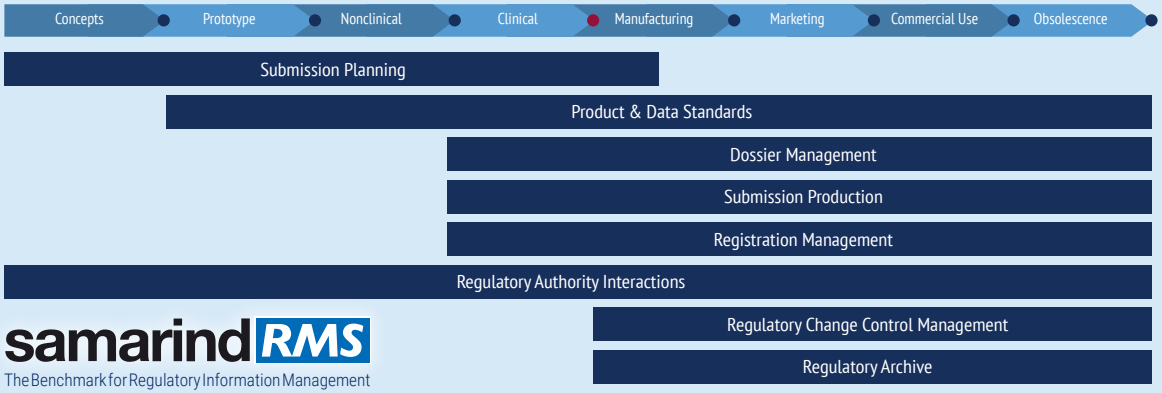
Today's medical device organizations are faced with unprecedented change, driven by the need for technology innovation amidst a rapidly evolving global regulatory framework. Greater volumes of data are also creating challenges for Regulatory Operations in their mission to stay compliant, while ensuring maximum commercial availability of their products.
Most companies today struggle to do this using manual or semi-manual processes that are not harmonized, are quite complicated, time consuming and costly to operate and manage.

True End-to-End Software that reduces submission times and maximizes revenue from your products



samarind RMS
The Benchmark for Regulatory Information Management

Practical features that produce powerful results
Reduce the time to agency submission and approval
Reduce the costs and delays in managing global registrations
Improve quality and compliance with global regulations
Access real-time regulatory information on devices and registrations
Leverage regulatory information as a corporate asset
Enable reporting on key performance metrics
Drive cross-functional product change management
Minimize time spent on data verification and remediation
Improve information exchange with ERP, PLM and EDMS

Historically, Regulatory Professionals within the Medical Device community have not had access to software solutions designed to meet their specific needs. Tracking data across multiple spreadsheets and cross-referencing files in document management systems was cumbersome, complicated and costly. Until now, the solutions available to Regulatory Professionals addressed just a small section of regulatory functions and as a result required large investments to make them fit for purpose.

Accessed online or installed on-site, the Samarind RMS Medical Device Software Solution offers a new approach. Samarind RMS provides the most efficient, practical and cost-effective way to manage all regulatory information in one place.

A comprehensive set of features, delivered through an intuitive software solution, help our customers more easily manage the full spectrum of regulatory activities needed to support the entire lifecycle, from product *Concept* through to *Obsolescence*.

Our pragmatic *single-place-of-truth*™ approach to systems design and implementation means that Instem customers can manage their products and registrations smoothly and efficiently, safe in the knowledge that at all times, they have access to real-time, accurate regulatory data.

Insight is now literally just a click away.

Samarind RMS is well known across the Medical Device industry as a high quality, sophisticated, user-friendly and well-architected solution. Every day, customers around the world use our solution knowing that they are supported by a level of customer service that is setting a new benchmark for client satisfaction.

Regulatory Standards – it's what we do...

Our dedicated global regulatory teams have provided thought leadership in the development and adoption of global data standards, such as UDI, IDMP and CDISC, and are actively engaged with industry bodies such as RAPS and TOPRA. Our involvement and influence ensure that Samarind RMS and our clients are fully compliant ahead of requirement start dates. The Samarind RMS Solution leads the way in the adoption of industry standards with full support for the FDA's UDI program and ongoing development to support EUDAMED.

Instem is one of the most trusted names for providing Information Solutions for Life.

