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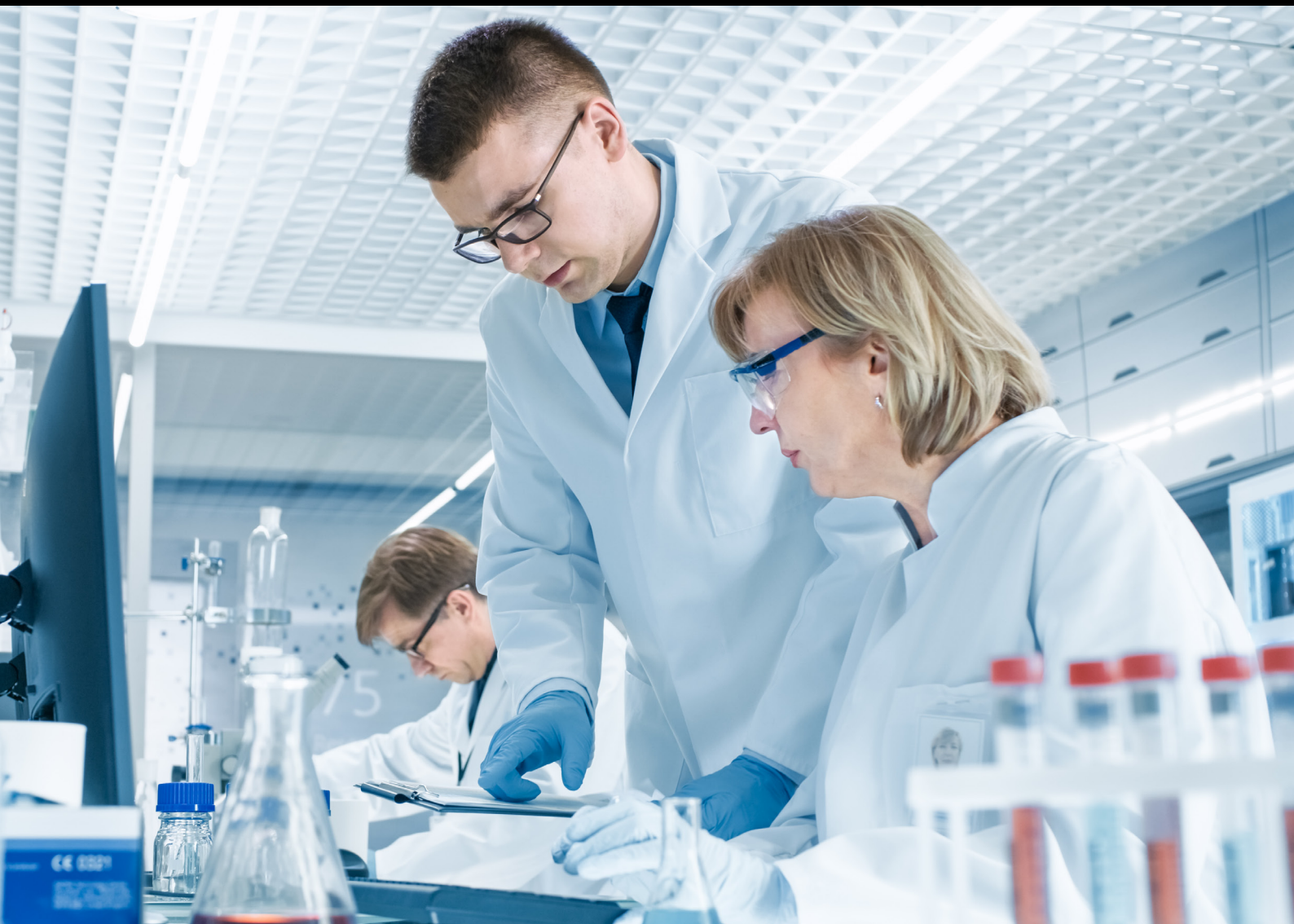
TCS ADD™ Risk-Based Quality Management



The life sciences sector is at an inflection point. Advancements in medicine and emerging demands have opened new potential markets. However, the absence of centralized information with data present in diverse systems and formats and reliance on human memory in clinical trial insight generation and monitoring are leading to delayed decision-making and market deployment of new drugs. Firms need a data science-led solution that leverages next-generation technologies such as AI and ML to provide predictive use cases like adaptive monitoring for quicker data-driven decisions and greater market success.

