

Drug Development Insights Platform

Life Sciences & Healthcare



Changing regulatory standards and growing service delivery expectations are driving pharmaceutical companies to adopt advanced data management strategies. Data standardization and collection, and enhanced reporting controls are now vital to gain an integrated view of data trends. However, information silos emerge in these organizations as they look to leverage next-generation technology tools for increased responsiveness. The demands from digitally-aware patients, medical investigators, and other relevant stakeholders for real-time information updates have also increased. Therefore, relevant data insights during clinical trials can offer a proactive approach to drug development and help in timely risk monitoring.

Tata Consultancy Services' (TCS') Drug Development Insights Platform offers the capability to aggregate clinical data from a range of structured and unstructured data repositories. This information is standardized, integrated, and fed into a centralized clinical data repository to check for regulations compliance, and to conduct cross-study analytics, and value-evidence programs.

Overview

To accelerate performance in a competitive market, pharmaceutical organizations require access to timely and relevant clinical data. The absence of real-time information and insights makes it difficult to monitor the number of patient dropouts or understand whether the trial is compliant with evolving regulations. It is also increasingly challenging to conduct course-corrections during the clinical trial process. This in turn increases rework and iterations across the development cycle and causes delays that negatively impact the decision-making process. With the inability to integrate data streams from myriad devices, patient diaries, and electronic Clinical Outcome Assessment (eCOA) solutions, pharmaceutical organizations may overlook business enhancing insights. Challenges emerging from manual clinical development processes have highlighted the need for a scalable technology platform that can address emerging issues.

TCS' Drug Development Insights Platform offers a single centralized data repository that caters to users throughout clinical operations and post-authorization processes, involving biostatisticians, medical writers, and regulatory teams. The study data can also be leveraged across several functions such as Clinical Data Management, Research and Development (R&D), Medical Affairs, and non-interventional studies, enabling detailed and faster responses to regulatory authorities. TCS' clinical data warehouse is based on industry-specific standards such as Study Data Tabulation Model (SDTM) and Biomedical Research Integrated Domain Group (BRIDG), and can be easily connected to a host of source systems.

Our Solution

The platform aggregates, ingests and analyzes clinical data from operational systems and provides risk-based monitoring, site selection analytics, patient recruitment and retention analytics, and study performance analytics. Key features include:

Configurable workflows: Covers comprehensive risk assessment and categorization, centralized monitoring and issue management processes

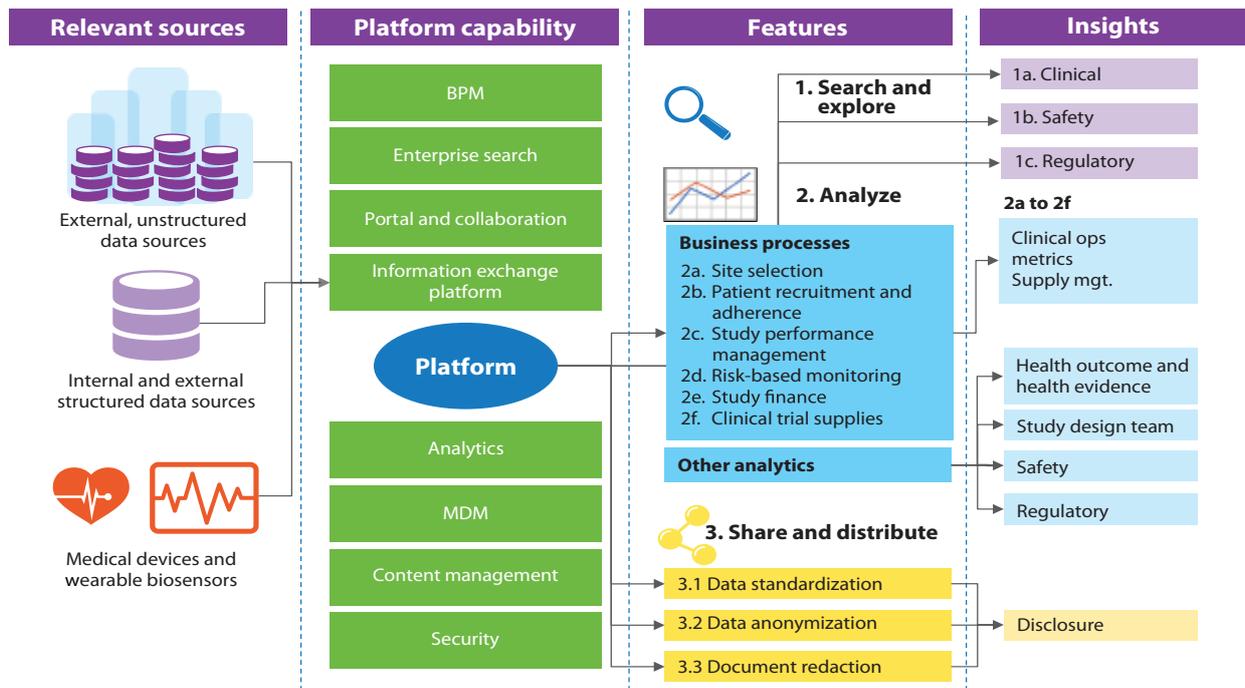
Integrated data browser: Enables the search and exploration of data across its lifecycle and the flexibility to plug in a variety of visualization tools to view information from the clinical data warehouse