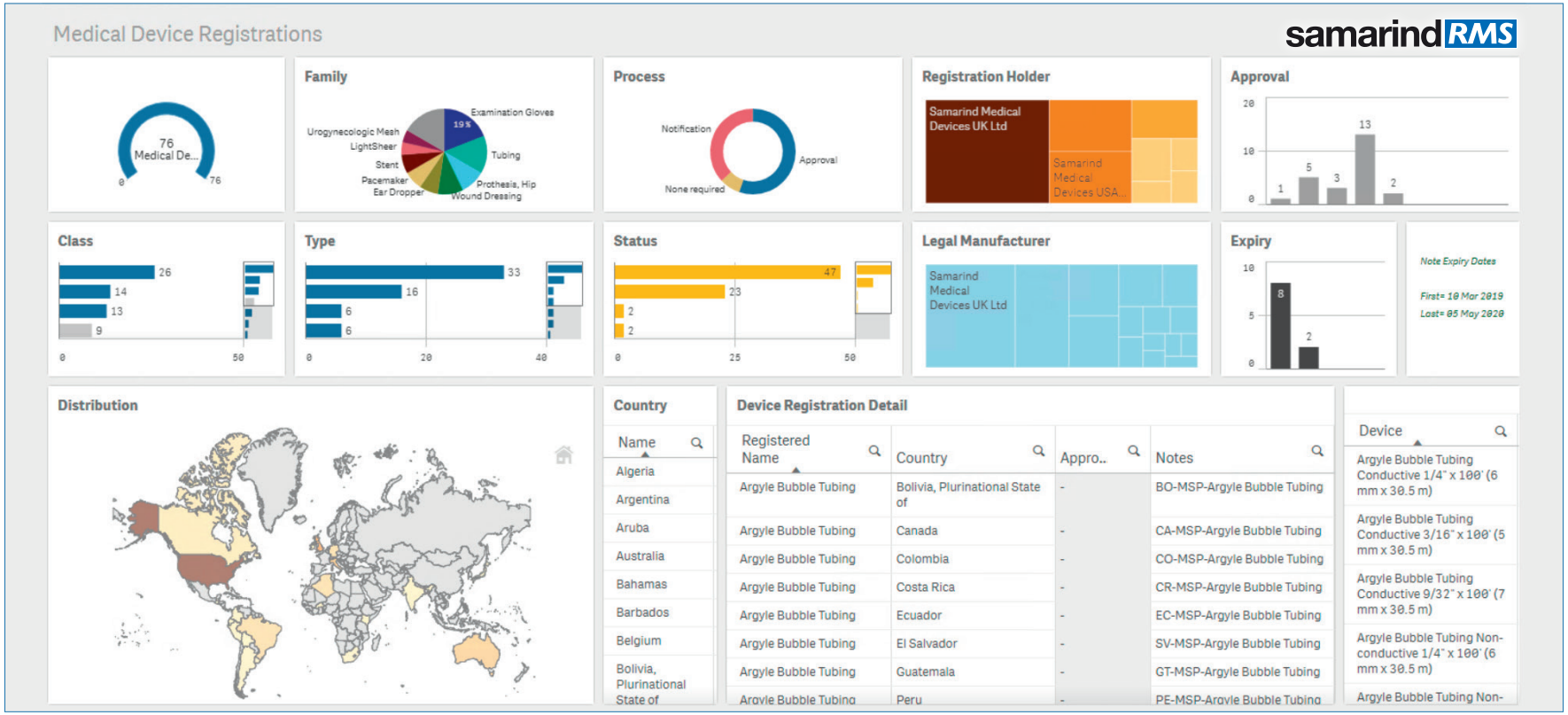
We help over 500 clients efficiently access, capture, analyze, report and submit high-quality regulatory data, while maintaining compliance for their products around the world. As a stable, publicly traded organization, Instem's mission critical software and services are supporting leading medical device organizations, drug developers, contract laboratories, consultants, universities, government agencies and health institutes in their missions.

We are large enough to give you the confidence you need while remaining agile and responsive to your requirements. It's a carefully managed balance – and a unique differentiator.

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 solutions. Through our Relationship Managers and value- added support tools, clients have access to a wealth of resources and support so they *stay focused on their science, not their software*™.

Access to the regulatory intelligence you need, when you need it.



The Samarind RMS Medical Device Solution provides

A secure Regulatory Information Management system that supports regulatory activities across all stages of the product lifecycle

- An electronic document management system (EDMS) for submission production and dossier management with version control and template management capabilities
- Support for regulatory authority interactions and change management through project planning and management tools, with automated notifications, alerts and dashboards
- Global product and facilities registration and notification management
- Support for data standards and information exchange including UDI management for handling any type of medical device
- Management of Facilities and Economic Operators and their relationships to products and registrations
- Regulatory impact assessment through user-defined queries and reporting capabilities enabled by managing relationships between regulatory data and documents across devices and regional registrations
- Ability to link to external document management systems such as Documentum™ or SharePoint™ and exchange information with PLM and ERP systems
- Interactive analytical tools that report performance metrics, accelerate decision making and enable strategic management of a world-wide market for multiple products
- For businesses with pharmaceutical or combination products, a single system for both drug and medical device data
- Easily deployed as a traditional on-site solution or via SaaS
- Tailored implementation programs to suit companies of all sizes, including access to dedicated application and industry specialists and extended customer care

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