, 2015 - -Instem, a leading provider of IT solutions to the global early development healthcare market, announced today that the Shanghai Institute of Materia Medica (SIMM) has committed to a further, major investment in Instem solutions to support growing demand for its services.  
Established in 1932, SIMM, part of the Chinese Academy of Sciences, ranks at the top in China for its drug discovery and development activities, with more than 100 drugs having been developed since its establishment. In 2010, SIMM purchased Instem’s integrated Provantis preclinical solution suite to automate study processes at its state of the art facility in Zhangjiang High-tech Park, Shanghai.  
Following a successful 5 year collaborative relationship, this latest investment by SIMM includes the purchase of the Provantis® Reproductive Toxicology module, as well as a range of solutions to support growing demand for Genetic Toxicology services.   
Key Facts  
  
SIMM to implement the Provantis Reproductive Toxicology module to support the management, performance, analysis and reporting of all reproductive study types  
Provantis Reproductive Toxicology to be accessed via the SaaS delivery model from Instem’s Shanghai-based data center, offering simple, cost effective software functionality, maintenance and support   
SIMM to deploy Comet Assay IV, a live video imaging system for fast, accurate and reproducible comet slide scoring   
SIMM to deploy the Ames Study Manager (ASM) software, an integrated suite of software for conducting the Bacterial Reverse Mutation Test, together with a Sorcerer Colony Counter and associated implementation services  
SIMM to upgrade to Provantis 9, the latest version of Instem’s world-leading preclinical software solution  
  
Likun Gong, Senior Toxicology Expert, SIMM, said “Provantis is without a doubt the leading solution across the world. It has been instrumental in improving our research processes and further enhancing the quality, accuracy and speed of service to our clients. We now look forward to harnessing the power of more of Instem’s solutions across our organization.”  
Mr. Neil Donaldson, VP Sales Europe & Asia, Instem, commented “SIMM is renowned as one of the leading interdisciplinary centers of excellence in China and is recognized worldwide for its outstanding achievements and distinguished research team. We are honored to further cement our relationship with them and look forward to continuing our successful partnership.”   
Instem’s Provantis solution was the first western toxicology/pathology software to enter into the Chinese market, deploying its initial system in one of the largest and most advanced vivariums during 2006. As the Chinese preclinical market continues to grow, Instem is leading the market, with Instem solutions deployed at more sites within the region than any competing product.  
Instem has an established full-service office in Shanghai and supports organizations through traditional on-site systems as well as through its SaaS delivery model from a secure, professionally managed data center based in Shanghai.  
About SIMM  
Shanghai Institute of Materia Medica (SIMM), part of the Chinese Academy of Sciences (CAS) has the longest history as a comprehensive research institution for drug discovery in China. SIMM evolved from the Peking Institute of Materia Medica, Academia Sinica, founded in 1932 by Professor Chenggu Zhao. In line with its mission of “Discovering new drugs to relieve patients suffering from various diseases”, SIMM has developed and commercialized over 100 new drugs in the past 60 years.   
Since the implementation of the Knowledge Innovation Program of CAS, developing novel drugs has become a paramount research focus of SIMM in recent years. In line with frontiers in life sciences, and aiming at solving key scientific problems in drug discovery, SIMM carries out both basic and applied studies and develops new theories, methods and technologies. Research priorities are given to treat major diseases, such cancers, cardio-cerebrovascular diseases, neuropsychiatric diseases, metabolic diseases, autoimmune diseases, and infectious diseases. SIMM also pays attention to the development of modern traditional Chinese Medicine (TCM).  
For further information about SIMM please visit http://english.simm.cas.cn/au/bi/  
About Instem  
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Instem’s portfolio of software solutions increases client productivity by automating study-related processes while offering the unique ability to generate new knowledge through the extraction and harmonization of actionable scientific information.  
Instem supports over 400 clients through full service offices in the United States, United Kingdom and China with additional locations in India and a full service distributor based in Japan.  
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BioReliance Selects Cyto Study Manager to Streamline Genetic Toxicology Services  
Instem Software Chosen to Support Acquisition, Management & Reporting of Genetic Toxicology Data  
CONSHOHOCKEN, PA - (BUSINESS WIRE) - October 30, 2015 - - Instem, a leading provider of IT solutions to the global early development healthcare market, announced today that BioReliance® has purchased the Cyto Study Manager (CSM) software system to support genetic toxicology processes at its research site in Rockville, Maryland.  
Developed by Perceptive Instruments, which now operates as part of Instem, Cyto Study Manager integrates data acquisition, auditing, reporting and study management into a single system that greatly improves efficiencies, while ensuring data integrity during genetic toxicology investigations.  
BioReliance, a provider of testing and manufacturing services to pharmaceutical and biopharmaceutical companies worldwide, is the largest supplier of safety testing services to the rapidly growing biologics sector and a long-time user of Instem technologies such as the Provantis preclinical software suite.  
Key Facts   
  
Long-standing client expands use of Instem technologies with purchase of Cyto Study Manager software system   
Integrated study setup, data collection and reporting will speed up processes and improve client response times  
Cyto Study Manager provides BioReliance GLP and FDA 21 CFR part 11 compliance for electronic signatures, comprehensive auditing, archiving and historical control features   
  
Gregor Grant, Senior Vice President, Instem, commented “It is extremely pleasing to see continued demand for our Cyto Study Manager software system and we are delighted to welcome a leading organization such as BioReliance to our growing user community.”  
Perceptive Instruments (Perceptive), now operating as part of Instem, develops, manufactures and supplies image analysis and data processing solutions that are primarily focused on the areas of genetic toxicology, microbiology and immunology. Perceptive solutions are deployed in over 50 countries at leading universities and research institutes and are supporting various government programs such as those at the National Center for Toxicological Research, a Food & Drug Administration division. Perceptive products also serve small and medium-sized companies along with many of today’s multinational organizations, including many of the leading global pharmaceutical companies.   
About Instem  
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FDA SEND Mandate for Regulatory Submissions Now In Force  
Study Submissions Must Adhere to FDA-Supported Formats  
CONSHOHOCKEN, PA – December 19, 2016 - The FDA SEND Mandate for providing regulatory submissions in electronic format is now in force. The FDA’s eStudy Guidance, published on December 18, 2014, mandated the provision of nonclinical submission data using the CDISC SEND standard with effect from December 17, 2016.  
This means that all organizations must now use the appropriate FDA-supported standards, formats and terminologies specified in the FDA Data Standards Catalog for NDA, ANDA, and certain BLA submissions.   
Failure to comply with the Mandate can result in the FDA’s technical rejection or refusal to file a submission, therefore, it is vitally important that organizations are SEND compliant.  
Instem has been heavily involved with the development of SEND since the beginning and has a wealth of unparalleled experience in supporting companies to prepare for the standard. Instem has helped to organize, educate and guide numerous clients to becoming SEND-Ready, identifying specific approaches that maximize the benefits of SEND, while ensuring regulatory compliance.  
In 2005 Instem developed submit™, the first commercially available SEND software solution on the market. Submit creates datasets from any electronic source, it then manages SEND datasets throughout their entire lifecycle including the ability to QC Review and perform advanced single and multi-study data visualizations and analyses.  
 Instem is also catering to the needs of its clients by providing a comprehensive range of outsourced SEND Services that meet organizations at any stage of SEND Readiness. Instem acts as an extension of their clients, providing internal and external stakeholders with dependable services including Initial SEND Training, SENDReady™ Consulting, Study Conversion Services, SEND dataset Verifications and more.  
The submit solution for SEND is uniquely meeting the very wide range of demands that span the needs of the largest multi-national pharmaceutical organizations and CROs, to the smallest organizations and their advisors.  
The submit suite of software and outsourced services are now the most widely adopted in the market, supporting over 47 client sites across 15 countries.  
Free Industry Resources  
Instem has produced an extensive library of informative SEND video resources from “Becoming SEND-Ready” and “Creating Submission-Ready SEND Datasets” through to “Advanced SEND Data Visualization & Analysis”. These resources are available free of charge by request.  
About Instem   
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Instem Appoints MaryBeth Thompson as Chief Operating Officer  
Thompson Joins Instem to Help Develop and Implement Next Phase of Growth   
CONSHOHOCKEN, PA - January 11, 2017 (Business Wire) --Instem, a leading provider of IT solutions to the global early development healthcare market, announced today that MaryBeth Thompson has joined its executive leadership team to serve as Chief Operating Officer (COO).  
Thompson has more than 18 years of life sciences industry experience with a primary focus in Regulatory Affairs and Operations, and is a proven leader in developing and optimizing outsourcing services businesses.   
“We are delighted to have appointed someone of MaryBeth's caliber and experience to Instem,” commented Phil Reason, CEO at Instem. “MaryBeth has a strong track record in building life sciences businesses and we look forward to the benefits she will bring as we embark upon our next phase of growth.”  
Prior to joining Instem, Thompson was Vice President of Global Regulatory Services at life sciences consulting firm PARAXEL International. During her tenure at PARAXEL and its predecessor organizations LIQUENT and CDC Solutions, she established and grew a 30-person regulatory outsourcing consultancy into a full global practice of 300 staff that generated in excess of $30m per year for clients throughout North America, Europe and India.  
Prior to PARAXEL, Thompson also held key senior regulatory management positions at AstraZeneca and Wyeth-Ayerst Laboratories.   
The announcement of Thompson’s appointment comes during a period when Instem has been actively fulfilling its mission to create a more connected ecosystem in the life sciences industry by consolidating and harmonizing what it sees as a fragmented IT marketplace. Instem has been increasing its presence and expanding its position through the opening of new offices, the introduction of new products and services, by increasing staff and through the completion of five key strategic acquisitions since 2011.  
“Instem’s reputation is excellent and their people are some of the finest in the industry,” comments Thompson. “In addition to their highly successful software products, Instem has introduced an exciting portfolio of outsourcing services into the market that are unique, effective and being taken up at a very fast rate. I’m eager to leverage my experience to help Instem build upon its successes and continue to create and deliver compelling solutions around the world.”  
Instem believes it is one of very few organizations that have developed the capacity and financial stability to maintain a global leadership position with established products, while introducing new regulatory compliant solutions and outsourced services options that are delivering the changes in productivity that clients are demanding.  
In her role as COO, Thompson will oversee strategy, planning, development and management of Instem’s Global Operations team to meet the demand, while continuing the commitment of delivering an exceptional client experience that helps bring life enhancing products to market faster.  
About Instem  
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Leading CRO Chooses Instem Software Solutions for Global Multi-Site Deployment  
Instem's Provantis Preclinical Study Management and submit-SEND solutions Chosen by International Contract Research Organization  
CONSHOHOCKEN, PA - (BUSINESS WIRE) – April 10, 2014 - -Instem, a leading provider of IT solutions to the global early development healthcare market, announced today that a leading international contract research organization has purchased the Provantis® software suite for managing their preclinical studies, along with the submit™ solution suite to support CDISC’s Standard for Exchange of Nonclinical Data (SEND).   
SEND defines the organization, structure, and format of standard nonclinical tabulation datasets for interchange between organizations such as sponsors and contract research organizations and for submission to the US Food and Drug Administration (FDA).  
The client provides a comprehensive range of preclinical and specialty services from facilities across Europe and North America. Together with its global partner network it also provides clinical bioanalysis, embryonic stem cell biomarker discovery and customized preclinical efficacy model services.  
Following an industry merger, the client, who was already using Provantis at a number of sites, re-evaluated the preclinical market as they looked to automate all of their combined sites covering a wider application area. This included a requirement for a solution that could convert data from any source system into SEND files and allow sponsors, CRO’s and regulators to share, visualize and analyze study data more efficiently.  
Key Facts   
  
Client to deploy entire suite of Provantis version 9  
Submit™ solution chosen to create, convert, visualize and share SEND data  
Purchase includes the Provantis Portal for remote study monitoring   
Instem chosen for global market leadership, stability and regional support center coverage  
  
“We are very encouraged to see another client enhance and expand their use of our solution suites within preclinical,” comments John Anderson-Carter, VP Sales at Instem. “Our client joins a roster of leading organizations turning to Instem to help further streamline their processes and increase the quality of study data while enabling seamless coordination between study partners and sponsors.”  
About Instem  
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Meeting clients at the intersection of investment & return™.  
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Instem Recognized for Outstanding Contributions to SEND  
Instem Receives Award for Leadership in its Support of Standard for Exchange of Nonclinical Data (SEND)  
CONSHOHOCKEN, PA - February 28, 2012 - - Instem is pleased to announce that Vice President of Business Development, Jennifer Feldmann was recognized at the CDISC Interchange North America meeting for her outstanding contributions toward the completion of the SEND 3.0 Implementation Guide (“IG”).   
FDA reviewers continue to receive mostly paper or electronic paper (PDF) submissions. Manually entering this data for further analysis is time consuming and inefficient, taking time away from the primary mission of reviewing the content of submissions. The SEND format enables more efficient review of nonclinical data, offering improved data quality, accessibility and predictability.  
The SEND IG is intended to guide the organization, structure, and format of standard nonclinical tabulation datasets for interchange between organizations such as sponsors and CROs and for submission to the US Food and Drug Administration (FDA).  
 “I am very gratified to have our work on SEND recognized and I have been impressed by the commitment that the FDA has shown by their participation in SEND,” commented Jennifer Feldmann. “Using data in SEND format, the industry can help improve the safety review process while streamlining the flow of data from collection through submission and facilitate data interchange within their organizations and with external study partners.”  
To help see the standard propagated throughout pharmaceutical companies and CROs worldwide for data exchange over the next few years, Instem has been providing education and outreach to promote SEND while demonstrating its own technology solution suite – submit™. Submit creates and manages SEND study datasets throughout their lifecycle, and allows sponsors, CRO’s and regulators to share, visualize and analyze study data more efficiently.  
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Instem Hosts Successful Preclinical Solutions Seminar in Japan  
Seminar Supports an Exciting Year of Continued Growth in the Region  
CONSHOHOCKEN, PA (BUSINESS WIRE) December 14, 2017 - Instem, a leading provider of IT solutions to the global life sciences market, is pleased to announce that it held an interactive and informative Preclinical Solutions seminar in Tokyo, Japan during November.  
The seminar, which was co-hosted by Instem’s Japanese partner CTCLS, showcased Instem’s leading IT solutions for preclinical data collection, analysis and regulatory submissions management. Sessions included Instem’s SENDTrial™, SENDExplorer® and SENDView™ solutions for SEND (Standard for Exchange of Nonclinical Data) data management, ACIS™ Instem’s Animal Care Information Management solution, and KnowledgeScan™, a unique informatics-based service that reduces the traditional costs of Target Safety Assessment development by up to 50%.   
The event was well attended, attracting delegates from across 15 pharmaceutical and contract research organizations in the region. In addition to presentations from key members of the Instem team, delegates also heard case studies from Instem partners BoZo Research Center and CTCLS. The event also included a half day User Group Meeting for Instem clients.  
This seminar follows on from a very successful and exciting period of growth in the region that has seen Instem add a raft of new customers to its client roster in Japan, including 6 organizations who have purchased SEND solutions.  
Neil Donaldson, VP Sales EU & Asia said “We were extremely delighted to welcome so many existing and prospective clients to our event and to see such high levels of engagement throughout the meeting. Japan continues to be a key market for us and this meeting is another example of our continued investment in the region.”   
Instem has been serving the Japanese marketplace since 2005 with its distribution partner CTCLS Life Science Corp and has embarked on an expansion plan to grow that relationship while also providing increased direct market support. To further support the region, during 2015 Instem opened an office in Tokyo, hired additional staff and expanded its technology offerings, and in 2016 Instem signed a partnership deal with BoZo Research Center who selected Instem as their SEND outsourcing partner in Japan.   
About Instem  
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USAMRIID Deploys Instem Software to Support Development of Biodefense Solutions  
  
