tcs ADD™

TATA

TCS ADD™ Risk-Based Quality Management

A next-gen, AI-native platform delivering proactive risk management, intelligent decision-making, and scalable cost efficiency.

Intelligent | Interoperable | Scalable | Predictive | End-to-End



The life sciences sector is at a critical inflection point, driven by rapid advancements in medicine and evolving market demands that are unlocking new opportunities. However, fragmented data across disparate systems and formats, coupled with reliance on human-driven insights, continue to slow decision-making and delay the commercialization of new therapies. To overcome these challenges, organizations need a data science-driven platform powered by next-generation AI/ML technologies to enable predictive capabilities and advanced features like Adaptive Monitoring - to drive faster, data-driven decisions and enhance trial efficiency.

TCS ADD™ Risk-Based Quality Management (RBQM) is a ready-to-use SaaS platform that seamlessly integrates data ingestion, risk assessment, centralized monitoring, advanced trial analytics, and quality oversight to deliver end-to-end RBQM - empowering Pharma, MedTech, Diagnostics and CROs to proactively manage risks, enhance quality, ensure compliance, and drive operational efficiency across clinical trials.

Overview

Clinical trial monitoring is increasingly challenged by the growing complexity of studies and the proliferation of data sources. This has led to fragmented oversight, inefficiencies in operations and monitoring, as well as delays in risk signal detection. Siloed systems, prolonged platform setup timelines and study onboarding efforts, lack of specialized skillsets, and limited AI/ML adoption are constraining trial efficiency, resulting in higher costs and compromising quality.

TCS ADD™ RBQM addresses these challenges with a unified, platform that delivers a consolidated view of critical risk insights across assessment, monitoring, and mitigation. The platform combines a comprehensive suite of modular capabilities with out-of-the-box Key Risk Indicators (KRIs) and Key Performance Indicators (KPIs) libraries and intelligent workflows for effective risk identification, evaluation, and communication. The Clinical Data Repository plug-in option offers scalable data models and leveraged advance analytics to ingest and harmonize data from multiple sources, including Electronic Data Capture (EDC), Interactive Web Response Systems (IWRS), Interactive Response Technology (IRT), Clinical Trial Management System (CTMS), Labs, electronic Trial Master File (eTMF), Safety systems, Real-World Data (RWD) etc., as well as devices and instruments specific data streams relevant to MedTech and Diagnostics organizations. This delivers robust, data-driven risk assessment and end-to-end RBQM execution, empowering organizations with actionable, context-specific insights to make faster, smarter decisions and drive superior clinical and operational outcomes.



Modules

The key components of TCS ADD™ RBQM platform are as follows:

Risk Assessment and Categorization Tool (RACT)

The RACT provides a systematic, AI-assisted framework to identify, assess, and categorize risks across programs and protocols. It enables quantification, prioritization, and classification of risks, translating them into actionable monitoring constructs such as KRIs, KPIs, Quality Tolerance Limits (QTLs), and Critical Data Points (CDPs) that drive downstream RBQM processes.

By combining structured risk methodologies with intelligent analytics, RACT ensures:

- **Standardized risk identification and scoring** aligned with study objectives and regulatory expectations.
- **Traceability from protocol design to monitoring strategy,** ensuring consistency across the RBQM lifecycle.
- **Dynamic risk categorization,** enabling continuous refinement based on evolving study data.
- **Seamless integration with centralized monitoring,** supporting proactive, data-driven decision-making.

Clinical Trial Analytics (CTA)

Clinical Trial Analytics is a multi-layered, AI-powered analytics engine that delivers operational and clinical insights across studies, sites, countries, regions, programs, and therapeutic areas. It provides configurable KRIs, KPIs, advanced statistical models, and AI models to continuously evaluate site performance through dynamic risk and performance scoring.

By combining predictive, prescriptive, and GenAI-driven analytics, CTA enables:

- **Real-time risk and performance visibility** across sites, studies, regions, and portfolios through intuitive dashboards
- **Dynamic monitoring and predictive insights,** including site profiling, workload forecasting, and early risk detection using statistical and AI/ML models
- **Prescriptive analytics and GenAI-powered recommendations** for proactive intervention
- **Drill-down and roll-up capabilities** for detailed analysis and enterprise-level oversight through configurable reports

The **Internal Site Overview Report (ISOR)** provides CRAs and quality teams with a concise yet comprehensive view of site performance to support site visits, audits and regulatory inspections.

Quality Tolerance Limits (QTLs)

The QTL module provides a unified, intelligent framework to define, configure, monitor, and manage Quality Tolerance Limits across clinical and operational domains. It enables centralized oversight of critical-to-quality factors through a configurable library of pre-defined QTLs, aligned to study objectives and regulatory expectations.

