

## Infosys ASM offerings in R&D, Safety & Regulatory (RDSR)

Research, Development, Safety & Regulatory (RDSR) is a core function that drives sales for IP-driven life sciences organizations by creating new and safe drugs. This function encompasses the pharma supply chain from molecule discovery to clinical trials and safety / compliance. Life sciences companies are facing multiple challenges with their existing IT solutions:

- High cost of maintenance and enhancements for custom developed or COTS applications
- Lack of well-defined governance model that can help track and monitor support and maintenance KPIs
- Lack of a scalable model with flexibility to add new applications and retire applications to align with business objectives
- Need for process and tool standardization

Infosys leverages its existing application support and maintenance (ASM) experience and enhances the value by creating IT and business specific differentiation. This is based on optimized execution, integrated offering, domain capability and product capabilities.



### Key ASM services offered

1. R&D, Safety and Regulatory application support and maintenance (ASM) services
2. Regulatory compliance services and regulatory submissions platform
3. Portfolio rationalization, application decommissioning, content migration, and archival services
4. Transformation, business analysis, and consultation services
5. Focus on implementing and supporting diverse set of industry leading products like Argus, ArisG, Lab Information management products, ELN products etc. across RDSR value chain.

Drug Discovery	Drug Development	Clinical Trials	Regulatory & Submissions	Pharmacovigilance
Labvantage	Accelrys Lab Notebook	GCDSTRACK	ECTD Xpress	AERS/Argus Safety
Biobook	LIMS Products		Viewpoint Submissions Management	Empirica
Discovery 360	Oracle Clinical/RDC		Rosetta Phoenix	ArisG
Activity Base	eLN Process Notebook	Siebel Clinical	Lorenz DocuBridge	Medidata Rave
Laboratory Data Archive	Symyx – Renaissance	Philips Telemetry	ISI Toolbox	
Aperio Spectrum		Quovadx Integrator	Oracle LSH	
Pathology Data Systems		Thesaurus Management System		
		Medidata CTMS		





## Benefits to our clients



- **Reduced total cost of compliance** – 30 to 50 percent leveraging value GDM and integrated shared services model
- **Improved adherence to regulatory requirements** – leveraging focuses COE on compliance and business analytics expertise – ensuring 99 to 100 percent compliance
- **Integrated end-to-end capability** – capability across RDSR value chain including some of the most critical COTS platforms and custom applications across service lines. Partnerships with key software vendors to support the capability

- **Global reach** – 24x7 coverage available using operations spread across the globe to service the application
- **Optimized portfolio** – proven portfolio rationalization capabilities, retirement and archival services
- **Enhanced flexibility in SLAs** across different business functions
- **Consolidated destination for all services** – namely L1, L2, and L3, consulting, migration, data integration, Business Intelligence and Analytics

## ASM practice highlights

Mature Practice	People	Tools/Accelerators	Partners/Alliances
 <ul style="list-style-type: none"> <li>• 25+ Life Sciences Customers</li> <li>• 10+ years experience in LS ASM offerings</li> </ul>	 <ul style="list-style-type: none"> <li>• 4000+ dedicated workforce including diverse blend of MDs, PhDs, MBAs, scientists, and industry veterans</li> <li>• 90+ life sciences domain experts</li> </ul>	 <ul style="list-style-type: none"> <li>• RDSR academy and certifications</li> <li>• Pharma IT process toolkit</li> <li>• IT audit toolkit</li> <li>• Regulatory Submissions Platform</li> </ul>	 <ul style="list-style-type: none"> <li>• Oracle</li> <li>• SAP</li> <li>• Pegasystems</li> <li>• StarLims</li> <li>• Pistoia Alliance</li> </ul>

## Success stories:

### ASM services for a leading global pharma company

ASM services for one of the world's largest pharmaceutical company based in the US – with operations in over 100 countries and many leading brands across a large number of therapies.

- Infosys has a successful engagement with the customer since 9 years providing ASM services for over 340 applications in the Drug Research, Development, Safety, Regulatory and Medical domains
- Team consists of over 300 members, handling nearly 4000 tickets every month
- Support for 32 business critical apps and 80+ COTS applications. 40 percent validated and GxP applications across value chain
- Savings of \$110,000 in the first year of contract for new application addition due to economy of scale built in the model

### Portfolio rationalization for a leading global pharma company

A pharma giant in the US had to undergo organizational transformations. One of the objectives was to reduce IT maintenance costs by identifying applications that can be retired or consolidated.

- Application portfolio rationalization for over 300 applications
- Over 20 recommendations on decommissioning and technology upgrades
- Savings of \$550,000 due to application rationalization and decommissioning
- Improved business and technical quality of portfolio achieved through retirement and consolidation of over 20 applications

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