

CLINICAL QUALITY MANAGEMENT SYSTEM



Industry Need

Clinical studies are becoming increasingly complex because of intricate protocols, adaptive trial design, disparate applications and non-standardized processes. This impacts the quality of clinical data and introduces additional risks for clinical development and research participants, resulting in:



Delays in delivering new medicines to patients



High cost of clinical development



Increased health authority and sponsor's time and resources



Infosys Solution

Infosys Life Science practice is leveraging the TransCelerate framework along with Pega's Business Process Management (BPM) tool to create a clinical quality management system framework, which can integrate with your existing clinical system to churn out trustworthy data.



Enterprise-wide clinical quality, risk management and SoP automation



TransCelerate Clinical QMS framework



Pega BPM foundation for flexibility, extensibility and reuse



ICH Q9 and ICH E6 compliant



Modular approach for easy integration



Knowledge management



Below are some of the key value propositions for Infosys Clinical Quality Management System:



Dashboard-driven unified quality and risk management



Assurance of data quality, integrity and audit readiness



Improving issue identification and management across the enterprise



Increasing oversight and timely intervention across clinical trial ecosystem