US Government Laboratory Purchases Expanded Package of NOTOCORD Solutions to Extend Safety Pharmacology Testing Capabilities  
CONSHOHOCKEN, PA (BUSINESS WIRE) July 5, 2017 - Instem, a leading provider of IT solutions to the global early development healthcare market, announced today that the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) has acquired additional NOTOCORD software solutions to expand Safety Pharmacology testing processes at its facility in Frederick, MD.   
NOTOCORD, now part of Instem, provides software solutions for data acquisition and analysis in preclinical studies and is a recognized leader in cardiovascular, respiratory, electrophysiology and nervous system research areas. Its flagship solution, NOTOCORD-hem, is a leading telemetry-based safety pharmacology data collection and analysis system used in preclinical studies.   
Since 1969, USAMRIID has served as the United States Department of Defense's lead laboratory for medical biological defense research. Research conducted at USAMRIID leads to medical solutions—therapeutics, vaccines, diagnostics, and information—that benefit both military personnel and civilians.   
USAMRIID is a long-term user of NOTOCORD solutions and this recent acquisition includes the purchase of additional servers and user licenses to support the latest TSE Stellar implants and DSI Physiotel Digital implants, as well as the ability to acquire and analyze EEG data.  
Gregor Grant, Executive Vice President of Instem, commented, “Our open systems approach enables our customers to acquire and analyze data from multiple hardware sources using a single software system. We are delighted that USAMRIID is utilizing our solutions and we look forward to continuing our long and successful relationship with them.”  
About United States Army Medical Research Institute of Infectious Diseases (USAMRIID)  
USAMRIID’s mission is to provide leading edge medical capabilities to deter and defend against current and emerging biological threat agents. The Institute plays a key role as the lead military medical research laboratory for the Defense Threat Reduction Agency’s Joint Science and Technology Office for Chemical and Biological Defense. USAMRIID is a subordinate laboratory of the U.S. Army Medical Research and Materiel Command. For more information, visit www.usamriid.army.mil  
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The information contained in this press release does not necessarily reflect the position or the policy of the U.S. Government and no official endorsement should be inferred.  
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Understanding the Cause and Prevention of Birth Defects: Southern Research’s DART Program Conducts Critical Reproductive Toxicology Work  
BIRMINGHAM, Ala. (August 20, 2012)—A recent study published in the journal Occupational and Environmental Medicine suggests that men engaged in certain occupations—including mathematicians, office workers and artists—have a greater risk of having children with birth defects. Last month, an Australian woman born without arms and legs after her pregnant mother took an anti-morning sickness drug reached a multimillion settlement with the drug’s distributor. Birmingham-based Southern Research conducts studies that it hopes will lead to a better understanding of why these things happen.  
“Clearly, the earlier a connection is made between a new drug or a chemical, and possible resulting birth defects, the better for all concerned,” said Eve Mylchreest, Ph.D., program leader for Developmental and Reproductive Toxicology (DART) at Southern Research. “Most reproductive disorders have unknown etiologies, but there is evidence that environmental factors can be the cause or a contributing factor. Identifying these factors and understanding the mechanisms underlying key processes, including key target molecules, are crucial in preventing reproductive disorders and birth defects.”  
Dr. Mylchreest came to Southern Research from Pfizer where she was a principal research scientist in reproductive toxicology. She has 15 years experience as a study director conducting Good Laboratory Practices (GLP) studies for drugs, pesticides and commodity chemicals. Since 2010, Dr. Mylchreest has worked with her Southern Research team to establish a program that investigates potential new drugs and environmental hazards, and determines the systemic impact to future parents and their offspring.   
The program—DART—is a key component in Southern Research’s comprehensive toxicology services—providing a range of GLP-compliant specialized assessments that determine a compound's effects on reproductive functions and developmental outcomes. The program is housed in state-of-the-art laboratories using market leading technologies, such as Instem’s integrated Provantis software system which is used to design and execute diverse study types to determine a compound's effects on fertility, embryo-fetal development, and pre- and post-natal development.   
“Southern Research was one of the first companies to validate its version of the Provantis software,” said John Boycott, Instem’s Product Manager, Reproductive Toxicology. “Because of the repro tox expertise of their scientific team, they created and added more than 50 new endpoints to meet the strenuous demands of DART data reporting.”   
Reproductive toxicologists or teratologists at Southern Research use the system to conduct studies including ICH protocols, multigenerational, developmental toxicity, behavioral and development neurotoxicity studies, among others. Their system and process has simplified the management of event driven studies while enabling the technical staff to generate both simple and complex custom reports.  
“Reproductive toxicology studies are complex, so the data needs to be reported in a comprehensive and meaningful way to facilitate the interpretation of results. We can now create endpoints that allow us to extract and calculate the precise data we need to evaluate if a compound has adverse effects,” said Dr. Mylchreest. “After all, the ultimate reason for conducting these preclinical studies is to ensure that new drug candidates do not cause harm to unborn children and do not impair the ability to have children.”   
 Southern Research conducts both contract research and basic research for clients, providing preclinical drug discovery, development, and clinical trial support services in cancer, infectious diseases, and CNS/neurological disease to pharmaceutical and biotechnology companies. Scientists conduct translational science to invent small molecules and advance them from the design stage to the clinic. Services available include medicinal chemistry, molecular biology, biochemistry, high-throughput screening and a full set of in-house GLP development services including toxicology, ADME/PK, animal models, formulations, and bioanalytical services.  
About Southern Research  
Southern Research Institute is a not-for-profit 501(c)(3) scientific research organization founded in 1941 that conducts preclinical drug discovery and development, advanced engineering research in materials, systems development, and environment and energy research. More than 550 scientific and engineering team members support clients and partners in the pharmaceutical, biotechnology, defense, aerospace, environmental and energy industries. Southern Research is headquartered in Birmingham, Ala., with facilities in Wilsonville, Ala., Frederick, Md., and Durham, NC and offices in Huntsville, Ala., New Orleans, La., and Washington, DC.   
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Instem Announces New Arrhythmia Module Featuring Leading-edge Machine Learning Technology to Aid Earlier Detection of Cardiac Risk  
Instem Showcasing New Software Solution and Presenting Scientific Posters at this Year’s Safety Pharmacology Society Annual Meeting in Barcelona  
CONSHOHOCKEN, PA – (BUSINESS WIRE) - September 17, 2019 - Instem, a leading provider of IT solutions to the global life sciences market is pleased to announce it will be exhibiting and presenting two posters at the 2019 Safety Pharmacology Society Annual Meeting (“SPS”), September 23–26 at the Centre de Convencions Internacional de Barcelona in Barcelona, Spain.  
“This will surely be one of the busiest and most important years for us at SPS,” comments Gregor Grant, Executive Vice President at Instem. “We have so much to share with our clients and the wider scientific community and I’m looking forward to interacting with visitors at our stand and our poster presentations.”   
NOTOCORD, an Instem Company and sponsor of this year’s SPS annual meeting, will be exhibiting at booth #905 where it will be showcasing its world-leading NOTOCORD-hem™ software solution, an advanced platform for the acquisition, display and analysis of physiological signals.  
Highlights at this year’s SPS include:  
Instem will be unveiling their latest development, a new arrhythmia module which has been built using unique industry-leading machine learning techniques. An online real-time arrhythmia solution, this new intuitive and easy-to-use software offers more robust signal perturbations and shape changes, using machine learning, neural network and multiresolution wavelet decomposition.   
Attendees at the exhibition can see Instem’s Poster #118: Machine Learning and Multiresolution Wavelet Decomposition to Improve Automated Cardiac Arrhythmia Detection and Classification  
 Instem will also be holding demonstrations of this new software at their stand.   
Visitors can see the recent NOTOCORD-hem™ version 4.4.0.2 release which, developed in line with Instem’s Open Strategy, offers compatibility with the latest DSI PhysioTel Digital implants (L and M series) and the new STE20 acquisition module from TSE Stellar Telemetry. Other key features of the 4.4.0.2 release include significant enhancements to the Excel Wizard and full compatibility with MATLAB® 64-bit versions.  
NOTOCORD-sense™ - a new cloud-based open collaboration platform for the analysis and sharing of experimental data. Easily monitor, acquire and analyze data from anywhere in the world. Watch a short explainer video for NOTOCORD-sense™.  
Submit™ for SEND Compliance - the most widely adopted suite of software and outsourced study services deployed at over 80 client sites in 15 countries. Instem helps educate and guide organizations through every stage of SEND readiness to help them ensure compliance while leveraging the value that SEND offers. Watch Instem’s short guide to SEND for Safety Pharmacology.  
Posters at SPS 2019  
Please stop by to review and discuss the following poster presentations:  
Poster #118: Machine Learning and Multiresolution Wavelet Decomposition to Improve Automated Cardiac Arrhythmia Detection and Classification  
Poster #99: Combining Field Potential Data and In Silico Simulated Data to Improve Machine Learning Approaches and Better Assess Drug Cardio-toxicity  
Poster #145: “INSPIRE”: A European Training Network in Safety Pharmacology Creating Opportunities for 15 PhD Students - while NOTOCORD is not presenting this poster, as a member of the scientific consortium involved in the INSPIRE project, the company has contributed to the content and would be happy to discuss the early stage research projects to be undertaken as part of the program. The research projects involve NOTOCORD-sense™ which offers powerful capabilities for secure data sharing and which will be used to prototype and deploy new analysis modules.  
Read Instem’s recent news announcement regarding the INSPIRE project.  
 This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 858070.  
Instem’s NOTOCORD group provides software solutions for data acquisition and analysis in preclinical studies and is a recognized leader in cardiovascular, respiratory, electrophysiology and nervous system research areas. NOTOCORD solutions are used by pharmaceutical companies, contract research laboratories, hospitals and academic research centers around the world.  
About Instem  
Instem is a global provider of leading software solutions and services that are helping over 500 clients bring their life enhancing products to market faster. We enable clients in the life sciences to more efficiently collect, analyze, report and submit high quality regulatory data, while maintaining compliance for their products around the world.   
Instem solutions are in use by customers worldwide, meeting the rapidly expanding needs of life science and healthcare organizations for data-driven decision making, leading to safer, more effective products.  
Instem supports its global roster of clients through offices in the United States, United Kingdom, France, Japan, China and India.   
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Instem Chief Scientific Officer Conducting Pistoia Alliance Panel Discussion  
Industry Leaders to Discuss Genomics and Impacts to New Modes of Healthcare  
CONSHOHOCKEN, PA – December 1, 2014 - - Instem, a leading provider of IT solutions to the global early development healthcare market, announced today that Gordon Baxter, CSO at Instem, will be moderating a Pistoia Alliance debate Webcast entitled, “Genomics, Pharmaceutical R&D Healthcare: Are we there yet?”  
As various genomics initiatives have promised to revolutionize healthcare for over 20 years, it is important to ask whether these have had the impact they were expected to make, and how we might take greater advantage of the technology available.  
Gordon Baxter will chair a panel comprised of experts in the field including Abel Ureta-Vidal, CEO at Eagle Genomics, Fiona Nielsen, CEO at DNA Digest, Dan Housman, Director at ConvergeHealth by Deloitte, and Etzard Stolte, former CIO of the Jackson Laboratory.  
The Pistoia Alliance, a global, not-for-profit alliance of life science companies, vendors, publishers, and academic groups that work together to lower barriers to innovation in R&D, is hosting a ‘Pistoia Alliance Debates’ webinar which will look at whether the economic, technical and regulatory barriers have been addressed, and how to overcome any that may remain.  
As well as exploring the remaining obstacles to greater adoption of genomics technology in healthcare, the panel will look at the success of recent genomics initiatives, the impact they have had, and will consider what future genomic innovation may bring to the industry. Following the discussion, webinar attendees will be able to ask questions of the panel.  
Gordon Baxter, Instem’s CSO, joined the Pistoia board in September 2013 and, leveraging his experience in R&D ontology, regulatory data exchange standards and clinical informatics, has been sharply focused on bringing data together from research, development and medical practice to generate new scientific insight.  
About Instem   
Instem is a leading supplier of IT applications to the early development healthcare market delivering compelling solutions for data collection, management and analysis across the R&D continuum. Instem applications are in use by customers worldwide, meeting the rapidly expanding needs of life science and healthcare organizations for data-driven decision making leading to safer, more effective products.  
Instem’s portfolio of software solutions increases client productivity by automating study-related processes while offering the unique ability to generate new knowledge through the extraction and harmonization of actionable scientific information.  
Instem supports over 400 clients through full service offices in the United States, United Kingdom and China with additional locations in India and a full service distributor based in Japan.  
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National Institute of Environmental Health Sciences Purchases Hosted Provantis Solution  
Provantis Reproductive Toxicology Software Module to be used by National Toxicology Program and Member Organizations  
CONSHOHOCKEN, PA - (BUSINESS WIRE) – August 12, 2010 - - Instem®, a leading provider of early drug development software solutions, announced today that the National Institute of Environmental Health Sciences (NIEHS) has purchased the Provantis® preclinical software solution to support the collection, management and maintenance of the reproductive, perinatal and developmental National Toxicology Program (NTP) studies. These studies are done predominantly at contractor laboratories at various sites throughout the United States.  
The value of the award to Instem, funded completely by the federal government, is $656,100.  
Managed by NIEHS, the NTP is an interagency program whose mission is to evaluate agents of public health concern by developing and applying tools of modern toxicology and molecular biology. The program maintains an objective, science-based approach in dealing with critical issues in toxicology and is committed to using the best science available to prioritize, design, conduct, and interpret its studies.  
The NIEHS will be using Instem’s SaaS (Software-as-a-Service) model offering simpler, more cost effective ways to provide software functionality, maintenance, and support over the Internet. Since 2005, Instem has utilized a state-of-the-art data center, which is being used by clients running GLP and non-GLP studies.  
Part of the integrated Provantis solution suite, this module will support the NTP reproductive toxicologist or teratologist in conducting all study types, including ICH protocols, multigeneration, developmental toxicity, behavioral and development neurotoxicity studies. Particularly flexible in its design, Instem’s solution supports a full range of data entry types, simplifies the management of event driven studies while enabling NTP program users to generate simple and complex custom reports.  
About Provantis®  
Provantis is a modern, fully integrated software system for single users and global organizations engaged in preclinical evaluation studies. Orchestrating every facet of preclinical drug safety assessment, Provantis streamlines processes and workflows with straightforward, intuitive functionality for simple or complex studies within a GLP or non-GLP environment, on-site or over the Web.  
About NIEHS  
The NIEHS supports research to understand the effects of the environment on human health and is part of the National Institutes of Health (NIH). Its mission is to reduce the burden of human illness and disability by understanding how the environment influences the development and progression of human disease.  
 For more information on environmental health topics, visit www.niehs.nih.gov.  
The NIH — The Nation's Medical Research Agency — includes 27 Institutes and Centers and is a component of the U.S. Department of Health and Human Services. It is the primary federal agency for conducting and supporting basic, clinical and translational medical research, and it investigates the causes, treatments, and cures for both common and rare diseases. For more information about NIH and its programs, visit www.nih.gov.  
About Instem  
Instem is a leading supplier of IT applications to the early development healthcare market, delivering compelling solutions for data collection, management and analysis across the R&D continuum. Instem applications are in use by customers worldwide, meeting the rapidly expanding needs of life science and healthcare organizations for data-driven decision making leading to safer, more effective products.  
Instem’s portfolio of software solutions increases client productivity by automating study-related processes while offering the unique ability to generate new knowledge through the extraction and harmonization of actionable scientific information.  
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Instem Exhibiting and Presenting at American College of Toxicology Annual Meeting  
Instem Showcasing its Preclinical Solutions and Hosting a Session on Submission-Ready SEND Packages with Panel of Industry Leaders  
CONSHOHOCKEN, PA – November 1, 2016 - - Instem, a leading provider of IT solutions to the global early development healthcare market, is pleased to announce it will be exhibiting and presenting at the 37th Annual Meeting of the American College of Toxicology (ACT) in Baltimore, November 6-9th.   
Visitors to Instem’s booth #206 will learn about:  
Submit™ - the most widely deployed set of SEND tools and services, adopted at 45 sites across 15 countries. Learn about the newest member of the submit™ suite, SEND Explorer®, the intuitive web-based application that provides advanced single and multi-study visualization and analysis capabilities for nonclinical study data in SEND format  
Provantis® - the undisputed leading software solution for preclinical study management  
  