TCS ADD™ Risk-Based Quality Management is an integrated, AI-driven platform designed on good clinical practice (GCP) guidelines. It assists in risk-based study execution through ongoing risk assessments, adaptive monitoring, and robust issue management. Our adaptive data science-driven platform enables increased efficiency and better patient safety and data quality thereby accelerating product market submission.

Overview

Clinical trial monitoring is facing challenges due to the increased complexity of trials, and the increasing number of data sources leading to inefficient operational and patient oversight and delayed signal detection. Siloed systems, a huge amount of time and effort taken to set up platforms and onboard studies, lack of required skillsets, and limited AI/ML capabilities are hampering conducting trials efficiently and impacting cost and quality adversely.

The TCS ADD™ **Risk-Based Quality Management** platform helps companies achieve a consolidated view of critical information pertaining to risk assessment, monitoring, and mitigation. The platform offers a complete suite of modular features with an out-of-the-box key performance and risk indicator library and workflow for effective risk assessment and communication. TCS ADD™ **Risk-Based Quality Management** offers discrete analytics models to ingest data from multiple sources, such as the electronic data capture (EDC), interactive web response systems (IWRS), central lab, safety portal, and others, via a clinical data repository to conduct risk assessments and drive risk-based quality management. This equips companies with tailored insights, enabling smarter trial decisions.

Solution

The following are the key components of the TCS ADD™ Risk-Based Quality Management platform:

- **Risk assessment and categorization tool:** RACT categorizes and assesses potential risks associated with any program or protocol. The tool helps to quantify and determine risk categories that become the KRIs/KPIs/QTLs and critical data points (CDP) in downstream monitoring systems.

- **Clinical Trial analytics:** It is a multi-layered operational analytics dashboard with built-in configurable KRIs, providing site ongoing performance/risk scores using advanced statistical algorithms. Clinical Trial analytics enables advanced predictive and prescriptive AI analytics with pluggable, intuitive, in-place drill-down and roll-up capabilities with customized reports providing actionable insights. Site workload predictions and GenAI-enabled trial insights make the platform a one-stop solution for reducing monitoring time and costs by up to 30%.

- **Quality tolerance limits:** To define, configure, and monitor QTLs from a single dashboard, accelerating the process of risk identification and management. The solution has a predefined list of QTLs across multiple domains- clinical and operational. Automated workflows, alerts, and notifications for QTL breaches, mitigation action, and reporting are enabled through a single one-stop platform.

- **Subject data analytics:** An advanced and integrated AI/ML-based solution to enable the seamless monitoring of a patient's medical data for timely decision-making. It facilitates patient profiling with risk scores, outlier detection, and alerts and notifications to easily identify safety risks and trends.

The sponsors have the option to subscribe to the clinical data repository, which provides a unified, interoperable, harmonized, and AI/ML-driven common data model for clinical, operational, and scientific data. It aids data ingestion from more than 15 sources (Electronic Data Capture, Clinical Trial Management System, Master Data Management, eCOA/ePRO, IxRS, safety, and labs) and provides a multi-layer data-driven architecture.

Benefits

The TCS ADD™ Risk-Based Quality Management platform offers the following benefits:

Increased efficiency: Reduces site monitoring costs by 30% through touchless study onboarding, user-driven study configurations, triggered remote monitoring, targeted source data verification (SDV), and predictive analytics.

Reduced workload: Enhances efficiency by 30%; enables data access and drill-down navigation with integrated task lists; leverages the use of case-specific algorithms and visualizations for quick and easy decisions (For example, understanding training effectiveness) when conducting trials. End-to-end workflow for multiple RBQM stakeholders like project management, data management, Clinical Operations, Centralized monitoring, medical monitors, and Quality assurance teams.

