Instem Acquires RIM Solution Provider Samarind

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- Instem, a leading provider of IT solutions to the global early development healthcare market, announced today that it has acquired the UK-headquartered Samarindorganization 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

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 450 clients through offices in the United States, United Kingdom, Japan, China and India.

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