Instem will also be holding the following Exhibitor Hosted Presentation:  
Best Practices for Creating Submission-Ready SEND packages   
Wednesday, November 9th, Kent B-C  
12:00 p.m. – 12:55 p.m.   
 Lunch will be provided  
Attendees to this session will hear first-hand experiences and insight from an industry panel about:  
  
Challenges of SEND for Bioanalysis Labs  
Effective SEND Communications between CROs and Sponsors   
A Sponsor’s Perspective on SEND in the Submissions Process  
Use of SEND Datasets for Submissions and Regulatory Responses  
  
No advanced registration is required for this session. If delegates would like more information, they can contact Instem at submit@instem.com or visit the staff during the exhibition at stand 206.  
Each year, ACT welcomes over 900 attendees from more than 20 countries around the world and hosts over 70 exhibitors. More information on ACT and their Annual Meeting can be found at www.actox.org.   
About Instem   
Instem is a leading supplier of IT applications and services to the early development healthcare market delivering compelling solutions for data collection, analysis and regulatory submissions management. Instem solutions are in use by customers worldwide, meeting the rapidly expanding needs of life science and healthcare organizations for data-driven decision making leading to safer, more effective products.  
Instem’s portfolio of software solutions and consulting services increases client productivity by enhancing product development processes while offering the unique ability to generate new knowledge through the extraction and harmonization of actionable scientific information.  
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Instem Acquires NOTOCORD; Extends Reach and Capabilities While Further Consolidating Preclinical IT  
  
  
  
  
  
  
  
  
  
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Instem Acquires NOTOCORD; Extends Reach and Capabilities While Further Consolidating Preclinical IT  
NOTOCORD Joining Instem Group to Help Drive Growth & Next Stage of Innovation  
CONSHOHOCKEN, PA - (BUSINESS WIRE) – September 5, 2016 - -Instem, a leading provider of IT solutions to the global early development healthcare market, announced today that it has acquired NOTOCORD® as part of its mission to further consolidate and harmonize key application areas that are helping customers streamline their research and development processes.  
Based in Paris, France, with a presence in the United States, NOTOCORD provides software solutions for data acquisition and analysis in preclinical studies and is a recognized leader in cardiovascular, respiratory, electrophysiology and nervous system research areas. NOTOCORD solutions are used by pharmaceutical companies, contract research laboratories, hospitals and academic research centers around the world.  
  
 Instem views the acquisition of NOTOCORD as another important and tangible step in its mission to help clients bring life enhancing products to market faster.  
NOTOCORD is a well-respected name in the life sciences software market and its solutions are used every day by top scientists for new drug development research within discovery, safety pharmacology and toxicology studies. Its most widely known solution, NOTOCORD-hem™, is a leading telemetry-based safety pharmacology data collection & analysis system used in preclinical studies.  
“The combined customers of NOTOCORD and Instem will be gaining a real advantage,” comments Philippe Zitoun, founder and Chief Executive Officer at NOTOCORD. “Our mission all along was to create technology that was easier and faster to use so our clients can do what they do best, every day. Since we were founded, we have relied on innovative and creative thinking to understand tomorrow’s needs in the marketplace. Becoming part of Instem will allow us to deliver more value, more quickly to more users everywhere. The entire team here at NOTOCORD is excited to be supported by a full complement of resources across Instem’s international offices. Instem shares in our commitment to excellence and is also well known for highly satisfied clients throughout all of the segments that they serve.”  
One of the key strategic benefits of this next acquisition for Instem is its ability to more easily enhance its submit™ solution that is supporting FDA’s SEND mandate (Standard for the Exchange of Nonclinical Data) by integrating another key data collection source. A new version of SEND standard (3.1) has recently been published, allowing SEND to include cardiovascular and respiratory Safety Pharmacology studies; this is in addition to toxicity and carcinogenicity studies supported by the current SEND 3.0 standard.  
Instem also sees this as an opportunity to integrate data from NOTOCORD systems into its market-leading Provantis® software suite to provide a more seamless approach within preclinical study management, which will help its clients evaluate data and findings more efficiently.  
“Notocord has a stellar reputation and a high quality team,” comments Phil Reason, Instem’s Chief Executive Officer. “Having known Philippe and their solutions for many years, we are confident that we will be successful together and that our clients will be very encouraged. As experts in safety pharmacology, the NOTOCORD team joins us just as this becomes a significant and additional focus area for SEND, one of our largest growth opportunities over the next several years. There are also some disruptive innovations in the safety pharmacology marketplace at the moment, so the timing was just right to bring them into the Instem group. We are in a strong position to increase their global reach and penetration with their existing products, while helping them fully launch new and exciting solutions.”  
The NOTOCORD team and its applications will be aligned with Instem’s Preclinical Study Management Solutions group, which provides focused software solutions that empower organizations of all sizes to more efficiently collect, review, analyze and manage preclinical safety evaluation study data.  
NOTOCORD will quickly be capitalizing on Instem’s global marketing, sales and support capabilities, while ensuring that its track record for delivering high-quality and highly reliable products continues to meet all of its clients’ requirements.   
More about NOTOCORD Solutions  
NOTOCORD-hem is an advanced software platform designed to acquire, display and analyze physiological signals. Covering Cardiovascular, Respiratory and Nervous system research areas, NOTOCORD-hem offers:  
  
Over 160 modules for a customized analysis  
In vivo, In vitro and Ex vivo  
Implants and non-invasive telemetry  
Simultaneous acquisition from different sources and systems  
Flexible user interfaces offering easy configuration and displays  
Ultra-fast access to data regardless of experiment file size  
Compliance with GLP & 21 CFR Part 11  
  
The NOTOCORD-fps™ solution is based on a new Field Potential Analysis (FPS) method for analysis supporting an upcoming change in an industry standard for novel safety screening using stem cell data. The Comprehensive in vitro Proarrhythmia Assay, or CiPA, is being considered by regulators and industry work groups and is expected to act as a prerequisite for all non-cardiac drug marketing approvals. The CiPA initiative is intended to move safety pharmacology from a predominantly traditional pharmacodynamics approach to in silico and in vitro drug toxicity assessment.   
NOTOCORD-sense® is the next generation platform encompassing new features of its hem and fps solutions along with new exciting capabilities.  
To find out more information about NOTOCORD solutions, please visit www.notocord.com.  
Instem has been increasing its presence and expanding its capabilities through the opening of new offices, new solution development activities and through key strategic acquisitions.   
 Instem believes that enabling its clients to more easily access data and help convert it to actionable knowledge is critical for their success in today’s competitive market. Instem has become uniquely positioned across key application areas of the R&D landscape, acting as a strategic partner for its clients throughout the Pharmaceutical, Government Research, Medical Device, Chemical and Agrochemical industries.  
 Today’s announcement follows recent news of Instem’s acquisition of the Samarind organization and its entry into the Regulatory Information Management (RIM) market.  
About Instem   
Instem is a leading supplier of IT applications and services to the early development healthcare market delivering compelling solutions for data collection, analysis and regulatory submissions management. Instem solutions are in use by customers worldwide, meeting the rapidly expanding needs of life science and healthcare organizations for data-driven decision making leading to safer, more effective products.  
Instem’s portfolio of software solutions and consulting services increases client productivity by enhancing product development processes while offering the unique ability to generate new knowledge through the extraction and harmonization of actionable scientific information.  
Instem supports over 500 clients through offices in the United States, United Kingdom, France, Japan, China and India.  
To learn more about Instem solutions and its mission, please visit www.instem.com  
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Instem to Exhibit and Present at the American College of Toxicology Meeting, Arizona  
Instem Continues Powerful Presentation Series Focusing on Their Use of Artificial and Augmented Intelligence Techniques to Improve Drug Development Processes  
CONSHOHOCKEN, PA - (BUSINESS WIRE) – November 13, 2019 - - Instem, a leading provider of IT solutions to the global life sciences market, is pleased to announce its participation in the 40th Annual Meeting of the American College of Toxicology (ACT), November 17-20 in Phoenix, AZ. In addition to exhibiting, and as part of its strategy to help bring life enhancing products to market more quickly and safely, Instem will deliver the next iteration of its unique presentation series which focuses on their use of artificial and augmented intelligence techniques to improve drug development processes.   
Attendees are encouraged to visit booth #113 to learn how Instem is helping clients more quickly discover, develop and manage life enhancing products around the world. Subject matter experts will be available to discuss:  
  
Submit™ for SEND - the most widely deployed set of tools and outsourced SEND study services, adopted at over 80 client sites in 15 countries. Submit with confidence™. Download a case study ahead of the event.  
Provantis® - the leading SaaS solution for preclinical study management, serving single users to multi-site clients. Learn how clients have reduced preclinical time from hours to minutes, download the case study.  
KnowledgeScan™ - Using a combination of artificial intelligence and human expertise KnowledgeScan is a unique technology-enabled service that is setting new standards in Target Safety Assessment (TSA). Customers can make faster, better informed decisions on their drug targets as a result of high-quality, unbiased and evidence-based TSAs. Download the fact sheet.  
  
