tcs ADD™

TATA

TCS ADD™ Metadata Repository

A next generation, inter-operable, end-to-end metadata management platform

Simple | Modular | Scalable | Flexible | Future-Fit

Life sciences industry routinely faces inconsistencies and challenges in managing diverse data standards and output templates, leading to process inefficiencies. Through the entire study build process — protocol, data collection, and analysis — life sciences industry has to deal with non-standard data. In addition, manual programming and disjointed downstream processing adds to the process time for study data tabulation models (SDTM). The aim, thus, is to build an all in one automated and integrated metadata-driven Platform that is easy to configure and provides compliance to industry clinical and regulatory standards.

The vision of TCS ADD™ is to enable digital data flow by automating all deliverables from protocol and data collection to submission.

TCS ADD™ Metadata Repository a ready-to-use SaaS-based Platform for Easy Onboarding of Standards, Robust Standards Management & Governance. The industry leading metadata driven AI solution with Connected Metadata that automates study build, enables robust governance through cross-departmental data lineage and rapidly transforms and generates submission-ready datasets for SDTM, and ADaM are collected data. Its metadata harmonization provides automated study build and transformation into submission-ready formats, enabling faster study set-up, increased quality, and compliance. In addition, the macro-based solution includes a comprehensive library of derivations and validations compliant with regulations like CDISC. The platform leverages intuitive mappings, real-time data availability and impact analysis, enabling digital data flow across the clinical value chain by leveraging standards and artificial intelligence (AI).

Overview

The challenges for life sciences industry start at the study level, with limited business and scientific content management across different products and therapeutic areas. Organizations seek an automated, integrated and controlled environment for assured standards compliance. The current process limits integration and usage of data from diverse sources, and historical and legacy data, leading to reduced statistical power and reliability. Further, the absence of a governance model for handling and maintaining ever evolving standards and its versions hamper cross-departmental data lineage and oversight. Converting data to a submission-ready format is yet another challenge with disjointed downstream processing increasing SDTM processing time. It leads to delay in ADaM dataset creation process due to often dependency on SDTM datasets.

Traceability back to raw data or SDTM dataset for ADaM datasets variables is always a crucial task, and maintaining this traceability can be challenging.

TCS ADD™ Metadata Repository provides an out-of-the-box next-gen platform to manage clinical standards for industry and sponsors. It automates the entire study build process while providing robust governance throughout the cycle. The platform comprises of a clinical study design workbench with automated data transfer agreements, automated study build capabilities, and the ability to generate submission ready SDTM data and packages. The platform offers a controlled environment for biometrics and provisions-integrated metadata management for any type of data including CDASH, SDTM, ADaM. non-CRF and ARS etc., This facilitates real-time availability of metadata for downstream processing.

Who we are?

