Integrated Centralized Monitoring Platform
Life Sciences & Healthcare

Awards & Recognition

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The pharmaceutical industry is facing challenges in adopting RBM due to a dearth of trained manpower to centrally monitor clinical trials and assess risks based on data-driven insights. Replacing conventional 100% SDV-based monitoring techniques with RBM will require effective enterprise-wide change management to harness resulting synergies.

TCS’ ICM Platform includes comprehensive risk management framework, signal detections algorithms, and the monitoring solution which help pharmaceutical enterprises to optimize their time to market and ensure data quality, patient safety, and trial trustworthiness. Quality by design (QbD) and quality risk management (QRM) approaches have been extensively leveraged in development our ICM Platform which include components to identify and communicate study/program risks, identification of outlier sites for triggered monitoring through the Key Risk Indicator (KRI) module, integrated data warehouse, data analytics and visualizations for data-driven decision-making and tracking study performance efficiently.

Our Solution

TCS’ ICM Platform consist of the following key components:

- **TCS RACT Tool:** An online risk assessment tool based on TransCelerate’s guidance for categorizing study and program level risks.
- **Integrated data warehouse:** Standardizes and consolidates clinical data from varied data sources including eDC, CTMS, Labs, IXRS and ePRO in accordance with industry standards.
- **KRI module:** Tracks KPIs to monitor trial site performance and outliers with workflows to connect various study team stakeholder groups on monitoring plans and allow triggered onsite monitoring.
- **Central data review:** Includes patient profile reviews to ensure risks mitigated at the subject level by review of subject data across key parameters including eligibility, safety, and endpoints. This module is configurable to allow study owner set KRI and/or threshold for the study.
- **Analytics and insights:** Uses statistical models including predictive analytics for trend identification and signal detection. TCS supports customized KRI and analytics reports using the QbD approach.

Benefits

With TCS’ ICM Platform, pharmaceutical and bio-pharmaceutical companies can reap the following benefits:

- **Minimized Drug Trial Costs:** Reduce site monitoring visits with centralized, remote monitoring, leading to 15% to 20% savings in trial costs.
- **Increased Patient Safety:** Through improvement in signal detection and quality of clinical trial data.
- **Faster Time to Market and Enhanced Data Quality:** Superior data quality, query resolution time and minimized query rate using robust technology and associated service offerings.
- **Enhanced Decision Making:** Take informed decisions by accurately identifying data patterns to derive risk scores for proactive risk management. TCS enables visualizations to review trends and patterns across the KRI and drill down options to mine data and review trends across study, geography, country, site and patient level.
- **Regulatory Compliance:** Comply with strict regulatory standards with high-quality clinical trial reporting.

The TCS Advantage

By partnering with TCS, enterprises can leverage the following differentiators:

- **Domain Expertise:** TCS has proven expertise in designing and implementing solutions for accelerating and streamlining clinical trials. We have a deep understanding of RBM methodologies and centralized monitoring operations needed for overhauling existing monitoring system. Our subject matter experts, project managers, central and remote monitors, data managers, medical data reviewers, statisticians, and programmers work with 13 of the top 15 global pharmaceutical companies.
- **ValueBPS™ Offering:** Employing robotic process automation (RPA), advanced data analytics, effective business process management and novel business process as-a-service (BPaaS) models, we help our clients achieve sustainable business results. Our maturity assessment and transformation model, FORE™, along with the tightly integrated IT and business process services (BPS) functions, assist enterprises to outdo competition and realize profitable growth.
- **Proven Platforms:** Our solution helps the pharmaceutical companies shift their focus from managing IT operations to core business services, with a reduction in cost and oversight. TCS offers a single application to view and act on monitoring results. It defines various user roles and provides the ability to view and interact with study dashboards.
The pharmaceutical industry is facing challenges in adopting RBM due to absence of industry benchmarks for implementation and the availability of several solution alternatives in the market. Moreover, there is a dearth of trained manpower to centrally monitor clinical trials and assess risks based on data generated insights. Replacing conventional 100% SDV-based monitoring techniques with RBM will require effective enterprise-wide change management to harness resulting synergies.

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**Overview**

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