Continuing the presentation series debuted at the 55th Annual Eurotox Conference earlier this year, attendees are invited to Instem’s Exhibitor Hosted Session on Wednesday, November 20th at 12:00 noon in Grand Sonoran H. The presentation entitled, “Leveraging the Combined Power of Technology, Expertise, and Regulatory Standards for Safer Outcomes”, outlines ways in which artificial and augmented intelligence technologies are being used to support the continuous exploration of safety topics from structured and unstructured, and public and private sources of data. The presentation also explores the opportunities and barriers to leveraging public and private data sources for commercial advantage in drug research and development.  
“We look forward to engaging with ACT attendees, exploring how artificial and augmented intelligence technologies will continue to shape data sources. For this presentation, we have incorporated client case studies that illustrate how Instem is setting new standards with technology innovations while driving pace and maintaining quality.” stated Dr. Frances Hall, Director, Scientific Solutions, Instem.   
For more information about Instem’s technology-enabled services visit the submit-for-SEND and KnowledgeScan Target Safety Assessment service web pages or contact info@instem.com   
About Instem  
Instem is a global provider of leading software solutions and services that are helping over 500 clients bring their life enhancing products to market faster. We enable clients in the life sciences to more efficiently collect, analyze, report and submit high quality regulatory data, while maintaining compliance for their products around the world.   
Instem solutions are in use by customers worldwide, meeting the rapidly expanding needs of life science and healthcare organizations for data-driven decision making, leading to safer, more effective products.  
Instem supports its global roster of clients through offices in the United States, United Kingdom, France, Japan, China and India.   
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Instem Exhibiting and Presenting at Safety Pharmacology Society Annual Meeting  
Instem showcasing latest release of NOTOCORD-hem™ while also promoting its next generation cloud-based platform for scientific collaboration   
CONSHOHOCKEN, PA – September 26, 2018 - - Instem, a leading provider of IT solutions to the global life sciences market is pleased to announce it will be exhibiting and presenting at the 2018 Safety Pharmacology Society Annual Meeting, September 30–October 3, 2018, at the Marriott Wardman Park, Washington, DC.  
NOTOCORD, an Instem Company, will be exhibiting at booth #319 and will be showcasing the latest version of its world-leading NOTOCORD-hem™ software solution, an advanced platform for the acquisition, display and analysis of physiological signals. In line with our Open Strategy which strives to provide customers with greater choice by offering increased compatibility with 3rd party hardware and devices, Version 4.3.0.77 is a significant release which offers:  
  
Compatibility with the latest version of DSI telemetry systems which supports an increase in the number of implants per PhysioTel Digital Communication Link Controller (CLC)  
A dedicated TSE Stellar Telemetry acquisition module for scheduled and continuous acquisition  
  
Visitors to the booth will also learn more about:   
NOTOCORD-sense® - our new cloud-based open collaboration platform for the analysis and sharing of experimental data. Easily monitor, acquire and analyze data from anywhere in the world.  
Submit™ for SEND Compliance - the most widely adopted suite of software and outsourced study services deployed at over 80 client sites in 15 countries. We help educate and guide organizations through every stage of SEND readiness to help them ensure compliance while leveraging the value that SEND offers.  
Continuing Education Course: SENDING Safety Pharmacology into the Future  
Sunday September 30th  
 8:00 – 12:00  
Instem SEND expert, Marc Ellison will be presenting “What you need to know about SEND and your Safety Pharmacology studies” which will cover everything the Safety Pharmacologist needs to know about compiling a SEND Submission package for a study; from explaining the guidance, through to understanding the Safety Pharmacology SEND domains for Cardiovascular, ECG and Respiratory data. Marc will also be available at the NOTOCORD booth on Monday October 1st to answer any SEND related questions.  
About Instem  
Instem is a global provider of leading software solutions and services that are helping over 500 clients bring their life enhancing products to market faster. We enable clients in the life sciences to more efficiently collect, analyze, report and submit high quality regulatory data, while maintaining compliance for their products around the world.   
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Instem to Present at European Teratology Society Meeting, Hamburg  
  
  
  
  
  
  
  
  
  
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Instem to Present at European Teratology Society Meeting, Hamburg  
Instem Presenting “Challenges of Reproductive Assessment of Continuous Breeding (RACB) Study Designs in Electronic Data Capture Systems”  
CONSHOHOCKEN, PA – August 21, 2014 - - Instem, a leading provider of IT solutions to the global early development healthcare market, is pleased to announce that Marc Ellison, Business Analyst, Instem, will present at the 42nd Annual Meeting of the European Teratology Society (ETS), Hamburg, Germany, 1st – 4th September, 2014.  
The poster presentation “Challenges of Reproductive Assessment of Continuous Breeding (RACB) Study Designs in Electronic Data Capture Systems” discusses the challenges that the RACB study design used by the US Government’s National Toxicology Program (NTP) poses for Electronic Data Capture Systems, and addresses how Instem and NTP were able to overcome these challenges.  
Mr. Ellison said “The RACB study design is unique in its intricacy, encompassing multi-littering and multi-generational analysis. The volume, complexity and diversity can prove difficult challenges for Electronic Data Capture Systems. Alongside the data collection there are demanding reporting requirements and the need to analyze the effect of time, dose level, generation and litter both individually and collectively. In order to overcome these challenges, a rigorous consultancy program was conducted with the NTP to produce a complete detailed understanding of the study design, a comprehensive set of system requirements and a fit for purpose software solution.”  
The National Toxicology Program is an interagency program established in 1978 to coordinate toxicology research and development across the Department of Health and Human Services. The program was also created to strengthen the science base in toxicology, develop and validate improved testing methods and provide information about potentially toxic chemicals to health regulatory and research agencies, scientific and medical communities, and the public.  
Headquartered at The National Institute of Environmental Health Sciences (NIEHS), the NTP is managed by the NIEHS and supported by the United States Food and Drug Administration and the Centers for Disease Control and Prevention. In 2010 NIEHS purchased Instem’s Provantis® preclinical solution suite to support NTP studies, deploying Provantis via Instem’s SaaS model to provide on-demand Internet-based access to NIEHS and NTP member sites.   
“Challenges of Reproductive Assessment of Continuous Breeding (RACB) study designs in Electronic Data Capture Systems” will be on display in the Foyer throughout the conference.  
About Instem  
Instem is a leading supplier of IT applications to the early development healthcare market, delivering compelling solutions for data collection, management and analysis across the R&D continuum. Instem applications are in use by customers worldwide, meeting the rapidly expanding needs of life science and healthcare organizations for data-driven decision making leading to safer, more effective products.  
Instem’s portfolio of software solutions increases client productivity by automating study-related processes while offering the unique ability to generate new knowledge through the extraction and harmonization of actionable scientific information.  
Instem supports over 400 clients through full service offices in the United States, United Kingdom and China with additional locations in India and a full service distributor based in Japan.  
Meeting clients at the intersection of investment & return™.  
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Lou Ann Kramer Joins SEND Management Team at Instem  
Instem Appoints Lou Ann Kramer to VP Role as submit-SEND Market Expands  
CONSHOHOCKEN, PA - (BUSINESS WIRE) – March 3, 2015 - -Instem, a leading provider of IT solutions to the global early development healthcare market, announced today that Lou Ann Kramer has joined its senior management team supporting CDISC’s Standard for Exchange of Nonclinical Data (SEND).   
Prior to joining Instem, Lou Ann held several key roles for over 30 years at Eli Lilly including team leader responsible for all preclinical submissions globally. Over the past 8 years Lou Ann also oversaw preclinical information services, was Lilly’s point leader for all SEND efforts and acted as an industry liaison with the FDA/CDER/Computational Sciences Center on data standards initiatives.  
In her role at Instem, Lou Ann will be helping organizations become SEND-enabled, guiding them from education through to the efficient management, exchange and submission of study data driven by Instem’s rich set of solutions and services.  
“Lou Ann Kramer is well known in the community and her rich experience in regulatory submissions and compliance coupled with her practical understanding within the preclinical segment will have an immediate positive impact for our clients around the world,” comments Mike Harwood, Senior VP at Instem. “As the current team leader for standards development and as a member of the technical leadership committee for CDISC, we are honored she has chosen to join us as we help industry prepare for SEND and leverage the capabilities of our submit™ platform.”  
“Having worked with SEND since its inception and having introduced the first complete software package to industry, Instem has become known as a world authority on SEND,” comments Lou Ann Kramer. “I’m very excited to be joining this experienced and well-regarded team of industry experts. Our common aspirations of ensuring organizations realize the benefits of SEND in health care and in their overall business effectiveness was a key element of my decision to join Instem.”  
Lou Ann has received an FDA/CDER Honor Award, was recognized by CDISC for her leadership and received the LRL Six Sigma Green Belt Team of the Year award by Eli Lilly.  
Following the issuance by FDA of the long awaited final Guidance for Standardized Study Data for providing regulatory submissions in electronic format in December of 2014, demand for Instem’s market-ready solutions has increased. Instem has licensed over 30 sites in 11 countries with its submit™ solution suite enabling clients to create and manage SEND study datasets throughout their lifecycle and is allowing sponsors, CRO’s and regulators to share, visualize and analyze study data more efficiently.  
About Instem  
Instem is a leading supplier of IT applications to the early development healthcare market, delivering compelling solutions for data collection, management and analysis across the R&D continuum. Instem applications are in use by customers worldwide, meeting the rapidly expanding needs of life science and healthcare organizations for data-driven decision making leading to safer, more effective products.  
Instem’s portfolio of software solutions increases client productivity by automating study-related processes while offering the unique ability to generate new knowledge through the extraction and harmonization of actionable scientific information.  
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Instem to Present at 17th International German Society for Good Research Practice Meeting, Dresden  
  
  
  
  
  
  
  
  
  
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Instem to Present at 17th International German Society for Good Research Practice Meeting, Dresden  
Instem Presenting “Living in the Cloud – New GxP Challenges”  
CONSHOHOCKEN, PA –September 11th, 2012 - - Instem, a leading provider of IT solutions to the global early development healthcare market, is pleased to announce that Vince D’Angelo, Instem Validation Services Manager, will be presenting at the 17th Annual Meeting of the DGGF (The German Society for Good Research Practice), taking place in Dresden, Germany from 19th – 21st September.  
The presentation will consider the issues surrounding the selection, implementation, validation and on-going use of Cloud technologies in a GxP regulated industry.   
“This method of deploying systems is becoming increasingly popular across many industries as it offers simpler, more cost effective ways to provide software functionality, maintenance and support over the internet.” comments Mr. D’Angelo “However, it is important for organizations to understand the tasks and responsibilities associated with this application delivery model, to be aware of the issues and risks, and to know how to ensure compliance with GxP regulations and best practices.”   
As a leading provider of preclinical systems, Instem has been offering a SaaS (Software-as-a-Service) deployment model since 2005. This deployment model has been embraced within the preclinical R&D arena and a large and growing number of clients are selecting Instem’s market-leading SaaS delivery model for running GLP and non-GLP studies. Instem utilizes secure state-of-the-art data centers that meet the highest standards for reliability, security and redundancy and are managed by experienced staff 365 days a year supporting pharmaceutical, contract research, academic and government agencies around the world.   
The German Society for Good Research Practice (Deutsche Gesellschaft für Gute Forschungspraxis, DGGF) was founded in 1995 and its members are drawn from R&D Departments across industry, contract research organizations, central clinical laboratories, hospitals and government agencies.   
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Instem Supports American Cancer Society Key Gala  
Instem Pledges Bronze Sponsorship of the 2014 American Cancer Society Key Gala Boston  
CONSHOHOCKEN, PA – March 31, 2014 - -Instem, a leading provider of IT solutions to the global early development healthcare market, is pleased to announce its support of the 2014 American Cancer Society (ACS) Key Gala taking place in Boston Massachusetts on April 3rd.   
The ACS is a nationwide, community-based, voluntary health organization dedicated to eliminating cancer as a major health problem by preventing cancer, saving lives, and diminishing suffering from cancer, through research, education, advocacy and service. Headquartered in Atlanta, Georgia, the ACS has regional and local offices throughout the country supporting 11 geographical Divisions.   
The annual Key Gala benefits the ACS’s AstraZeneca Hope Lodge Center in Boston and this year’s event will honor the generosity and support of Charles River Laboratories and its Chairman of the Board, President and Chief Executive Officer, James Foster. Former Lodge guest and cancer survivor Fran Kokonowski will be a special guest speaker.   
The Gala will be hosted by Boston media personality Joyce Kulhawik and will feature dinner, raffles, live and silent auctions and live entertainment from the band Beantown. Last year’s event raised more than $800,000.  
Gary Mitchell, VP Global Marketing, Instem said “We are extremely proud to support the excellent work of the American Cancer Society and the AstraZeneca Hope Lodge Center. Instem is honored to be working with the world’s leading pharmaceutical organizations and associated institutions in the mission to improve and enhance life.”   
About American Cancer Society’s Astra Zeneca Hope Lodge Center Boston  
Located in Jamaica Plain, AstraZeneca Hope Lodge Center Boston serves as a "home away from home" and provides free lodging for cancer patients traveling more than 40 miles to their outpatient treatments.  
Since its opening in November 2008, the AstraZeneca Hope Lodge Center Boston has provided more than 62,000 nights of free lodging to 1,900 cancer patients, saving them more than $11 million in housing costs.  
Just minutes from the city’s world-class medical facilities, AstraZeneca Hope Lodge Center Boston has welcomed guests and their caregivers from 46 states and 12 countries over the past five years.   
For more information about the work of the ACS visit www.cancer.org  
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Instem Showcasing New Solutions and Expanded Offerings to Preclinical Community at Annual Toxicology Meeting  
Instem Exhibiting and Presenting at Society of Toxicology Annual Meeting and ToxExpo Event in Baltimore, Maryland  
CONSHOHOCKEN, PA – March 8, 2017 - - Instem, a leading provider of IT solutions to the global early development healthcare market, is pleased to announce it will be exhibiting at the Society of Toxicology Annual Meeting and ToxExpo at the Baltimore Convention Center March 12-16th.   
Visitors to Instem’s booth, #1819, will learn more about:   
  
Submit™ for SEND Management- the most widely adopted software and outsourced study services in 15 countries. New in 2017, booth visitors will enjoy a preview of SENDTrial, a new solution from Instem that reduces the time and complexities associated with the creation of SEND trial design domains. Instem will also be unveiling the latest version of SEND Explorer™, the leading solution for data visualization and analytics.   
Provantis® - the undisputed leading solution for preclinical study management, now includes an e-learning platform with its latest release. The Provantis Academy is helping clients become better at what they do.  
KnowledgeScan™ - enabling optimal Target Safety Assessment, is helping clients reduce time and costs by at least 50%.  
NOTOCORD-hem™- The latest addition to the Instem family of solutions, this advanced software platform enables organizations to acquire, display and analyze physiological signals, covering cardiovascular, respiratory and nervous system research areas  
  
Perceptive Instruments, an Instem Company, will be promoting their Genetic Tox solutions at booth #1933. Stop by and learn more about:  
  
Comet Assay IV – the market leading live video imaging system for fast, accurate and reproducible slide comet scoring  
Cyto Study Manager – Data acquisition, integration and reporting for genetic toxicology assays  
  