The module supports end-to-end QTL lifecycle management through:

- **Centralized configuration and monitoring** from a single, intuitive dashboard
- **Pre-built and configurable QTL frameworks** for rapid setup and standardization
- **Automated monitoring and threshold management,** against approved quality limits
- **Workflow-driven alerts and notifications** for QTL breaches
- **Integrated mitigation and tracking mechanisms** with full traceability and audit readiness
- **Comprehensive reporting and analytics,** supporting quality reviews and regulatory submissions

By embedding automation and intelligence into QTL management, the module accelerates risk identification, enhances data quality, and strengthens proactive compliance.

Subject Data Analytics (SDA)

The SDA module is an advanced AI/ML-driven capability designed for continuous patient-level monitoring across clinical trials. It provides deep visibility into subject data by integrating clinical, operational, and safety parameters to support timely, informed decision-making.

The module enables comprehensive patient-centric analytics through:

- **Dynamic patient profiling and risk scoring** using AI/ML models
- **Advanced outlier detection** to identify disparities and potential safety or data integrity concerns
- **Real-time alerts and notifications** for emerging safety risks and trends
- **Trend analysis across subjects and cohorts** to support proactive intervention
- **Integrated clinical insights** by combining multiple data sources into a holistic view of patient health and study progression

By embedding intelligence at the subject level, SDA helps detect risks earlier, improve patient safety, strengthen data quality, and enable proactive clinical trial oversight.

Additionally, sponsors can subscribe to the **TCS ADD™ Clinical Data Repository (CDR),** which provides a unified, interoperable, and harmonized common data model for clinical, operational, scientific, and RWD. Powered by AI/ML-driven **SMART ingestion** and a multi-layer data architecture, it supports data ingestion from **20+ sources,** including EDC, IWRS/IRT, CTMS, labs, MDM, eTMF, eConsent, eCOA/ePRO, Safety and Regulatory systems, RWD/RWE, laboratory and biomarker systems, sample tracking systems, devices, instruments, claims, and Electronic Health Record (EHR) systems.



Benefits

The TCS ADD™ RBQM Platform offers the following benefits:



Reduced Workload & Operational Efficiency

Shifts monitoring from manual, resource-intensive processes to targeted, risk-based oversight. Automates workflows, alerts, reporting, and monitoring activities while reducing reliance on traditional SDV/SDR. Focused oversight of high-risk sites and subjects boosts productivity and cuts operational costs.



Proactive Risk Detection & Early Intervention

Leverages AI/ML-driven analytics to continuously identify risks across sites, studies, therapeutic areas, and patient populations. Supports early detection of protocol deviations, quality concerns, and safety risks, enabling timely intervention and proactive monitoring across complex clinical environments.



Improved Data Quality & Oversight

Enhances data integrity through early detection of duplicate, inconsistent, and missing data. Combines KRIs, QTLs, and advanced statistical models to identify trends, anomalies, and emerging risk signals, ensuring reliable and inspection-ready data.



Enhanced Patient Safety

Provides patient-level analytics for risk stratification, trend analysis, and near real-time safety monitoring. Detects outliers and emerging safety signals early, enabling proactive intervention and improved patient safety outcomes.



Regulatory Compliance & Audit Readiness

Provides end-to-end traceability across risk identification, monitoring, and mitigation activities. Supports compliance with ICH E6(R3), TransCelerate, IVDR, and ISO 13485 requirements while generating audit-ready reports and documentation.



Accelerated Study Execution & Time-to-Market

Enables rapid study setup through a low-code/no-code framework and automated data ingestion from diverse clinical data sources. Accelerates analytics generation, study execution, and product submissions.



End-to-End Lifecycle Visibility

Provides real-time visibility across study, program, and enterprise levels through unified dashboards and monitoring capabilities. Supports lifecycle oversight from feasibility and study setup through post-market surveillance, enabling data-driven governance and strategic decision-making.



Scalable Enterprise Adoption

Supports scaling from individual studies to global portfolios and multi-program deployments. Harmonizes RBQM processes, enabling standardized execution and enterprise-wide RBQM transformation.



AI-Driven Clinical & Operational Intelligence

Combines GenAI-powered insights and predictive analytics to deliver deeper visibility into risks, trends, and operational performance. Supports continuous optimization of monitoring strategies and enables smarter, faster, data-driven decision-making across clinical operations.

The platform has been deployed across **4,000+ studies,** supporting more than **29,000 users, 30,000 sites, and 2.5 million** subjects for operational monitoring, advanced analytics, and dynamic site oversight. With some of the **fastest implementation timelines in the industry,** the platform has helped organizations reduce monitoring costs, enhance operational efficiency, minimize workload, and accelerate time-to-market for clinical and diagnostic programs.

The TCS Advantage

TCS ADD™ is a strategic Products & Platforms business unit of Tata Consultancy Services (TCS), focused on delivering **innovation-led, IP-driven solutions** for the Life Sciences and Healthcare industry.
Designed to address the growing complexity across clinical research & development, TCS ADD™ combines **advanced digital technologies, domain expertise, and proprietary platforms** to transform how organizations plan, execute, monitor, and optimize clinical trials.

