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Metadata Registry and Transformation Platform

Life Sciences & Healthcare

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In order to reduce the time-to-market for new drugs, life sciences organizations are looking to optimize their research and development (R&D) operations. Streamlining clinical trials and drug approval processes continues to be a key imperative for pharmaceutical companies, which are expected to adhere to stringent norms while submitting test results. Consequently, these firms are adopting robust clinical metadata management practices to achieve test data standardization, with a view to boosting operational efficiency and ensuring regulatory compliance.

Tata Consultancy Services' (TCS') Metadata Registry and Transformation (MRT) Platform provides life sciences enterprises a robust framework to effectively manage clinical metadata. The offering helps integrate and validate raw clinical data coming from diverse sources, and enables easy conversion of the information into standard formats. With the standardized information, pharma and contract research organizations (CROs) can eliminate data inconsistencies across R&D processes, thus reducing the time taken to submit drug approval applications.

Overview

Pharma and biotechnology enterprises operate in a dynamic regulatory environment, and are expected to submit clinical trial data as per standards set by bodies like the Clinical Data Interchange Standards Consortium (CDISC). Clinical studies are conducted by a multitude of research entities using a varied range of setups, spanning multiple geographies and involving different languages. This heterogeneity creates tremendous scope for varied data formats, resulting in delayed study on-boarding and potentially leading to interoperability issues. Mergers and acquisitions in the life sciences industry pose yet another challenge to data standardization, as different sponsors often follow varied information formats.

TCS' Metadata Registry and Transformation Platform extracts data from a variety of structured and unstructured data sources and ensures cost-effective storage, governance, validation, and conversion of clinical information to CDISC formats. The solution's metadata registry (MDR) module helps users set up project-specific metadata through an intuitive graphic user interface (GUI). The SAS-based clinical data transformation (CDT) component of the offering converts trial-related information to CDISC or sponsor-specific data standards. The solution stores all metadata in a central registry, and automatically maps new study metadata with the existing database. The MRT platform expedites clinical metadata setup, leading to faster study on-boarding, and enables CROs to conduct several studies in parallel.

Our Solution

The solution is fully compliant with 21 CFR Part 11, and is hosted on a regulatory compliant, TCS-owned data center. Key features of the platform include:

Workflow management: Automates workflows for creating new data standards or maintaining existing ones

Automated study setup: Automatically maps new study metadata with the central library, ensuring timely availability of data to new users; communicates directly with electronic data capture (EDC) to set up studies