Instem will also be holding the following Exhibitor Hosted Session:  
Best Practices for Creating Submission-Ready SEND Packages   
Tuesday, March 14th, Room 337, Baltimore Convention Center  
4:30pm – 5:30pm  
 Join a panel of industry experts to hear about best practices for creating submission-ready SEND packages, with focus on the most challenging areas such as multi-site integration, verification against study report, Define-XML generation, Study Data Reviewer’s Guide, and final package integration with eCTD.  
 This session will offer complimentary appetizers, drinks and a prize draw.  
The Society of Toxicology Annual Meeting and ToxExpo is the largest event of its kind and expects to welcome over 6,500 toxicologists and industry professionals from more than 50 countries around the world. Over 350 exhibitors are expected to participate. The meeting and exhibition includes networking events, stimulating lectures and presentations on scientific breakthroughs, important continuing education and professional training.  
About Instem  
Instem is a leading supplier of IT applications and services to the early development healthcare market delivering compelling solutions for data collection, analysis and regulatory submissions management. Instem solutions are in use by customers worldwide, meeting the rapidly expanding needs of life science and healthcare organizations for data-driven decision making leading to safer, more effective products.  
Instem’s portfolio of software solutions and consulting services increases client productivity by enhancing product development processes while offering the unique ability to generate new knowledge through the extraction and harmonization of actionable scientific information.  
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Shenyang Research Institute Selects Provantis Preclinical Software Solution for Chinese Drug Safety Evaluation Center  
Prestigious Chinese Research Institute Deploying Provantis SaaS to Increase Efficiencies and Further Streamline Preclinical Processes  
CONSHOHOCKEN, PA – May 24, 2016 - Instem, a leading provider of IT solutions to the global early development healthcare market, announced today that the Shenyang Research Institute of Chemical Industry (SYRICI) has purchased the Provantis® preclinical software solution suite to manage preclinical processes at its National Center for New Drug Safety Evaluation, Shenyang, China (SYRICI CEC）.  
Established in 1949, SYRICI CEC, now part of the Sinochem Group, was the first national, comprehensive chemical research institute in China, and the first Chinese safety evaluation institution to achieve OECD GLP (Good Laboratory Practice) certification. SYRICI CEC focuses on the safety assessment of pesticides, medicines, dyestuffs and chemical industrial products, as well as providing a preclinical evaluation service for new drugs and the registration of pesticide and chemical risk assessment.  
Provantis will replace SYRICI’s existing in-house developed software solution, delivering increased efficiencies in the collection, storage and reporting of preclinical data. In addition, by harnessing Instem’s SaaS deployment model, SYRICI will benefit from lower infrastructure and support costs, together with the flexibility and scalability to meet changing business demands.   
Key Facts  
  
SYRICI to deploy an extensive suite of modules including General Toxicology, Reproductive Toxicology, Pathology, Protocol Report & Assembly and Data Import  
Contract awarded following a detailed competitive evaluation; Provantis recognized as the global market leader and the overwhelming standard within China, with multiple, proven, successful implementations across the region   
SYRICI to deploy the SaaS delivery model from Instem’s state-of-the-art Shanghai-based data center   
A range of professional services purchased to facilitate quick implementation and a rapid return on investment   
  
Director Hang Su, Assessment Center Integrated Management Department, SYRICI, said, “As we sought to replace our existing system, it was important to choose not only a world-leading product, but also a data management vendor with the knowledge, experience and capabilities to support our continued growth. We believe that Instem and Provantis can meet our aim and we look forward to a successful partnership.”   
Neil Donaldson, VP Europe & Asia, Instem, commented, “We are proud to welcome SYRICI as our latest client in China and look forward to forging a long and successful relationship with them. It is particularly pleasing to add SYRICI to our established and rapidly growing SaaS client roster; a trend that we are increasingly seeing across the region as more and more Chinese R&D organizations are recognizing the proven value of Instem’s SaaS and Hosted services.”   
Instem’s Provantis solution was the first western toxicology/pathology software to enter into the Chinese market, deploying its initial system in one of the largest and most advanced vivariums during 2006. As the Chinese preclinical market continues to grow, Instem is leading the market, with its Provantis solution deployed at more sites within the region than any competing product.  
Instem has an established full-service office in Shanghai and supports organizations through traditional on-site systems, as well as through its SaaS delivery model from a secure, professionally managed data center based in Shanghai.  
About Shenyang Research Institute of Chemical Industry (SYRICI)  
Shenyang Research Institute of Chemical Industry (SYRICI), established on January 8, 1949, is the first national comprehensive chemical research institute. In May 1999, through the approval of Ministries and Commissions directly under the State Council, SYRICI became a large-scale scientific and technological enterprise unit directly under the central government. In April 2007, under the approval of the State Council, SYRICI was reorganized with a Fortune 500 company China "Sinochem Group" to be a wholly-owned subsidiary.   
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Instem Launches New In Silico Toxicology Blog  
Value-added blog to provide unique industry and regulatory insight and best practice guidance for computational toxicology scientists and professionals  
CONSHOHOCKEN, PA – September 10, 2020 - Instem, a leading provider of IT solutions to the global life sciences market, announced today that it has launched In Silico Insider, a bi-weekly Blog developed specifically for scientists and professionals working in the field of Computational Toxicology.  
This valuable new resource is co-authored by Dr. Glenn Myatt, Instem’s Vice President of Informatics and Dr. Candice Johnson, Instem’s Lead Research Scientist, who both joined Instem in November 2019 as part of Instem’s acquisition of Leadscope, Inc., a leading provider of In Silico Safety Assessment Solutions.   
Dr. Myatt and Dr. Johnson are leading experts in the field of In Silico Toxicology and have built deep relationships with regulatory authorities and leading organizations in the pharmaceutical, chemical and consumer products industries. They have a wealth of experience in the management of international consortia to develop industry protocols and position papers and have a reputation in the market as true collaborators.  
“Glenn and Candice’s scientific and regulatory know-how, combined with a clear passion for their field, make them uniquely positioned to provide the insight, thought leadership and proven best practice guidance that the In Silico Tox community highly values,” comments Julie Jones, Informatics Marketing Manager at Instem.  
To read the first blog post and to subscribe for future bi-weekly updates, please visit https://insilicoinsider.blog/  
About Instem  
Instem is a global provider of leading software solutions and services that are helping over 500 clients bring their life enhancing products to market faster. We enable clients in the life sciences to more efficiently collect, analyze, report and submit high quality regulatory data, while maintaining compliance for their products around the world.   
Instem solutions are in use by customers worldwide, meeting the rapidly expanding needs of life science and healthcare organizations for data-driven decision making, leading to safer, more effective products.  
Instem supports its global roster of clients through offices in the United States, United Kingdom, France, Japan, China and India.   
About Leadscope  
Leadscope are renowned leaders in computational toxicology and their clients include pharmaceutical, chemical and consumer products organizations, as well as international regulatory agencies. Leadscope’s innovative solutions allow researchers to combine their own proprietary data with publicly-curated toxicity databases. Clients searching Leadscope’s toxicity databases can access well over 500,000 toxicology studies for more than 200,000 chemicals, enabling fast, accurate, defendable and regulatory accepted predictions.   
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WuXi AppTec Selects Instem's Submit™ Software Suite to Meet Growing Demand for SEND  
  
  
  
  
  
  
  
  
  
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WuXi AppTec Selects Instem's Submit™ Software Suite to Meet Growing Demand for SEND  
Leading China Based CRO Purchases Full Submit Software Suite for Complete SEND Management  
January 17, 2017 - Instem, a leading provider of IT solutions to the global early development healthcare market, announced today that China based Contract Research Organization (CRO), WuXi AppTec (WuXi), will be deploying its submit™ software suite for the creation and management of SEND (Standard for Exchange of Nonclinical Data) compliant datasets.   
Established in 2000, WuXi has over 15 years’ experience in providing outsourced R&D services to the pharmaceutical, biotechnology and medical device markets. WuXi’s purchase of submit is in response to increasing customer demand for SEND compliant datasets, as organizations take steps to adhere to the FDA’s SEND mandate which came into force on December 17, 2016. The mandate states that all organizations must now use the appropriate FDA-supported standards, formats and terminologies specified in the FDA Data Standards Catalog for NDA, ANDA, and certain BLA submissions.  
Key Facts  
  
WuXi to implement the complete submit software suite for the creation and management of SEND datasets and associated documents   
WuXi also deploying SENDView™, an Instem tool for simplified QC review of SEND datasets  
Contract awarded due to comprehensive submit product functionality and Instem’s unrivalled SEND expertise and leadership  
This purchase follows the recent procurement of the Provantis® Toxicology Resource Planning (TRP) and Business Objects modules, to further streamline preclinical study processes  
  
Dr. Yi Jin, Chief Scientific Toxicologist at WuXi, said “Instem is widely regarded throughout the Chinese R&D sector as the gold standard for IT solutions. We have been working in partnership with Instem since 2009 and over the course of our eight-year relationship we have been continually impressed with their best-in-class solutions and their commitment to customer service. Their experience and global leadership in the SEND domain made the decision to invest in submit a straightforward and logical one.”   
Bill Harrison, Head of Toxicology Services, WuXi, added: “In an increasingly competitive market, CROs need to remain flexible and adaptable in order to meet changing market demands, while maintaining regulatory compliance. Here at WuXi, we are actively improving our capabilities and capacity through new expansions in our global business. Our deployment of submit is yet another step in our deep commitment to providing growing, comprehensive support to our clients worldwide and we look forward to providing consistent, high quality, SEND compliant datasets to our Sponsors.”   
Neil Donaldson, Vice President of Global Sales Europe & Asia, remarked: “We are honored that WuXi has pledged further commitment to Instem and our solutions. The deployment of submit will help to consolidate WuXi’s position as one of China’s leading CROs, and we look forward to further strengthening our relationship with them as they continue to develop their services to meet the demands of the global R&D industry.”  
The submit solution is uniquely meeting the very wide range of demands that span the needs of the largest multi-national pharmaceutical organizations and CROs, to the smallest organizations and their advisors. Submit creates datasets from any electronic source, it then manages SEND datasets throughout their entire lifecycle including the ability to QC Review and perform advanced single and multi-study data visualizations and analyses. Originally developed in 2005, the submit suite of tools and outsourced services is now the most widely adopted SEND solution in the market across 15 countries.  
About WuXi AppTec  
Serving the global market, WuXi AppTec is a leading pharmaceutical, biopharmaceutical, and medical device open-access capability and technology platform. WuXi provides efficient solutions to clients across the globe, helping organizations to bring new medicines and products to market through cost-effective outsourced R&D. Working in both China and the USA, WuXi’s 26 sites in 7 countries are committed to developing an alternative to the traditional R&D model in order to continue to serve and transform the global life sciences market.  
For further information please visit www.wuxiapptec.com  
About Instem  
Instem is a leading supplier of IT applications and services to the early development healthcare market delivering compelling solutions for data collection, analysis and regulatory submissions management. Instem solutions are in use by customers worldwide, meeting the rapidly expanding needs of life science and healthcare organizations for data-driven decision making leading to safer, more effective products.  
Instem’s portfolio of software solutions and consulting services increases client productivity by enhancing product development processes while offering the unique ability to generate new knowledge through the extraction and harmonization of actionable scientific information.  
Instem supports over 500 clients through offices in the United States, United Kingdom, France, Japan, China and India.  
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Toxicology Research Laboratory Chooses Instem Software Solutions  
Chicago based Contract Research Organization Selects Instem's Provantis Preclinical Study Management and submit-SEND software  
CONSHOHOCKEN, PA - (BUSINESS WIRE) – October 28, 2014 - -Instem, a leading provider of IT solutions to the global early development healthcare market, announced today that Toxicology Research Laboratory (TRL) has purchased the Provantis® software suite for managing their preclinical studies, along with the submit™ solution suite to support CDISC’s Standard for Exchange of Nonclinical Data (SEND).  
TRL is a GLP operated, AAALAC International accredited facility located within the University of Illinois at Chicago. TRL has conducted many preclinical toxicology programs on potential therapeutic agents and other chemicals. Organizations such as the National Cancer Institute, the World Health Organization, the U.S. Army Medical Research and Development Command, and several biotechnology, pharmaceutical, and agricultural companies utilize the expertise and commitment of the interdisciplinary TRL team.  
TRL selected Provantis to replace their existing preclinical software with a more modern, robust and efficient integrated system that would also deliver improved regulatory reporting capabilities.   
TRL’s selection of Instem’s submit solution suite will allow them to fully support CDISC’s SEND initiative. SEND defines the organization, structure, and format of standard nonclinical tabulation datasets and enables more efficient review of study data while helping to improve data quality, accessibility and predictability. Submit will enable TRL to convert data from any source system into SEND files, allowing them to share, visualize and analyze study data with their sponsors and regulators more efficiently.  
Key Facts   
  
Provantis chosen to replace aging legacy solution  
TRL deploying a range of Provantis version 9 modules including General Toxicology, Pathology, Tables & Statistics and Clinical Pathology instrument interfaces  
Submit™ solution chosen to create, convert, visualize and share SEND data  
Specialized Solutions program selected for rapid deployment, using a more tailored approach to implementation, training, validation and support   
  
Matt Lindeblad, Study Director & Senior Toxicologist, TRL said “We were seeking a world leading solution to help us deliver the next level of efficiencies within our laboratory and to enable us to further improve our level of client service. Using Provantis we believe we have found such a solution and look forward to seeing the benefits of our investment.” Mr. Lindeblad continued “In addition, as we gear up for the SEND initiative, we look forward to joining the numerous organizations that are now utilizing Instem solutions to create and manage SEND data sets.”  
Ed Lorenti, VP Global Sales, Instem added “We are delighted to welcome TRL as our newest client. We look forward to forging a long and successful relationship with TRL and are pleased to help them advance their mission of providing the highest levels of client service and responsiveness to their customer base.”   
  