Strategic Industry Collaboration

TCS partners with leading **Pharma, Diagnostics (IVD), MedTech organizations, and CROs** to drive innovation.

- Active participation in global industry forums and collaborative ecosystems
- Joint engagements with clients through workshops, virtual sessions, and co-innovation initiatives
- Thought leadership (e.g., industry publications) on AI-driven RBQM and predictive monitoring

Enables clients to adopt industry-aligned, future-ready RBQM strategies

Patented Technology & Innovation

TCS ADD™ Risk-Based Quality Management leverages **patented technologies and proprietary accelerators** to deliver differentiated capabilities across risk assessment, analytics, and monitoring.

- Embedded innovation across AI/ML models, analytics frameworks, and automation layers
- Accelerators supporting faster implementation, standardized workflows, and performance
- Continuous investment in R&D to drive next-generation RBQM capabilities

Delivers sustained innovation and competitive differentiation

Enterprise Scalable & High-Performance Architecture

The platform is built on an intelligent, seamless data foundation designed for enterprise-scale performance.

- Processes high volumes of data across diverse clinical, lab, and device sources
- Supports multi-study, multi-program, and global portfolio deployments
- Optimizes resource utilization through efficient scaling mechanisms

Delivers consistent performance at enterprise scale

Flexible & Interoperable Integration

The platform seamlessly integrates into existing clinical and data ecosystems.

- Interoperates with upstream and downstream systems (EDC, CTMS, labs, imaging, devices)
- Integrates horizontally across analytics, monitoring, and reporting layers
- Enables unified data flow and consistent RBQM execution

Provides future-ready flexibility with minimal disruption to existing investments

Modular & Configurable Design

Built for adaptability across diverse study and business requirements.

- Components can be implemented independently or as part of an integrated solution
- Configurable to align with different study designs, therapeutic areas, and regulatory frameworks
- Supports phased deployment for faster value realization

Ensures fit-for-purpose and scalable adoption

Flexible Support Model

Backed by a comprehensive and scalable support framework tailored to global clinical programs.

- Structured L1/L2/L3 support model ensuring rapid issue resolution
- Combination of platform support, RBQM domain expertise, and managed services
- Global delivery model and scalable support aligned to study complexity, volume, and geography

Ensures reliable operations, faster turnaround, and reduced operational risk

Technology & Domain Expertise

TCS combines deep industry expertise with strong technology and integration capabilities.

- Certified SMEs across clinical research, quality, data, and analytics domains
- Integrated capabilities spanning clinical services, platforms, and global systems integration
- Proven track record in delivering large-scale RBQM transformations

Enables trusted execution and domain-driven innovation

Awards and accolades:

- TCS named as the second most valuable brand in the “Most Valuable IT Services Brands 2026” by Brand Finance
- TCS named to World’s Most Admired Companies List 2023, 2024, 2025 & 2026 by FORTUNE® Magazine
- TCS recognized as One of the World’s Top 50 Brands in 2025 by Kantar BrandZ
- TCS listed as a 2026 top employer in Europe for the 14th Consecutive Year by the Top Employers Institute

TCS ADD™ Awards and Recognition

Seven-Time Winner of Indian 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 platform**
- 2019 for “Excellence in Ancillary Pharma Services” awarded to **TCS ADD™ Metadata Repository**

TCS ADD™ Safety won the "Best Technical Implementation for AI" award at the **2021 Global Annual Achievement Awards** for Artificial Intelligence for its transformative impact on safety case processing in pharmacovigilance

TCS ADD™ Connected Clinical Trials won the “Best Patient Facing Tech Initiative” award at the **Citeline Awards 2020** for technology excellence in clinical research & drug development

TCS ADD™ Connected Clinical Trials won the “European Innovation Awards” for applying thoughtful approach to solve tough industry problems at **Scope Europe 2019**

About TCS ADD™ Platform

TCS ADD™ is a next-gen suite of AI-driven platforms enabling digital ecosystems, simplifying data complexity, and accelerating access to new and effective medicines and therapies. Built on a secure, scalable cloud foundation and powered by a proprietary cognitive intelligence engine, advanced analytics, and agentic capabilities, it makes clinical trials and regulatory compliance more agile, intelligent, and safe. TCS ADD™ AgentHub introduces configurable autonomy and human-centric design to the suite, with purpose-built AI agents across the most critical and high-trust industry domains.

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About Tata Consultancy Services Ltd (TCS)

Tata Consultancy Services (BSE: 532540, NSE: TCS) is the 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.

It has set an aspiration to become the world's largest AI-led technology services company and is enabling its clients to transform themselves across the full AI stack, from infrastructure to intelligence.

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 spread across 56 countries and 194 service delivery centers 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, Tata Mumbai Marathon and TCS Sydney Marathon with a focus on promoting health, sustainability, and community empowerment.
TCS generated consolidated revenues of over US $30 billion in the fiscal year ended March 31, 2026. For more information, visit www.tcs.com

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