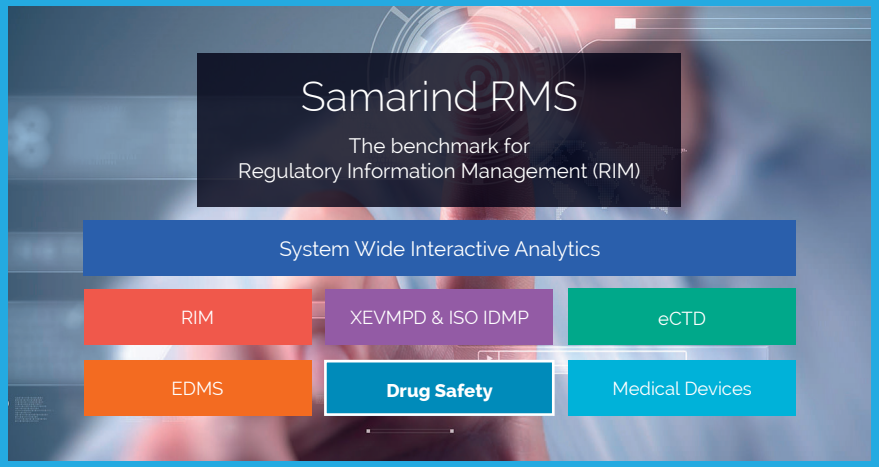
The benchmark for regulatory information management, Samarind RMS is a fully integrated software application that has been purpose built to mirror the processes associated with acquiring and maintaining a pharmaceutical product license.



Key RMS Benefits

Increased administrative efficiency, allowing timely response to critical deadlines
Improved global regulatory communications
Improved planning and optimization of current staff resources
Transparency of global activities and current status, keeping tight and timely control of all milestones and deadlines
Greater security of critical data, supporting better information control
Increased compliance via secure access, audited activities and permissions
Reduce costs through single data entry, extensive reporting and alerts

Our pragmatic approach to systems design and implementation means that our customers can manage their information smoothly and efficiently, safe in the knowledge that our *single-place-of-truth*™ approach for regulatory affairs professionals delivers a complete end-to-end system.

The Samarind RMS Drug Safety Solution offers one of the most efficient and practical ways to manage all business-critical pharmacovigilance activities from within a single environment. Today's Regulatory Affairs Specialists are now accessing, processing and analyzing all of their regulatory data in one place, with complete confidence.

Key capabilities include:

Heightened Compliance

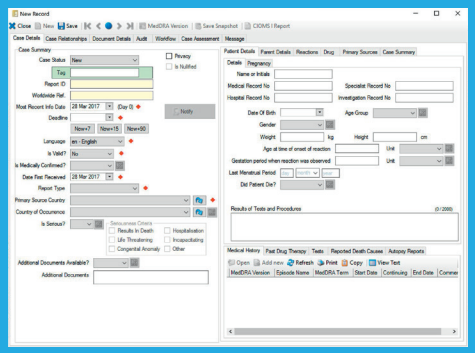
- Reduced efforts with full MedDRA integration combined with bulk version updates
- Secure tracking and audit trailing of developing cases for 21 CFR Part 11 compliance
- Full history of developing situations
- Maintains a full record of regulatory communications including ICSR XML messages

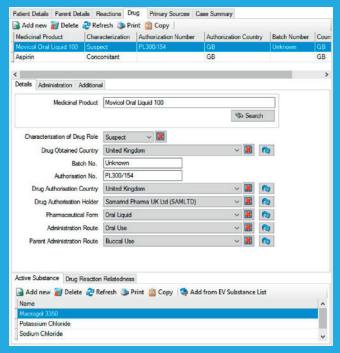
Heightened efficiencies

- Integrated product, license & safety information reduces time and errors
- Visibility and processing of master cases and their related cases
- Integrated electronic document control
- Personalized task lists to help avoid costly oversights

Better Controls

- Integrate product, license and safety data for easier trend identification
- Faster decision making abilities with real time analytics
- Powerful yet intuitive search, reporting and analytics





Regulatory Information Management

The core of Samarind RMS is its regulatory information management database. This has been carefully structured to allow you to accurately record and maintain all your medicinal product information throughout its lifecycle.
The Samarind RMS Windows software application provides the security, flexibility and ease of use that your regulatory affairs team needs to meet its regulatory and commercial obligations.

- At-a-glance visibility of all the products in your portfolio;
- A secure central repository of all your product licenses documentation, from SmPCs and PILs to PSURs and business contracts;
- Sophisticated administrator-configurable role-based user permissions, for flexible security;
- Event tracking for drug licensing applications, variations, PSURs and renewals;
- Record information about key partners e.g. API manufacturers and QC Testing sites;
- Time stamped historical audit of all previous submissions and variations;
- System-generated notifications and alerts by email at key stages;
- All data is contained within the same SQL database for security, robustness and performance;
- Extremely flexible and user friendly search and reporting facilities;
- A modern, user friendly, Microsoft-style graphical interface.

It's Time...

If your regulatory data is currently held in a variety of databases and/or spreadsheets, we encourage you to speak with us about implementing Samarind RMS. Our subject matter experts will ensure the Samarind RMS solution will quickly help you consolidate all existing data into a single system and enable you to realize an immediate return on your investment.

Contact us today for a no-cost or obligation conference call at samarindRMS@instem.com

Information Solutions for Life

Instem is a global provider of leading software solutions and services to the life sciences community. To create a more connected ecosystem, Instem is consolidating and harmonizing the marketplace, its technology solutions and their processes, and enabling disparate sources of data to be harnessed into more actionable insight.

Learn more about the mission at instem.com

Have YOU heard the news?

Samarind has become part of the international Instem organization!
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 and staff have been aligned with Instem's eStudy Data and Regulatory Information Management group, where they are providing software and outsourced services for converting, managing, storing, sharing, submitting and maintaining information compliant with FDA, EMA and other agency regulations.

For more than 500 clients, Instem is helping bring their products to market faster and more efficiently in the following areas:

Preclinical Study Management
Solutions that empower organizations to more efficiently collect, review and manage preclinical safety evaluation study data

eStudy Data & Regulatory Information Management
Software and outsourced services for converting, managing, storing, sharing, submitting and maintaining information compliant with FDA, EMA and other agency regulations
samarindRMS

Big Data Analytics & Information Sciences
Allowing researchers to generate new scientific insights through the identification, extraction and analysis of actionable information

Early Phase Clinical Study Management
Cutting edge integrated Electronic Data Capture and site automation solutions driving the processes of Phase I Clinical trials for evaluating new drugs or treatments

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