Improved data quality and oversight: Optimizes data quality and integrity by detecting duplicates, collecting missing data, and achieving early identification of trends and signals.

Improved patient safety: Provisions next-gen analytics for intelligent insights into signals related to outliers, trends, and patterns resulting in improved patient safety.

Increased compliance: Provides a unified and collated list of pending activities across all source systems used in the study for increased compliance.

Accelerated product market submission: Automates data ingestion from various data sources to extract insights through AI/ML, expediting the development of use case-specific algorithms and visualizations. Additionally, a unique low-code/no-code approach provides an accelerated study setup, thereby expediting the product market submission process.

The platform is currently live at Top 3 global pharma for over **1,300 studies** and has a user base of **29,000+ users, 30,000 sites, and over 2.5 million subjects** for operational monitoring, analytics, and dynamic site monitoring. With some of the fastest implementation timeframes in the industry, we have helped firms to significantly lower site monitoring costs, increase efficiency, reduce workload, and accelerate time to market.

The TCS Advantage

- **Cross-industry collaboration:** TCS ADD™ hosted a customer-partnered virtual event that provided insights into a data science-led approach to risk-based monitoring in clinical trials. Thought leaders from major global pharma organizations and TCS presented their views on the role played by predictive analytics and artificial intelligence (AI) in dynamic monitoring and oversight of clinical trials.
- **Scalability:** Intelligent seamless pipeline catering to data processing, scaling to handle diverse sources, study volumes, and metrics at scale with optimized resource pooling
- **Flexible:** Companies can implement the platform as a standalone solution on top of the existing solutions or integrate with other TCS solutions for life sciences.
- **Modular:** The platform is highly modular with its components capable of being implemented separately or in combination, mapped to the business requirement.
- **Cross-solution integration:** The platform is modular and interoperable, seamlessly integrating with upstream and downstream systems, and also horizontally with other TCS ADD™ offerings.
- **End-to-end offering:** TCS provides IP-led solutions combined with clinical service capabilities helping life sciences organizations leverage a one-stop destination for serving their business requirements.
- **Technology and domain expertise:** TCS-certified subject matter experts combine the capabilities of clinical research service providers, platform solution providers, and global systems integrators to deliver strategic solutions fulfilling customer requirements.

Awards and accolades:

- TCS ADD™- Four-time winner of the India Pharma awards:
  - 2023 for “Excellence in Ancillary Pharma Services” and “Excellence in the use of technology” awarded to TCS ADD™ Metadata Repository
  - 2022 for “Excellence in Ancillary Pharma Services” awarded to TCS ADD™ Connected Clinical Trials
  - 2021 for “Excellence in Ancillary Pharma Services” awarded to TCS ADD™ Regulatory
  - 2019 for “Excellence in Ancillary Pharma Services” awarded to TCS ADD™ Metadata Repository
- Won the Global Annual AI awards for transforming safety case processing to reduce time and increase throughput for TCS ADD™ Safety at AI Awards 2021
- Won the “best patient facing tech initiative” award for technology excellence in clinical research and drug development for the TCS ADD™ Connected Clinical Trials platform at Citeline Awards 2020
- Won the “European Innovation Awards” for applying a thoughtful approach to solve tough industry problems for the TCS ADD™ Connected Clinical Trials platform at Scope Europe 2019

To know more

Visit the TCS ADD™ Risk-Based Quality Management page on tcs.com

Email: add.platform@tcs.com

About Tata Consultancy Services Ltd (TCS)

Tata Consultancy Services is a purpose-led transformation partner to many of the world’s largest businesses. For more than 50 years, it has been collaborating with clients and communities to build a greater future through innovation and collective knowledge. TCS offers an integrated portfolio of cognitive powered business, technology, and engineering services and solutions. The company’s 469,000 consultants in 46 countries help empower individuals, enterprises, and societies to build on belief.

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