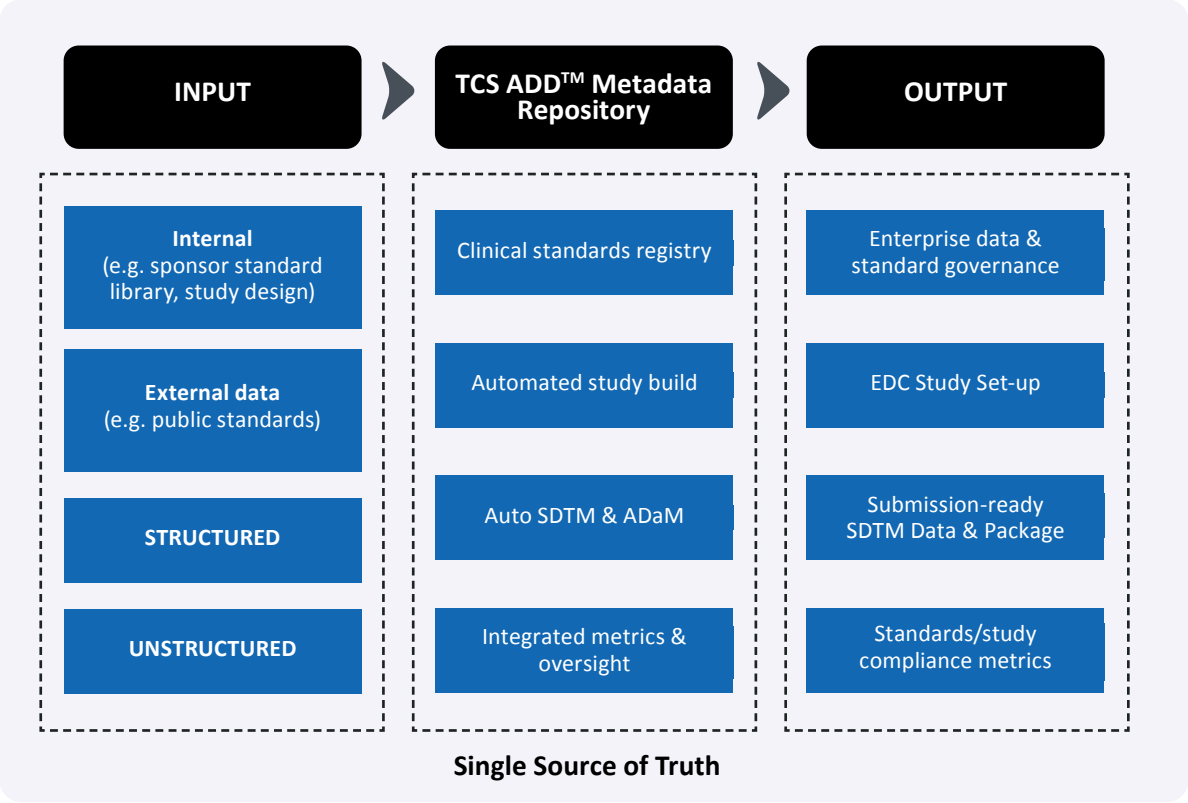
TCS ADD™ Metadata Repository Platform is a ready to use, interoperable metadata Platform that automates study build, provides robust governance and enables cross- departmental data lineage. The platform facilitates effortless configuration, 100% compliance to CDISC standards and integrates with market-leading EDCs.

Our solution

- **Clinical standards registry:** Scalable Metadata Repository for multiple standards and templates, including source collection EDC (Electronic data capture) and non-EDC (Electronic data capture), SDTM (Study Data Tabulation Model), and ADaM (Analyst Data Model) and ARS (Analysis Results Standards).
- **Automated study build:** Automated study design based on standards and templates via bidirectional integration to the EDC system. Bidirectional integration also allows users to compare metadata set up in MDR and EDC.
- **SDTM, ADaM & ARDS Transformation Metadata Registry:** Automated creation and downstream setup of transformation metadata for newer source collections leverage cognitive technologies like AI/ML to deliver efficiency and accuracy. This process includes seamless API integration, extracting transformation metadata based on standards, identifying target structures, and leveraging AI-driven mapping to predict transformation metadata for new source databases.

  The automation extends to study setup, enabling the creation of ready-to-use SDTM metadata and facilitating ADaM transformation based on study analysis requirements using standard libraries. It also encompasses the setup of domain/dataset metadata and transformation metadata for both SDTM and ADaM.

  By incorporating these advanced automations, we streamline metadata management, minimize errors, and accelerate the analysis submission process.
- **Integrated Metrics & Oversight:** Interconnected CRF, SDTM, ADaM, and ARS data models across the entire study lifecycle. Visualizing the relationships between different data elements like CRF to SDTM linkage, showing how they interact and depend on each other.