About Toxicology Research Laboratory  
Toxicology Research Laboratory (TRL) is an independent contract research laboratory located within the Department of Pharmacology at the University of Illinois at Chicago (UIC). TRL offers a GLP compliant and AAALAC accredited facility for performing a range of preclinical services including General Toxicology, Pharmacokinetics, Reproductive Toxicology, ADME, Genotoxicity and Efficacy Studies, In-Vitro and In-Vivo Toxicology and Analytical and Bio analytical Support. TRL is located in the middle of the “Illinois Medical District”, within close proximity of 4 major hospitals, giving TRL the opportunity to collaborate with world renowned experts in specific areas of research. By offering the resources of a major State University and UIC Hospital System with a wide range of experienced staff, professors and other leading medical specialists, TRL can propose an endless variety of disease models and conduct preclinical studies seamlessly in conjunction with clinical trials at the UIC General Research Center to evaluate potential drugs.  
To learn more about TRL, please visit trl.uic.edu/home  
  
About Instem   
Instem is a leading supplier of IT applications to the early development healthcare market delivering compelling solutions for data collection, management and analysis across the R&D continuum. Instem applications are in use by customers worldwide, meeting the rapidly expanding needs of life science and healthcare organizations for data-driven decision making leading to safer, more effective products.  
Instem’s portfolio of software solutions increases client productivity by automating study-related processes while offering the unique ability to generate new knowledge through the extraction and harmonization of actionable scientific information.  
Instem supports over 400 clients through full service offices in the United States, United Kingdom and China with additional locations in India and a full service distributor based in Japan.  
Meeting clients at the intersection of investment & return™.  
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NOTOCORD User Group Meeting Voted a Great Success by Delegates  
Instem Reports Successful NOTOCORD User Meeting; Featuring 2 Full Days of Presentations, 1:1 Advice Clinics and Networking  
CONSHOHOCKEN, PA - February 6, 2017 - -Instem, a leading provider of IT solutions to the global early development healthcare market, announced today that the 2017 NOTOCORD User Group Meeting has been deemed a very successful event by clients.  
The meeting, which was held at the Pavillon Henri IV Hotel, Saint-Germain-En-Laye, France on January 26th & 27th, provided 2 full days of presentations, 1:1 Advice Clinics and a lively networking and social program.   
The meeting was the first NOTOCORD user event since the company was acquired by Instem in September last year and forms part of Instem’s overarching Customer Involvement Program (CIP). The CIP provides opportunities for Instem clients across the globe to hear the latest news on product strategy, gain in-depth knowledge of Instem’s products and services, help shape and influence product development and become more engaged with key industry initiatives such as SEND.   
The agenda featured presentations from the Instem and NOTOCORD team, alongside excellent guest speakers from organizations including Sanofi, Orion Corporation, Aptuit, Biotrial, Janssen Pharmaceuticals, Pluriomics and Inria. Additionally the meeting included a “Hardware Manufacturers Showcase”, giving a platform for NOTOCORD’s hardware partners to demonstrate their capabilities.   
The conference covered a range of topics including Data Analysis with NOTOCORD-hem, NOTOCORD’S flagship software platform for the acquisition, display and analysis of physiological signals; an introduction to NOTOCORD-Sense, a new cloud-based collaborative platform for data acquisition and analysis; and a session on new trends in MEA data analysis.   
The conference also featured a very informative SEND (Standard for Exchange of Nonclinical Data) session headed by Lou Ann Kramer, National CDISC SEND Team Leader and VP of Regulatory Solutions at Instem, who outlined the current SEND status and future implications for Safety Pharmacology data.  
Gregor Grant, Executive Vice President, Instem said “The conference was a great success, it was very interactive and provided an excellent opportunity for us to connect with a core group of key customers. Client feedback both during and following the meeting has been excellent and we look forward to continuing to work with our clients to deliver high-quality and highly reliable solutions that continue to meet and exceed their expectations.”  
Reflecting on the meeting, Philippe Zitoun, NOTOCORD founder added “It was fantastic to see such high levels of client engagement, and I am very encouraged to see that our users are already starting to realize the benefits of being part of the Instem group.”   
About Instem  
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Instem Reports Growing Demand for Cyto Study Manager Software Solution   
Leading Organizations Select Cyto Study Manager to Streamline Genetic Toxicology Study Workflows  
CONSHOHOCKEN, PA (BUSINESS WIRE)– October 2, 2017 - -Instem, a leading provider of IT solutions to the global early development healthcare market, is pleased to announce it has seen increased demand for its unique Cyto Study Manager (CSM) genetic toxicology software solution.  
Leading R&D organizations across the globe, including Roche and Charles River Laboratories, have selected Cyto Study Manager to help them streamline genetic toxicology study workflows, reduce costs, increase efficiencies and improve regulatory compliance.  
Cyto Study Manager, originally developed by Perceptive Instruments and now part of the Instem solutions portfolio, integrates data acquisition, auditing, reporting and study management processes into a single intuitive system that greatly improves efficiencies while ensuring data integrity during genetic toxicology studies. CSM includes modules for the comet assay, micronucleus, chromosome aberrations and more.   
To support this increased demand, Instem is hosting an Express Webcast on Thursday October 5th titled “How to Create More Efficient GeneTox Study Workflows”. Webcast attendees will learn how:  
  
CSM is replacing multiple genetox systems with one comprehensive, easy to use solution  
CSM combines experimental set up, data collection and automatic report generation  
CSM is helping clients reduce paperwork and deliver results sooner   
  
REGISTER HERE  
Gregor Grant, Executive Vice President Preclinical Solutions, Instem, said “We are delighted to see an increasing number of clients recognizing the potential of Cyto Study Manager to deliver dramatic efficiency gains in their genetic toxicology operations. CSM is an extremely flexible solution that can be easily customized to meet our clients’ individual genetox workflows.”   
About Instem  
Instem is a global provider of leading software solutions and services that are helping over 500 clients bring their life enhancing products to market faster. We enable clients in the life sciences to more efficiently collect, analyze, report and submit high quality regulatory data, while maintaining compliance for their products around the world.   
Instem solutions are in use by customers worldwide, meeting the rapidly expanding needs of life science and healthcare organizations for data-driven decision making, leading to safer, more effective products.  
Instem supports its global roster of clients through offices in the United States, United Kingdom, France, Japan, China and India.  
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Multi-National Organization Purchases Instem's Complete SEND Solution Suite  
Instem Client selects submit™ Solution Suite for Europe and Asia Deployment  
CONSHOHOCKEN, PA – July 21, 2014 - - Instem, a leading provider of IT solutions to the global early development healthcare market, announced today that a leading multi-national corporation has purchased the submit™ solution suite to support CDISC’s Standard for Exchange of Nonclinical Data (SEND).   
SEND defines the organization, structure, and format of standard nonclinical tabulation datasets for interchange between organizations such as sponsors and contract research organizations and for submission to the US Food and Drug Administration (FDA). Guidance by the FDA was released earlier in 2014, paving the way for SEND to become a requirement with preclinical study submissions.  
Key Facts  
  
Multi-national organization purchases complete submit™ suite, including submit, SENDView and SEND validation services for Europe and Asia deployment   
Solution purchase supports client’s FDA eStudy Data guidance compliance objective   
Submit suite enables users to efficiently create, convert, manage and share SEND datasets throughout their lifecycle  
Client to consolidate and organize external data sources via a flat file data adaptor which will also automate processes; a submit file store option will act as a central console for managing the creation of data sets as well as providing version control capabilities  
Purchase also includes an upgrade to Provantis 9, the latest version of Instem’s market leading  
 preclinical software solution   
  
“As an innovative company that strives to stay at the forefront of technology, it is fitting that our client has chosen to join other Instem clients in embracing SEND,” commented Neil Donaldson, Instem Vice President of Sales, Europe and Asia. “Through the purchase of the submit suite and upgrade to Provantis 9, it is pleasing to see our client reaping value from Instem and our solutions, and continuing to build upon their initial investments.”  
About Instem   
Instem is a leading supplier of IT applications to the early development healthcare market, delivering compelling solutions for data collection, management and analysis across the R&D continuum. Instem applications are in use by customers worldwide, meeting the rapidly expanding needs of life science and healthcare organizations for data-driven decision making leading to safer, more effective products.  
Instem’s portfolio of software solutions increases client productivity by automating study-related processes while offering the unique ability to generate new knowledge through the extraction and harmonization of actionable scientific information.  
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Meeting clients at the intersection of investment & return™.  
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Instem Exhibiting at Leading Industry Conferences in China and Japan  
Instem to Showcase Solutions for Preclinical Study Management, SEND and Genetic Toxicology   
CONSHOHOCKEN, PA - - June 15, 2016 - - Instem, a leading provider of IT solutions to the global early development healthcare market, is pleased to announce its continued support and involvement at the following industry conferences in China and Japan this month:  
The 6th National Congress of the Chinese Society of Toxicology (CSOT)  
 June 28 – July 1   
 Chongqing City, China  
 Booth C-3  
43rd Annual Meeting of the Japanese Society of Toxicology (JSOT)  
 June 29- July 1  
 WINC AICHI (Aichi Industry & Labor Center), Nagoya, Japan  
 Booth 84  
Visitors to the conferences will learn about:  
  
Submit™ - the most widely deployed set of SEND tools and services, adopted at 36 sites across 13 countries   
Provantis® - the undisputed leading solution for preclinical study management  
Comet Assay IV – the market leading live video imaging system for fast, accurate and reproducible slide comet scoring  
Ames Study Manager – Integrated Ames plate counting, study management and reporting   
  
“CSOT and JSOT are key events that enable us to connect with existing clients in the region, as well as providing the opportunity to showcase our comprehensive and growing portfolio of solutions to the wider preclinical R&D community,” said Neil Donaldson, Vice President of Sales, Europe and Asia. “Additionally, as we see a spike in demand for SEND management solutions across China and Japan, we find that our knowledge and experience is securing Instem’s place as the leading SEND supplier for these countries.   
Further supporting its rapid growth in the Japanese SEND market, Instem was recently selected by Gotemba-based contract research organization, BoZo Research Center, as their exclusive SEND outsourcing partner in Japan. BoZo, will be holding an open luncheon during this year’s JSOT exhibition with Instem representatives on hand to discuss Instem’s SEND tools and services. For more information about the luncheon contact info@bozo.co.jp or read the full news release about this partnership.  
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SEND Implementation Guide for DART Issued by CDISC  
Study Design Coverage Expanding  
CONSHOHOCKEN, PA - August 16, 2016 - The CDISC/SEND Leadership Team has announced the publication of the CDISC SEND Implementation Guide: Developmental and Reproductive Toxicology (DART) Version 1.0 (Provisional).   
The SENDIG-DART is based on and should be used in conjunction with the SENDIG v3.1. This extends the SEND standard into Reproductive Toxicology by supporting study data typically found in embryo-fetal development (EFD) toxicity studies and introduces new concepts, such as study phase days based on reproductive events. Additional study designs (e.g., Fertility, Postnatal Development - Multi-generational) will be covered in future releases.  
SENDIG-DART v1.0 is provisional because it introduces new variables that are not yet in a published version of the overall model, SDTM. The final publication will depend upon a future SDTM model release.   
In addition, remember that the timing of adoption by the FDA is a process separate from standards development. The FDA site to watch for standards adoption for submissions is: http://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm   
This is the second SEND Team release in recent weeks but represents many years of effort by the SEND Repro sub team.   
Refer to the CDISC announcement www.cdisc.org/send for access to the document. As always, we’re here to help with any questions you may have about the standard.  
 Instem will shortly make available, upon request, a pre-recorded presentation that will provide an explanation of the changes to the standard, along with guidance on implementation considerations. Look for more information coming soon.  
Instem developed submit, the first commercially available SEND software solution in 2005 and its comprehensive set of tools are now the most widely adopted in the market, supporting over 45 client sites across 15 countries. The submit platform is meeting the very wide range of demands that span the needs of the largest multi-national pharmaceutical organizations and CROs to the smallest organizations and their advisors.  
During this period of preparation and especially following FDA’s long awaited final guidance (December 18, 2014) for standardized study data for providing submissions in electronic format, the demand for outsourced SEND services has rapidly grown. Now across every stage of SEND-Readiness, clients can choose from one or more Instem solution-services that will help them in their journey towards SEND compliance, while minimizing the impact within their organization. This includes the option for organizations to completely turn to Instem as their fully-outsourced SEND department.  
More information about how organizations can Submit™ with confidence can be found here.   
About Instem   
Instem is a leading supplier of IT applications and services to the early development healthcare market delivering compelling solutions for data collection, analysis and regulatory submissions management. Instem solutions are in use by customers worldwide, meeting the rapidly expanding needs of life science and healthcare organizations for data-driven decision making leading to safer, more effective products.  
Instem’s portfolio of software solutions and consulting services increases client productivity by enhancing product development processes while offering the unique ability to generate new knowledge through the extraction and harmonization of actionable scientific information.  
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Instem Announces Centrus Solution Suite for Early Drug Development  
New Centrus™ Solution Suite to Provide Unique Capabilities for Accessing, Transforming, Viewing and Sharing Scientific Information in Early Drug Development  
CONSHOHOCKEN, PA - (BUSINESS WIRE) – September 10, 2010 - - Instem, a leading provider of early drug development software solutions, announced today details of their newest product line, Centrus™, for enterprise information integration in early drug development. Centrus provides a single, secure environment to access, harmonize and use early drug development information from a variety of sources, including current data acquisition systems, legacy systems, warehouses, partner and contract research applications, to meet the rapidly-expanding needs of life science organizations for data-driven decision making.  
Based on innovative Instem technology already licensed to clients to support electronic FDA submissions, the core of the Centrus suite is its open, service-oriented architecture with vendor-neutral communications and a data transformation strategy providing connectivity both inside and outside of an enterprise.   
Offering an integrated global view of data from biology-related development activities ranging from lead optimization through phase I clinical, in areas such as the safety and efficacy assessment of drugs, diagnostics, biomarkers and medical devices, Centrus will prove to be highly efficient for both researchers and administrators. Rather than accessing multiple systems and relying on the capabilities they each may have, Centrus will provide sophisticated review, reporting and analytical capabilities across all systems and studies through a single access point.   
“Centrus breaks the mold; it is truly unique in its pairing of advanced data aggregation technology with a variety of visualization capabilities that meet the unique needs of the nonclinical user,” commented Jennifer Feldmann, Instem’s Vice President of Business Development. “Only Instem has the depth of knowledge in early development data and workflows, the core technology, and the collaborative mindset to partner and integrate with other leading solution providers in the discovery, chemistry and clinical markets.”  
During a period of strong growth opening new offices, expanding existing facilities and hiring more staff to support a growing number of users from new and existing clients, Instem is investing heavily in their Centrus solution suite. In addition to serving its existing market, Instem will continue to enter into new segments and geographies directly and through strategic partnerships with this newest offering.  
“Centrus is the next logical step in the evolution of Instem’s 30 year commitment to the nonclinical research and development community,” stated Phil Reason, Instem CEO. “The continued globalization and restructuring of drug development activities demands a new approach to scientific knowledge management, and Centrus will finally allow organizations to unlock silos and leverage the information for better decision-making across the value chain. We see tremendous opportunity for our existing clients and for the development and regulatory communities as a whole.”  
The Centrus solution suite will allow organizations to continue to use their chosen early development data acquisition systems, providing a single, powerful toolset to liberate the value in the data they have collected. Utilizing consistent, flexible and easy-to-use Centrus modules, day-to-day needs such as data review, comparative statistics and reporting can be met efficiently while supporting more specialized requirements such as the exchange of data between companies, electronic submissions and advanced analytics.  
Connections with discovery and clinical data are also facilitated with Centrus, allowing early development information to integrate with translational science and comparative effectiveness research initiatives seeking to transfer research knowledge for improved patient outcomes.   
Although a natural fit for users of Provantis®, Instem’s industry leading preclinical data management system, Centrus is designed to be completely data source independent and enables all organizations of any size involved in early drug development to take advantage of its benefits.  
Instem is kicking off an international marketing campaign as they introduce Centrus to the early development market. In addition to on-site presentations, Instem will be holding numerous Web events and be working closely with strategic channel partners to demonstrate the power of their new solution suite.   
More details about the Centrus suite and Instem’s promotional activities will be listed on a new section of their Web site, which will be unveiled later this month.  
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Instem Presenting at Society of Toxicologic Pathology Annual Meeting  
Instem Presenting on Extraction and Normalization of Toxicologic Pathology Terminology  
CONSHOHOCKEN, PA - June 19th, 2012 - - Instem, a leading provider of IT solutions to the global early development healthcare market, is pleased to announce that Instem Life Scientist, Stephanie Berry will be representing Instem’s poster presentation at the 31st Annual Society of Toxicologic Pathology Meeting and Symposium in Boston, MA.  
The presentation will outline how Instem's Metawise™ technology was used to harmonize the varied language used within key guideline sources of pathology nomenclature. Poster co-author and Head of Semantic and Visual Applications with Instem, Paul Bradley commented, “The results of this work could form the basis of a microhistopathology controlled terminology for use in current studies. It also provides a means for retrospective translation and alignment of pathology findings from historic studies, which is particularly relevant in the current climate of pharmaceutical companies looking to maximise data reuse and accessibility."  
The Society of Toxicologic Pathology (STP) is a nonprofit association of pathologists and other scientists who focus on advancing pathology as it applies to changes in pharmacological, chemical, or environmental agents.  
“Metawise: Extraction and Normalization of Toxicologic Pathology Terminology from the INHAND Project for Enhanced Search” will be on display at the STP Exhibit Hall from Sunday evening, June 24th through Wednesday afternoon, June 27th, 2012.  
This year’s annual meeting is expected to attract over 600 attendees and 33 exhibitors from around the world to the Boston Marriott Copley Place. Instem will be exhibiting at booth #206 during the Exhibit Hall which will be open from Monday, June 25th through Wednesday, June 27th.  
About Instem  
Instem is a leading supplier of IT applications to the early development healthcare market, delivering compelling solutions for data collection, management and analysis across the R&D continuum. Instem applications are in use by customers worldwide, meeting the rapidly expanding needs of life science and healthcare organizations for data-driven decision making leading to safer, more effective products.  
Instem’s portfolio of software solutions increases client productivity by automating study-related processes while offering the unique ability to generate new knowledge through the extraction and harmonization of actionable scientific information.  
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University of Maryland Division of Translational Radiation Sciences Selects Provantis Preclinical Software Solution   
Provantis Selected to Automate and Optimize Study Processes at One of the World’s Largest Medical Countermeasure Programs   
CONSHOHOCKEN, PA (BUSINESS WIRE) November 14, 2017 - Instem, a leading provider of IT solutions to the global early development healthcare market, announced today that the University of Maryland School of Medicine, Baltimore, MD has purchased the Provantis® preclinical software solution to automate and optimize study processes at its Medical Countermeasure (MCM) Program, located within the Division of Translational Radiation Sciences.   
The Division of Translational Radiation Sciences is dedicated to tackling the most important challenges in radiation-induced normal tissue injury, radiation cancer treatment and cancer survivorship.  
The University of Maryland selected Provantis® to support an increasing research workload at their facility, enabling them to automate preclinical study processes and deliver increased efficiencies in the collection, storage and reporting of preclinical data. By harnessing Instem’s SaaS deployment model, the client will benefit from lower infrastructure and support costs, together with the flexibility and scalability to support further growth.   
The Division of Translational Radiation Sciences was established to accelerate the discovery and clinical implementation of new therapeutic strategies to improve tumor response in clinical radiotherapy, minimize post-radiation therapy complications, and mitigate/treat the life-threatening health effects of a radioactive or nuclear agent. The division is home to one of the largest medical countermeasure programs in the world, conducting preclinical efficacy screens in the areas of acute radiation sickness (ARS) and delayed effects of acute radiation exposure (DEARE).   
Isabel L. Jackson, PhD, assistant professor in the University of Maryland School of Medicine Department of Radiation Oncology and director of the Medical Countermeasure Program in the department’s Division of Translational Radiation Sciences said, “The implementation of Provantis will play a key role in enabling us to further expand our life-saving research, allowing us to automate and streamline processes and further improve data integrity, while maintaining Good Laboratory Practice (GLP) compliance.”   
Key Facts  
  