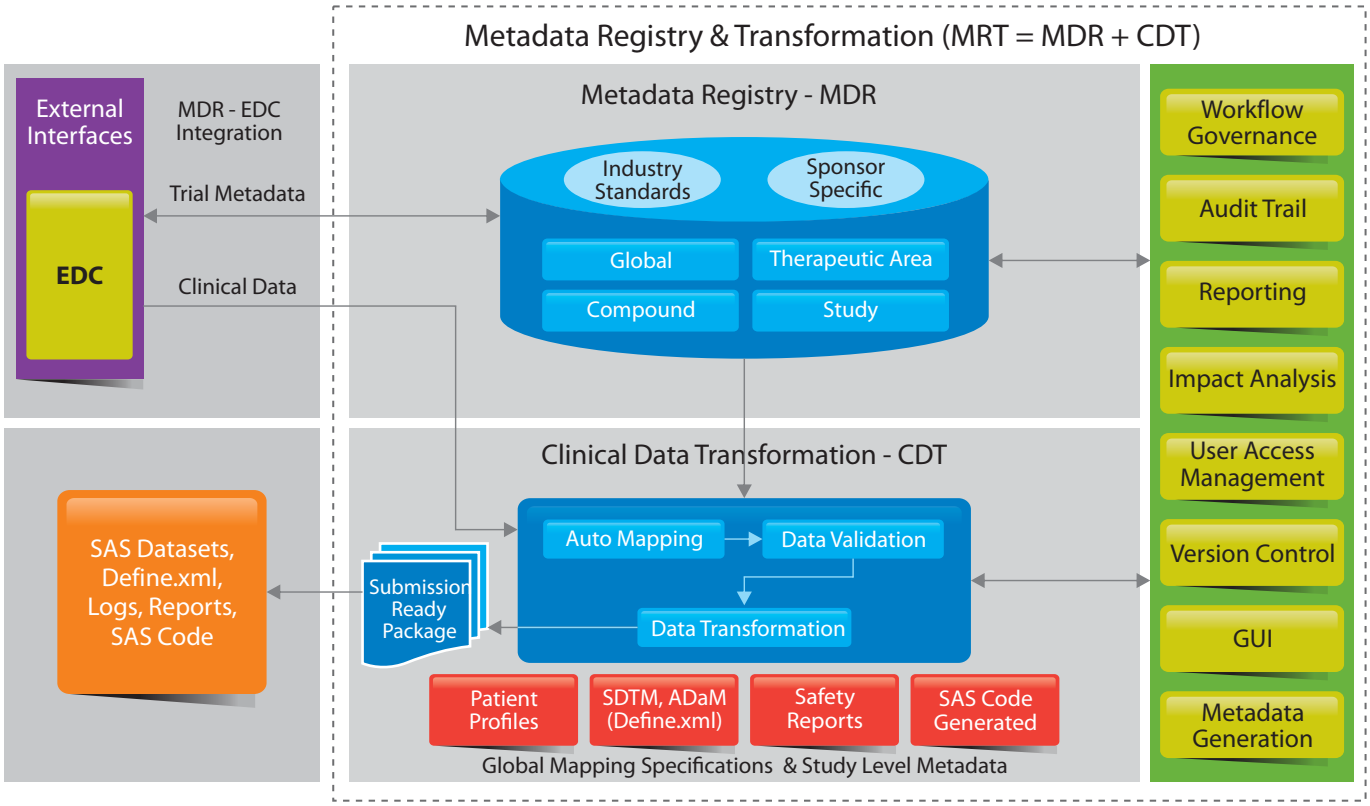
Parallel execution: Enables parallel execution of multiple studies

Reports and dashboards: Provides standard dashboards at various levels as well as the flexibility to define customized reports based on user preference; tracks any addition, deletion, or change in each object by maintaining an audit trail

Web Services: Provides web services for data exchange

Impact Analysis: Provides change impact analysis in user friendly and intuitive dendrogram

User management: Assigns roles and access privileges to users based on business needs



Benefits

With TCS' Metadata Registry and Transformation Platform, pharma companies and CROs can reap the following benefits:

Accelerated drug launches: Reduce the time-to-market for new products by gaining faster drug approvals; convert raw data to standard formats to streamline clinical trials

Regulatory compliance: Adhere to stringent data related norms stipulated by standard setters and other regulatory authorities

Optimized R&D operations: Minimize human intervention in data handling; enable maximum reutilization of existing metadata and data assets; enhance patient recruitment processes by analyzing past data and control associated costs

Enhanced business agility: Retain critical information that could be leveraged in future clinical studies; define data by various industry level standards to catalyze reuse in other projects; leverage flexible data models to accommodate various standards for data collected using multiple devices

The TCS Advantage

By partnering with TCS, organizations can take advantage of the following differentiators:

Agile approach: The solution comprises ready-made data integration and standardization capabilities which help users perform data operations on-demand

Focus on reusability: TCS' macro-based platform comes with an exhaustive library of derivations and validations conforming to CDISC regulations. Data can be auto-mapped to on-going or concluded clinical studies and users can also create copies of data or metadata from existing projects

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Awards & Recognition

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About Tata Consultancy Services Ltd (TCS)

Tata Consultancy Services is an IT services, consulting and business solutions organization that delivers real results to global business, ensuring a level of certainty no other firm can match. TCS offers a consulting-led, integrated portfolio of IT and IT-enabled infrastructure, engineering and assurance services. This is delivered through its unique Global Network Delivery Model™, recognized as the benchmark of excellence in software development. A part of the Tata Group, India's largest industrial conglomerate, TCS has a global footprint and is listed on the National Stock Exchange and Bombay Stock Exchange in India.

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