TCS ADD™ Metadata Repository Platform: Schematic Overview

Benefits

TCS ADD™ Metadata Repository offers the following benefits:

- **Customer Technology Landscape:**
  - **Technology Simplification** – Reduction in redundant tools, leading to a 20-30% decrease in IT maintenance costs.
  - **Data Reusability** – Standardized and reusable metadata across studies, improving operational efficiency by 40%.
  - **Process Automation** – Eliminated manual metadata governance, reducing FTE effort by 25-30%.
  - **Scalability & Future Readiness** – Enabled AI/ML-based metadata recommendations for futuristic clinical trials.
  - **Migration from SAS to R** – The platform act as a key enabler

- **Increased efficiency & reduced workload:**
  - **Standardization & Reusability** – Metadata is now centrally managed, reducing duplication and improving consistency.
  - **Robust Governance** – Change management is now centrally controlled study level request changes to standards.
  - **End-to-End Automation** – Eliminated manual data transformation and validation, reducing effort by 30-40%.
  - **Proactive Compliance** – Regulatory checks integrated early in the process, reducing rework and submission delays
  - **Faster Decision-Making** – Real-time metadata access enables quicker study design approvals and execution.
  - **Operational Efficiency** -
    - Real time global library sync and auto study build.
    - Industry leading SDTM efficiency matrix requires only 6 person-days (2 Developers, 3 Days) per study, significantly surpassing the industry average by a huge margin
- **People and Organizations:**
  - **Empowered Teams & Reduced Silos** – Unified access to metadata fosters better collaboration across clinical, regulatory, and IT teams.
  - **Skill Transformation & Upskilling** – Employees shift focus from manual tasks to strategic roles like analytics, AI-driven insights, and compliance strategy.
  - **Robust Governance** – Change management is now centrally controlled with covering both data collection as well as analysis standards.
  - **Faster Onboarding & Knowledge Retentions** – Automated workflows reduce training time, ensuring new employees are productive faster.
  - **Reduced SME Overload** – AI-driven recommendations allow teams to self-serve metadata, freeing SMEs for high-value advisory roles.
  - **Greater Organizational Agility** – Faster metadata management and study setup enable the organization to scale clinical trials efficiently.
- **Improved data quality & oversight:**
  - Enhanced Quality of Standards
  - With a central repository metadata (Such as variable names and derivations) can be reused across multiple studies, significantly reducing the time and effort needed for ADaM dataset creation

- Increased compliance with industry and sponsor standards
- Easy accessible audit trail across all activities
- Cross-depth metadata lineage oversight
- The integration of Standard and AI-driven mapping significantly decreases SDTM efforts at the study level
- Instantaneous SDTM availability as soon as RAW data arrives

TCS ADD™ Metadata Repository platform advantage

- **Agile approach:** Ready-to-use data integration and standardization helps users perform data operations on demand. Our platform allows quick and hassle-free onboarding of CDISC-compliant SDTM and NCI-controlled terminology metadata.
- **Focus on reusability:** Our platform offers an exhaustive library of derivations and validations conforming to CDISC regulations. Data can be auto-mapped to ongoing or concluded clinical studies, and users can create copies of data or metadata from existing projects and the global library. Transmission mapping can be reused and auto-mapped based on study metadata.
- **Scalability, Flexibility:** Our platform can be scaled to any level based on the business need and can be implemented as a standalone solution or on top of existing solutions.
- **Supplementary services:** The platform extends Standards Governance Advisory (SGA) services for customers in need along with supporting SDTM compliant deliverables through its services capabilities and dedicated implementation team.
- **Technology and domain expertise:** TCS-certified subject matter experts combine our extensive capabilities as clinical research services provider, platform solution provider and global systems integrator to deliver strategic solutions.

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 & 2024 by **FORTUNE® Magazine**
- TCS recognized & retained its no 1 spot as a most valuable global brand 2024 by **Kantar Brandz**
- TCS ranked number one for tenth consecutive year in Customer Satisfaction by **Whitelane Research Survey 2024**
- TCS Europe Listed as a 2024 top employer for the ninth consecutive year 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 modern and open drug development platform for life sciences 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

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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 15 of the world's most prestigious marathons and endurance events, including 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 $29 billion in the fiscal year ended March 31, 2024.

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