

samarind **RMS**
regulatory management software



THE EASIER WAY TO MANAGE
YOUR REGULATORY AFFAIRS

Samarind RMS | Powerful | Effective | Compliant | Flexible | Secure

samarind **RMS** regulatory management software



“With a large portfolio of products we needed a modern and flexible software system to cope with all of the variables and the worldwide diversified portfolio”



RMS On Demand

The Samarind approach

Samarind RMS is a regulatory submissions tracking database that has been purpose-built to mirror the processes associated with acquiring and maintaining a pharmaceutical product licence. All regions are supported, making the system a powerful application for managing product portfolios of all sizes and complexities, and it is scalable to an unlimited number of users.

Acknowledged by users in over one hundred countries as being a user-friendly and time-efficient regulatory software toolset, Samarind RMS is a sophisticated and flexible system for managing the entire lifecycle of medicinal product licences.

Easy to use

Based on the latest Microsoft technologies, the software has a logical, user-friendly interface that is easy to learn and use. It's carefully and intelligently structured, which means that it's easy to find what you're looking for, and information entered once flows automatically through to all applicable areas of the system. One day's training is all it takes for you to start using the system effectively.

Secure

Samarind RMS has a sophisticated role-based security system. This allows system administrators to set up roles where read-only access to certain parts of the system is combined with read-write access to other areas, meaning critical information can be disseminated in the most effective way possible. Access can also be controlled by country or region, so that staff in regional offices can have ownership of their own country's data without being able to affect shared or global information.

The system also features a rigorous audit trail, where 'before' and 'after' values of key data are logged along with the details of when it was changed and by whom, and automated alerts and notifications to remind you by email of up-coming deadlines.

Built-in document management, eCTD and EVMPD

Samarind RMS includes a built-in electronic document management system (EDMS) with full version control and automated PDF creation. Documents are linked to the submissions, licences, variations and companies they relate to without duplication. The software also includes fully integrated tools for eCTD creation and management, and provides automated collation of XML EVMPD data for upload to the EMA.

Architecture

The software's robust architecture, built on Microsoft's world class SQL server, offers immense security, flexibility and scalability, meaning it's suited to businesses of all sizes. For larger companies, Samarind RMS presents the opportunity to standardise on a single, globally deployed system, which brings enormous benefits, including common working practices.

Samarind RMS has been developed entirely by Samarind Limited, a long established (since 1987) and award winning software house based in the United Kingdom.

Business critical software is all about the end-user, which is why we work with experienced RA professionals to ensure Samarind RMS helps them accomplish their key regulatory tasks.

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Samarind RMS is a feature-rich software application, beautifully constructed to provide a single cohesive and compliant regulatory software toolset.

Key features include:

'At a glance' visibility of all the products in your portfolio and the numbers and types of licences and variations pending and approved

Product launch planning and tracking, to enable you to maximise the earnings potential of your new licences

Comprehensive tracking of submissions placed via MRP, DCP and CP in the EU to help ensure everything happens according to the relevant timetable

Recording and tracking of LOD/RFI information and associated documents, by agency department if necessary as required by the US

Automated tools to simplify the management of parallel submissions, grouped variations and manufacturer information, easing the administrative burden of keeping related information consistent and up to date

PSUR scheduling and renewal history tracking, with associated reminders to help ensure that everything is done on time

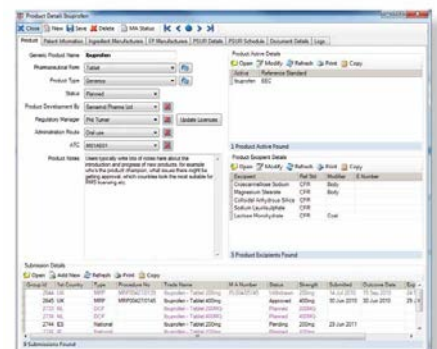
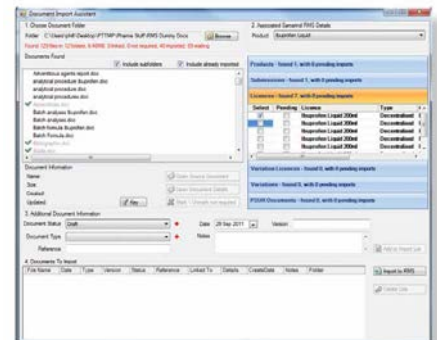
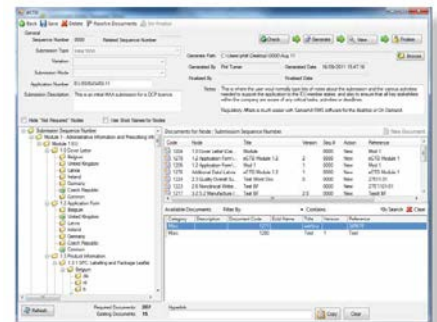
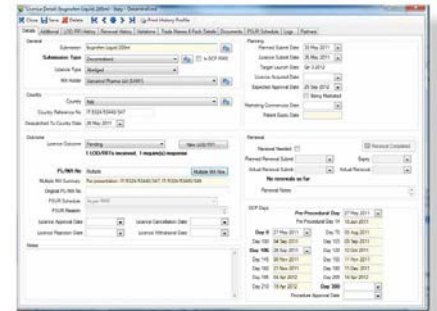
A secure central repository of all your product licence documentation, from SmPCs and PILs to PSURs and business contracts, so that everyone knows where to find the most up-to-date version of these key documents

A sophisticated role-based and country-centric security system that allows read-only and read-write access to be configured for different areas of the system

A built-in Electronic Document Management System (EDMS) with template facilities and version control that ensures that issued documents cannot be changed and the history of all previous versions of a document is archived in the database

Integrated eCTD publishing and viewing tools that allow you to create your electronic dossiers in the correct XML format as defined by the ICH and the various regional authorities

Automatic collation of EudraVigilance MPD data for transmission to the EMA to help you meet your vital pharmacovigilance obligations.



Samarind Limited, established in 1987, is a privately owned, award winning software developer that specialises in creating world-class business critical database applications for Windows, the Internet, and mobile devices. We have a rich pedigree in developing bespoke software applications and an excellent reputation for delivering complex projects, on time and within budget.

Our work in the pharmaceutical industry stretches back almost twenty years, during which time we have developed a wide range of bespoke systems including EDMS, various laboratory/analytical type applications, and regulatory affairs systems including Samarind RMS, our own regulatory management software with built-in EDMS and eCTD tools.

Samarind RMS is available for both Windows and as a cloud based 'On Demand' solution, winner of the inaugural TOPRA Innovation Award in 2010.

To find out more about how we can help your company please contact us.



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