Comprehensive suite of Provantis modules to be deployed including General Toxicology, Pathology, Clinical Pathology and Protocol & Report Assembly  
Provantis to replace existing manual processes and legacy software systems  
Client to harness the power of the Instem University e-learning platform, enabling users to quickly become proficient in Instem solutions  
University of Maryland has purchased a range of implementation services to ensure rapid deployment and quicker Return on Investment  
Client to access Provantis via the SaaS delivery model  
  
Gregor Grant, Instem’s Executive Vice President of Preclinical Solutions said “The University of Maryland School of Medicine is widely recognized as a leader in the field of translational radiation science and we are honored that they have chosen Instem and Provantis to support them in their vital work. We warmly welcome them to the growing Provantis user community.”  
About University of Maryland Division of Translational Sciences  
Under the directorship of Zeljko Vujaskovic, MD, PhD, the Division of Translational Radiation Sciences (DTRS), within the Department of Radiation Oncology at the University of Maryland School of Medicine, is dedicated to tackling the most important challenges in radiation cancer treatment and cancer survivorship. The division was established to accelerate the discovery and clinical implementation of new therapeutic strategies to improve tumor response in clinical radiotherapy, minimize post-radiation therapy complications, and mitigate/treat the life-threatening health effects of a radioactive or nuclear agent. DTRS offers a multidisciplinary approach to address the knowledge gaps in radiation oncology, biology, and physics to facilitate discovery and innovation. This is accomplished through building on the experience and multidisciplinary expertise of faculty members within the Division. The Division provides a comprehensive set of services to the U.S. government, pharmaceutical, biotechnology, and medical device companies in the areas of medical and radiation oncology, radiation biology/physics and biodefense.   
For further information please visit http://www.medschool.umaryland.edu/radonc/divisions/translational/   
For further details about the Medical Countermeasure Program please visit http://www.medschool.umaryland.edu/radonc/divisions/translational/Medical-Countermeasure-Program/  
About Instem  
Instem is a global provider of leading software solutions and services that are helping over 500 clients bring their life enhancing products to market faster. We enable clients in the life sciences to more efficiently collect, analyze, report and submit high quality regulatory data, while maintaining compliance for their products around the world.   
Instem solutions are in use by customers worldwide, meeting the rapidly expanding needs of life science and healthcare organizations for data-driven decision making, leading to safer, more effective products.  
Instem supports its global roster of clients through offices in the United States, United Kingdom, France, Japan, China and India.   
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Instem to Host Solutions Seminar in Tokyo to Support Continued Growth in Japan  
Instem Showcasing Solutions for Preclinical Data Collection, Analysis and Regulatory Submissions Management  
CONSHOHOCKEN, PA – October 21, 2016 - -Instem, a leading provider of IT solutions to the global early development healthcare market, announced today that it will be holding an on-site solutions seminar in Tokyo on Thursday October 27th.  
The free seminar, which is being hosted by Instem and its Japanese distribution partner CTCLS, will showcase Instem’s leading IT solutions for preclinical data collection, analysis and regulatory submissions management, including Instem’s submit™ and SENDView™ solutions for SEND (Standard for Exchange of Nonclinical Data) data management.   
In addition to presentations from key members of the Instem and CTCLS teams, delegates will also hear from representatives from BoZo Research Center, Instem’s SEND outsourcing partner in Japan, and Primetech Corporation, distributors of the NOTOCORD data acquisition and analysis software solution suite, now owned by Instem following Instem’s recent acquisition of NOTOCORD.   
The seminar includes a User Group Meeting for Instem clients during the morning, followed by an open afternoon session which is available to all professionals within the Japanese life sciences community. All delegates are invited to join Instem for a Social Hour at the end of the seminar.   
Neil Donaldson, VP Sales EU & Asia, Instem, said, “This seminar further illustrates Instem’s continued commitment to the Japanese life sciences community and underlines our growing SEND leadership in the region. We look forward to an interactive and engaging event.”   
For further information including agenda and registration details please send an email to info@instem.com.  
Instem has been serving the Japanese marketplace since 2005 with its distribution partner CTCLS Life Science Corp and has embarked on an expansion plan to grow that relationship while also providing increased direct market support. Instem has recently opened an office in Tokyo, has hired additional staff and has expanded its technology offerings. In June of this year, Instem signed a partnership deal with BoZo Research Center who selected Instem as their SEND outsourcing partner in Japan.  
About Instem   
Instem is a leading supplier of IT applications and services to the early development healthcare market delivering compelling solutions for data collection, analysis and regulatory submissions management. Instem solutions are in use by customers worldwide, meeting the rapidly expanding needs of life science and healthcare organizations for data-driven decision making leading to safer, more effective products.  
Instem’s portfolio of software solutions and consulting services increases client productivity by enhancing product development processes while offering the unique ability to generate new knowledge through the extraction and harmonization of actionable scientific information.  
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Instem Showcasing Study Management and Genetic Toxicology Solutions at International Toxicology and Safety Evaluation Workshop  
Instem Sponsors the NCDSER Workshop and Study Director Course in Shanghai  
CONSHOHOCKEN, PA – May 6, 2016 - -Instem, a leading provider of IT solutions to the global early development healthcare market, is pleased to announce that it will sponsor the International Workshop/ Study Director Course on Toxicology and Safety Evaluation taking place May 9-12th in Shanghai.  
Held for the first time in China, the training course will be jointly organized by the American College of Toxicology (ACT) and Chinese Society of Toxicology (CSOT). This comprehensive workshop will discuss conducting, supervising and monitoring toxicology studies in an ever- increasingly stringent regulatory environment.   
Instem will exhibit at stand #1 where visitors can learn about:  
  
Provantis® - The undisputed leading solution for preclinical study management  
Comet Assay IV – The market leading live video imaging system for fast, accurate and reproducible slide comet scoring  
Ames Study Manager – Integrated Ames plate counting, study management and reporting   
Submit™ - The most widely deployed set of tools and SEND services, adopted at 35 sites across 12 countries.  
  
The event will take place at the Renaissance Shanghai Pudong Hotel and is expected to attract over 300 attendees from the Asia-Pacific region, with speakers from around the globe.   
About Instem   
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Ranbaxy Purchases Instem’s Preclinical Software Suite  
Provantis Preclinical Software Suite Selected to automate R&D Laboratory Processes in India  
CONSHOHOCKEN, PA – May 8, 2014 - - Instem, a leading provider of IT solutions to the global early development healthcare market, is pleased to announce that Ranbaxy Laboratories Limited (Ranbaxy) has purchased the Provantis® preclinical software suite to automate laboratory processes at their R&D Headquarters in Gurgaon, India.   
Ranbaxy is a research based international pharmaceutical company serving customers in over 150 countries. Ranbaxy develops, manufactures and markets generic, branded generic, value-added and Over-the-Counter (OTC) products, Anti-retrovirals (ARVs), Active Pharmaceutical Ingredients (APIs), and Intermediates. The company also carries out new, innovative research.   
Ranbaxy’s continued focus on research & development has resulted in several regulatory approvals in both developed and emerging markets, including the development of India’s first New Chemical Entity (NCE), Synriam™, a new age cure for Malaria.   
Key Facts  
  
Ranbaxy to implement Provantis 9, the latest version of Instem’s market leading preclinical software solution   
Comprehensive suite of integrated Provantis modules to be deployed, including Inlife, Pathology, Tables  
 & Statistics, Clinical Pathology, Protocol & Report Assembly  
Provantis to replace in-house developed applications to streamline processes and further improve productivity  
A range of professional services purchased to facilitate quicker, smoother implementation and faster  
 return on investment  
Provantis software to provide enhanced compliance capabilities   
  
Provantis will be delivering demonstrable efficiency improvements to Ranbaxy at its Gurgaon R&D center in India and will offer enhanced compliance capabilities, integrated reporting and reduced QC burden.   
  