Service-based model: Provides insights through a Business Process as a Service (BPaaS) model pertaining to clinical data management, risk-based monitoring, biostatistics, and clinical operations

Unified data processing: Allows data from local and central labs, CROs, patient diaries, EDC systems, medical devices and other data sources to be integrated and validated seamlessly with a metadata-driven approach

Advanced and predictive analytics: Uses statistically defined algorithms with univariate and multivariate statistical models to identify problematic sites, study level and site level risk scores

An Overview of TCS Drug Development Insights Platform



Benefits

TCS' Drug Development Insights Platform helps enterprises reimagine their existing clinical data processes and enables the pharmaceutical industry to achieve their business objective of bringing medicines faster to patients. The solution accelerates and improves clinical data management and analytics, while a metadata-driven approach addresses non-standardized data and exceptions in data range and type. This enables robust data validation and quality assurance, while reducing overall programming and on-boarding efforts. By adopting the offering, enterprises can:

Ensure rapid study setup and execution by leveraging metadata capabilities in all stages of clinical development

Address scientific and operational analytical needs across units by establishing an accessible, comprehensive and definitive data source, and by implementing a robust data-tracking mechanism across key processes and systems

Effectively utilize resources and minimize human intervention in data management and operational processes, by automating and streamlining the flow of clinical information

Reuse and reduce hand-offs by driving collaboration across units, building a comprehensive knowledge repository, and through established standards

Ensure prompt action on regulatory queries by generating submission-ready outputs

Drive informed decisions by leveraging actionable business insights from clinical data, to ensure product quality and meet regulatory requirements

The TCS Advantage

The platform helps enterprises gain both business agility and deliver innovative products and services. We deliver tangible results through:

A flexible and scalable approach: TCS provides information on demand through significant expertise in delivering accurate, 'analytics-ready' data. The comprehensive set of out-of-box, ready-to-use features drives data integration, aggregation, and analytics

Reinforced data protection: The validated and externally-hosted solution incorporates stringent security measures, and is up-to-date with the changing compliance and regulatory requirements of the pharmaceutical industry

Domain experience and relevant technology expertise: TCS' combines its extensive capabilities as a clinical research services provider, platform solution provider, and global systems integrator to deliver strategic solutions fulfilling various customer requirements

Analyst recognition: TCS was designated as a Leader in Worldwide Life Sciences R&D Risk-Based Monitoring by global market intelligence firm, IDC, in the "IDC MarketScape: Worldwide Life Science R&D Risk-Based Monitoring 2015 Vendor Assessment," (April 2015) report. TCS was recognized as a leader for its overall capability and extensive experience working with life science companies across all three sections of the industry: pharmaceutical, biotech and medical devices

Awards & Recognitions



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