

TCS ADD™



TCS ADD™ Risk Based Quality Management



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TCS ADD™ Risk Based Quality Management Platform

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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 there by accelerating product market submission.

Overview

Clinical trial monitoring has been facing challenges due to the increased complexity of trials. The problem has been compounded by the increasing number of data sources leading to inefficient operational and patient oversight as well as delayed signal detection. Siloed systems, a huge amount of time and effort taken to setting up platforms and onboard studies, lack of required skillsets, and limited AI/ML capabilities are hampering conducting trials efficiently. It has also impacted on 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 labs, safety portal, and others, via a clinical data repository to conduct risk assessments and drive risk based quality management (RBQM). This equips companies with tailored insights, enabling smarter trial decisions.



Modules

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

- **Risk assessment and categorization tool(RACT):** The module categorizes and assesses potential risks associated with any program or protocol. The tool helps to quantify and determine risk categories that become the Key Risk Indicators(KRIs), Key Performance Indicators(KPIs), Quality Tolerance Limits(QTLs) and critical data points (CDP) in downstream monitoring systems.
- **Clinical trial analytics (CTA):** 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 module for reducing monitoring time, efforts and costs by 30%. The internal site overview report (ISOR) delivers a concise yet comprehensive analysis of site performance, enabling clinical research associates (CRAs) and quality assurance teams to efficiently prepare for site visits, audits, and regulatory inspections.
- **Quality tolerance limits (QTL):** To define, configure, and monitor QTLs from a single dashboard, accelerating the process of risk identification and management. The module 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 (SDA):** An advanced and integrated AI/ML-based module 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 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:** We have been consistently partnering with pharma organizations and driving impact through several industry events and joint virtual engagements. As part of this ongoing effort, TCS ADD™ hosted a customer-partnered virtual event that provided insights into a science-led, data-driven approach to risk-based monitoring in clinical trials. Joint whitepaper from leading global pharma companies and TCS shared their perspectives on the role of predictive analytics and artificial intelligence (AI) in enabling dynamic monitoring and effective oversight of clinical trials - [Link](#)
- **Scalability:** Intelligent seamless pipeline catering to data processing, scaling to handle diverse sources, study volumes, and metrics at scale with optimized resource pooling
- **Flexibility:** The platform is modular and interoperable, seamlessly integrating with upstream and downstream systems. Companies can implement the platform as a standalone on top of the existing solutions (both in-house and Third Party) or integrate with other TCS platform 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-platform 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:** Our end-to-end TCS ADD™ Risk Based Quality Management Platform unites RACT, KPI/KRI and QTL configuration modules, powerful analytics, and an integrated workflow into a single ecosystem—delivering real-time risk visibility, optimized monitoring, and data-driven quality oversight from start to finish.
- **Technology and domain expertise:** TCS-certified subject matter experts (SME) combine the capabilities of clinical research service, platform, solution providers, and global systems integrators to deliver strategic solutions fulfilling customer requirements

Awards and accolades:

- TCS named as the second most valuable brand in the “Most Valuable IT Services Brands **2024**” by **Brand Finance**
- TCS Named to World’s Most Admired Companies List 2023 by **FORTUNE® Magazine**
- TCS recognized as a most valuable global brand 2023 by **Kantar Brandz**
- TCS ranked number one for tenth consecutive year in Customer Satisfaction by **Whitelane Research Survey 2023**
- TCS Europe Listed as a 2023 Top Employer by **Top Employers Institute**

TCS ADD™ Awards and Recognition

- TCS ADD™ 7 times winner of **India Pharma Awards**
 - 2024 for “Excellence in Ancillary Pharma Services” awarded to TCS ADD™ Safety and “Excellence in the Use of New Age Technology” awarded to TCS ADD™ Risk Based Quality Management
 - 2023 for “Excellence in Ancillary Pharma Services” and “Excellence in 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 Platform
- Won the Global Annual AI Awards for transforming safety case processing to reduce time and increase throughput for TCS ADD™ Safety platform at Awards. **AI Awards 2021**
- Won the “Best Patient Facing Tech Initiative” award for technology excellence in clinical research & drug development for TCS ADD™ Connected Clinical Trials platform at **Citeline Awards 2020**
- Won the “European Innovation Awards” for applying thoughtful approach to solve tough industry problems for TCS ADD™ Connected Clinical Trials platform at Scope Europe 2019

About TCS ADD™ Platform

TCS ADD™ is a suite of modern and open AI powered suite of life sciences platforms that enables digital ecosystems, simplifies data complexity and provides faster access to new and effective drugs for patients in need. The platform is powered by our proprietary cognitive intelligence engine data driven smart analytics and Internet of Things (IoT) that makes clinical trials more agile and safe. TCS ADD™ leverages the best of cloud architecture and personalized user experience design in compliance with quality guidelines and privacy regulations.

To know more about platform, visit - <https://www.tcs.com/what-we-do/products-platforms/tcs-add/solution/tcs-add-risk-based-quality-management-platform>



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About Tata Consultancy Services Ltd (TCS)

Tata Consultancy Services (TCS) (BSE: 532540, NSE: TCS) is a digital transformation and technology partner of choice for industry-leading organizations worldwide. Since its inception in 1968, TCS has upheld the highest standards of innovation, engineering excellence and customer service.

Rooted in the heritage of the Tata Group, TCS is focused on creating long term value for its clients, its investors, its employees, and the community at large. With a highly skilled workforce of over 607,000 consultants in 55 countries and 180 service delivery centres across the world, the company has been recognized as a top employer in six continents. With the ability to rapidly apply and scale new technologies, the company has built long term partnerships with its clients – helping them emerge as perpetually adaptive enterprises. Many of these relationships have endured into decades and navigated every technology cycle, from mainframes in the 1970s to Artificial Intelligence today.

TCS sponsors 14 of the world’s most prestigious marathons and endurance events, including the TCS New York City Marathon, TCS London Marathon and TCS Sydney Marathon with a focus on promoting health, sustainability, and community empowerment. TCS generated consolidated revenues of US \$30 billion in the fiscal year ended March 31, 2025. For more information, visit www.tcs.com.

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