 Instem’s VP Global Sales, Europe & Asia, Neil Donaldson, commented “We are delighted to welcome Ranbaxy as our newest client in the Asia Pacific region and look forward to a long and successful partnership. Instem recognizes the increasingly important role that Indian organizations play in the global pharmaceutical market and we are committed to supporting the future growth and development of the Indian R&D community”.  
Instem entered the early drug development market in India during 2005 when they welcomed their first Indian customer, Advinus Therapeutics. Instem maintains a physical presence in the region through its office in Pune.   
About Ranbaxy   
Ranbaxy Laboratories Limited, India’s largest pharmaceutical company, is an integrated, research based, international pharmaceutical company producing a wide range of quality, affordable generic medicines, trusted by healthcare professionals and patients across geographies. Ranbaxy’s continued focus on R&D has resulted in several approvals, in developed and emerging markets, many of which incorporate proprietary Novel Drug Delivery Systems (NDDS) and technologies developed at its own labs. The company has further strengthened its focus on generics research and is increasingly working on more complex and specialty areas.  
Ranbaxy serves its customers in over 150 countries and has an expanding international portfolio of affiliates, joint ventures and alliances, ground operations in 43 countries and manufacturing operations in 8 countries.   
Ranbaxy is a member of the Daiichi Sankyo Group. Through strategic in-licensing opportunities and its hybrid business model with Daiichi Sankyo, a leading global pharma innovator headquartered in Tokyo, Japan, Ranbaxy is introducing many innovator products in markets around the world, where it has a strong presence. This is in line with the company’s commitment to increase penetration and improve access to medicines, across the globe.  
For more information, please visit www.ranbaxy.com.  
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Global Healthcare Leader Becomes SEND-Ready; Completes Purchase of Instem Submit Software Suite  
International Pharma to Standardize Upon Instem's SEND Software Platform  
CONSHOHOCKEN, PA - (BUSINESS WIRE) – November 19, 2014 - -Instem, a leading provider of IT solutions to the global early development healthcare market, announced today that a Fortune 500 pharmaceutical leader has purchased its complete submit™ solution suite to support CDISC’s Standard for Exchange of Nonclinical Data (SEND).   
Instem’s submit solution suite creates and manages SEND study datasets throughout their lifecycle and allows sponsors, CRO’s and regulators to share, visualize and analyze study data more efficiently.  
The global pharmaceutical client invests over $5 billion per year in R&D related expenditures providing life enhancing products in over 100 countries.   
Instem’s submit solution suite will enable this global client to manage SEND datasets for their entire study portfolio, regardless of where those studies are conducted, and will allow simplified data review and search while automating workflows to improve operational efficiencies concerning SEND. Submit will also provide the client with capabilities for define.XML and define.pdf creation, SEND rule checking and the secure version-controlled 21 CFR Part 11 storage of SEND files.  
“Since 2004 we have been deeply involved with SEND, and having launched our first product in 2005 we are so very pleased to include another global powerhouse in the rapidly growing list of clients that have acknowledged our leadership position,” comments Gary Mitchell, VP Global Marketing at Instem. “Instem has been raising awareness, conducting training, consulting and providing data conversion services to help clients become SENDReady™. Following FDA’s issuance of draft guidance earlier this year, we have seen a surge in interest and orders for our submit software solution.”  
Instem’s submit solution has been licensed to more than 30 sites in 10 countries and during 2013 won the VOLTAGE Award for technical innovation. Instem has been recognized by CDISC for its exceptional SEND contributions and remains an active member of PhUSE.   
Key Facts   
  
Global healthcare provider deploying Instem’s complete submit™-SEND software suite  
Global provider deploying integrated software package, including capabilities for SEND file receipt and creation, data review and search, define.XML and define.pdf creation, SEND rule checking, secure version-controlled 21 CFR Part 11 storage of SEND files  
Instem selected for SEND market leadership, product functionality and strong corporate reputation   
About Instem   
Instem is a leading supplier of IT applications to the early development healthcare market delivering compelling solutions for data collection, management and analysis across the R&D continuum. Instem applications are in use by customers worldwide, meeting the rapidly expanding needs of life science and healthcare organizations for data-driven decision making leading to safer, more effective products.  
Instem’s portfolio of software solutions increases client productivity by automating study-related processes while offering the unique ability to generate new knowledge through the extraction and harmonization of actionable scientific information.  
Instem supports over 400 clients through full service offices in the United States, United Kingdom and China with additional locations in India and a full service distributor based in Japan.  
Meeting clients at the intersection of investment & return™.  
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Instem to Present at Society of Quality Assurance Annual Meeting in Tampa  
Instem Co-Presenting on Cloud Validation's Impact on the Pharma Industry  
CONSHOHOCKEN, PA - April 10, 2015 - - Instem, a leading provider of IT solutions to the global early development healthcare market, is pleased to announce that Quality Manager, Vince D’Angelo will be co-presenting with Frank Moschetto , Director of Quality, Roche Innovation Center, New York, at the Annual Society of Quality Assurance (SQA) Meeting in Tampa, FL.   
SQA is a professional quality assurance organization whose mission is to promote and advance the principles and knowledge of quality assurance essentials to human, animal and environmental health.  
The presentation will discuss the changing roles and responsibilities involved in validation and auditing when a software vendor makes available their software applications in a Software as a Service (SaaS) environment. Also to be discussed are the differences in SaaS validation compared to traditional validation, and the time-saving benefits to the client.   
“The thirst for knowledge and guidance when using SaaS/Cloud solutions continues to be demanded by Quality Assurance professionals. Instem and Roche continue to share their combined experiences of implementing and maintaining such GLP regulated systems for the benefit of those taking their first steps with this model of deployment,” said Mr. D’Angelo at Instem.   
“Validation and Auditing Responsibilities when using SaaS Products” will be presented by Instem and Roche on Wednesday, April 14th at 1:30pm Eastern.  
This year’s annual meeting is expected to attract over 800 attendees and 47 exhibitors from around the world to the Marriott Tampa Waterside Hotel and Marina, and Tampa Convention Center. Sessions will run from Tuesday, April 14th through Thursday, April 16th and will focus on regulatory-based topics in GMP, GLP and GCP areas.   
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Instem plc Environmental Policy  
Context of the Business  
Instem’s mission is to provide advanced and best-in-class IT solutions and services to the global health and life sciences community, which help to bring life-enhancing products to market faster.  
In the pursuit of this, Instem is committed through an Environmental Management System (EMS) to enhance the environmental performance of its business operations.  
Through direction and support, each employee will have a proper understanding of the importance of the Environmental Management System (EMS), their responsibility to contribute to its effectiveness, and its direct relevance to the environmental performance of the Organisation.  
Objectives  
It is the objective of this policy and the supporting system to enhance Instem’s environmental performance through the following commitments.  
  
Employ systems and procedures that ensure compliance with all relevant laws, regulations and other requirements relating to the environment.  
Consider the environmental impact as part of business planning and the implementation of these plans  
Prevent pollution, reduce waste and minimise the consumption of resources through effective purchasing and recycling processes  
Educate, train and motivate staff to act in an environmentally responsible manner  
Monitor our environmental impact in order to implement and support initiatives that mitigate this impact  
  
Continual Improvement  
As an organisation we are committed to the on-going review and improvement of our EMS. This Policy will be reviewed yearly as part of the management review process.  
This Policy will be communicated to all staff, contractors and relevant third parties, and will be made available through the Instem website.  
  
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At times, we may restrict access to some parts or all of our website, to users who have registered with us. If at any time you are provided with a user identification code, password or other information as part of our security procedures, you must treat the same as confidential, and must not disclose it to any third party. We have the right to disable any user identification code or password, whether chosen by you or allocated by us if in our opinion you have failed to comply with any of the provisions of these Terms of Use.  
You are responsible for making all arrangements necessary for you to have access to our website and for ensuring that all persons who access our website through your internet connection are aware of these Terms of Use and that they comply with them.   
You must use your own identity at all times when using the website including if you submit any information to us for any reason and must make sure that all information which you provide is accurate and up to date. You must not submit information relating to any other person except with their express written permission nor information which is copied from any other source.  
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Instem Modern Slavery Policy   
Slavery, child labour and human trafficking are serious crimes and a violation of fundamental human rights. There are various forms of this ‘Modern Slavery’ which deprives victims of their liberty and usually involves financial exploitation.   
At Instem we conduct our business fairly, ethically and with respect for fundamental human rights. We are fully committed to the prevention of all forms of slavery, forced labour or servitude, child labour and human-trafficking, both in our business and in our supply chains. We will not tolerate it. You must immediately report any suspicions of Modern Slavery or human trafficking in our business or supply chains to our Anti-Slavery Officer (ASO), Eve Leconte. Our ASO will investigate and report to our Executive Committee, within a reasonable time, on actions which may require to be taken.   
Failure to comply with this policy may result in disciplinary action, including dismissal, or termination of the contract between you and the Company. It could also involve other legal steps being taken against you. If you breach this policy or are found to have slavery or human trafficking in your business, or knowingly in your supply chain, the Company may terminate the contract with you and pursue its legal remedies against you.   
The Company makes appropriate checks on all employees, recruitment agencies and suppliers, to know who is working for, or on behalf of us. The Company provides every employee with a written contract of employment. We pay every employee in accordance with the law. We comply with our legal obligations to ensure the health and safety of all of our employees and workers, including in relation to working hours, rest breaks and holidays.  
   
   
  
  
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This cookies statement explains how cookies are used on our website at www.instem.com. It should also be read alongside our Privacy Policy.  
About cookies and how we use them  
Cookies are small data files which are placed on your computer or mobile when you visit our website. The cookies are then used to gather information about your use of our site or in some cases, to allow you to be recognised as an existing user when returning to the website.   
Cookies are commonly used to help websites work more efficiently and to provide information to owners of the website.   
They help our website to work in the way that you would expect so that we can provide you with a good experience when you use our website. They also enable us to improve our site and make our marketing activities more efficient. We don’t use cookies to pass personally identifiable information to third parties.   
Cookies can be categorised into the following broad categories:   
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Analytical/performance cookies: allow recognising and counting of the number of visitors and to see how visitors move around a website. Help improve the way websites work, for example, by ensuring that users are finding what they are looking for easily.  
Functionality cookies: allow a returning user and his/her preferences to be recognised, enabling personalised content.  
Targeting cookies: record visits to a website, the pages visited and the links followed. These cookies are used to tailor content and advertising.   
We use the types of cookies as set out below, on our website at www.instem.com. The table below also provides information about what the cookies are used for.   
  
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These cookies allow users to share content via social networking sites and email. When we provide links to third party services you find useful, they may place a cookie on your device to make their service easier to use.  
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These cookies are used to collect information about how visitors use our site. From this data, we are able to improve our website usability. All user data is anonymous.  
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Please also note that third parties for example, advertising networks and providers of external services may also use cookies. We not have any control over those.   
Cookie settings  
You can block cookies by activating the setting on your browser which allows you to refuse the setting of cookies. Please note however that if you use browser settings to block cookies, then from time to time, you may not be able to access all or some parts of the site and our site may not work as intended. You can find out more about how to manage and delete cookies by visiting www.allaboutcookies.org.   
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English law now requires all websites to request permission when using cookie technology. If your browser is set to take cookies and if you continue to use our website then we will understand this to mean that you consent to the use of cookies. However, if you wish to remove or stop use of cookies from our site then you should either stop using the site or adjust your browser as explained above to disable cookies.   
  
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Please read this privacy policy carefully. By using this website, you agree to the way in which your personal information will be used as set out in this policy.   
Information we may collect from you and track  
When you use our website, we track, collect and process personal information about you.   
This includes information which you may provide to us when you complete one of the forms on our website. For example, you may do this to make an enquiry with us or to request further information from us about one of our products or services. This might include a request for a quote or a virtual demonstration.   
From time to time, we also advertise vacancies on our website and you may apply for a position with us which may involve sending personal information about yourself through our website or by contacting us by email for example, if you send in a copy of your CV. Similarly, we invite interest from students who may be looking for an internship or work experience and again, this may involve providing personal information to us.   
More generally, we may also hold information if you contact us in other ways for example, to raise an enquiry via email or perhaps over the phone.   
The information which we may hold about you will usually include your name and job title and contact details including your address, telephone number and email address. If you are applying for a position or work experience with us, then we may also hold information about your experience and work history. We might also collect information from you about any disabilities that you may have in order for us to make reasonable adjustments if necessary for example, if you attend an interview with us.  
We may also hold information about interest which you have shown in any of our products and services and may also keep a record of correspondence which you have sent to us, including a record of any complaints.  
Using certain secure technologies, we are often able to track what pages on our Web site you have visited, can confirm what business entity you are associated with and identify the general location (country, state) of your business. When receiving email from us, we are also able to confirm if you have read our messages and the type of device and browser you may have been using at that time.  
How we use your information  
Your personal data will be held on our records and used for the proper administration of our business, including by way of example, to deal with and process your enquiries and to provide you with any further information which you may have requested.   
From time to time we may also contact you about our products and services and which we feel may be of interest to you. You have the right to be removed from our mailing list (known as “opting out”). You also have the right to ask to be removed from our database and that all of your information be completely erased. To do so, you can write to us at info@instem.com. Similarly, when we send out our email marketing communications, you can click on the “Subscription Preferences & Rights” link.  
Where you have sent information to us as part of an application for a vacancy or to enquire about work experience, we will use the personal information which you provide to assess your application. We may also retain that information for future reference.  
We are an international business and have offices in Europe and in other parts of the world including North America and the Far East. This means that in some cases, the information which we collect from you may be transferred to and stored at a destination which is outside the European Economic Area. Examples of situations in which we might transfer your details overseas to our other offices, include if you are applying for a position in one of our overseas offices or if your enquiry is best dealt with by one of those offices.   
We do take data security seriously and we will take steps as reasonably necessary to ensure that your data is treated securely and in accordance with this policy. Please note however that the transmission of information via the internet can never be guaranteed as entirely secure. Therefore, whilst we will do our best to protect your personal data, we can’t guarantee the security of your data transmitted to our site and therefore any transmission of data is at your own risk.  
We may disclose your personal data where we are under a legal obligation to do so, for example, as explained in our Terms of Use or for our proper business purposes for example, if we were to buy or sell any business (if relevant). We may also disclose your personal information to any member of our group of companies which means one or more of Instem plc’s subsidiaries. From time to time we might appoint external third parties to help us with our business functions for example, external consultants and sub-contractors. We therefore may make your data available to those entities if reasonable to do so in order to deal with your enquiry or otherwise as part of our usual business practices.   
By providing your personal data to us, you agree to the transfer, use and storage of your data as set out in this policy.   
If at any time you need to give information to us about another person, for example, a work colleague, then you should ensure that that person has given their consent to providing relevant details to us and you should bring this policy to their attention.   
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You have the right to ensure that any information which we hold about you is accurate and up to date. If you believe that the information that we may hold on you is incorrect or is no longer up to date, then please tell us. Our contact details are set out below.  
You have the right to be removed from our mailing list (known as “opting out”); and you have the right to ask that all of your information be completely erased from our database.  
You also have a right to access the personal information held about you. To obtain a copy of the information, please write to us at the address below.   
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As required by Article 27 of the GDPR, Instem’s EU representative office can be contacted.   
FAO Data Protection Officer  
 60 Route de Sartrouville  
 Parc les Grillons  
 Bâtiment 1   
 Le Pecq   
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 78230  
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Where we provide links on our website to third party sites, please note that those sites will be directly responsible for the information which you may provide to them. If you do use other websites, the operators of those sites may collect information from you which might be used in a different way to how Instem plc and its group of companies uses information and therefore privacy policies on other websites may differ from this policy.  
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From time to time, we may make changes to this privacy policy in which case, a revised policy will be posted on our website.  
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For the purposes of the EU General Data Protection Regulation (GDPR), Instem Plc together with its subsidiary companies as appropriate, act as data controller.   
  
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