

tcs ADD™



# TCS ADD™ Metadata Repository

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

Simple | Modular | Scalable | Flexible | Future-fit







The life sciences industry faces persistent challenges in managing diverse data standards and templates, often resulting in inefficiencies, delayed submissions, and increased costs. Manual programming, non-standard data, and disjointed downstream processing slows the generation of Study Data Tabulation Model (SDTM), Analysis Data Model (ADaM), and Table, Figures, Listing (TFLs).

TCS ADD™ addresses these issues with an all-in-one, automated, metadata-driven platform that streamlines compliance with clinical and regulatory standards from protocol to submission.

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

## Overview

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

Traceability back to raw data or SDTM datasets 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 a clinical study design workbench with automated data transfer agreements, automated study build capabilities, 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 Clinical Data Acquisition Standards Harmonization (CDASH), SDTM, ADaM, non-Case Report Form (CRF), Analysis Results Standard (ARS), and so on. This facilitates real-time availability of metadata for downstream processing.

## Our solution

### **Clinical standards registry:**

- Scalable metadata repository supporting multiple standards and templates
- Includes electronic data capture (EDC) and non-EDC source collections, SDTM, ADaM, and Analysis Results Datasets Standards (ARDS) based on a metadata-driven approach
- Built on a metadata-driven approach for consistency and reusability



### Automated study build:

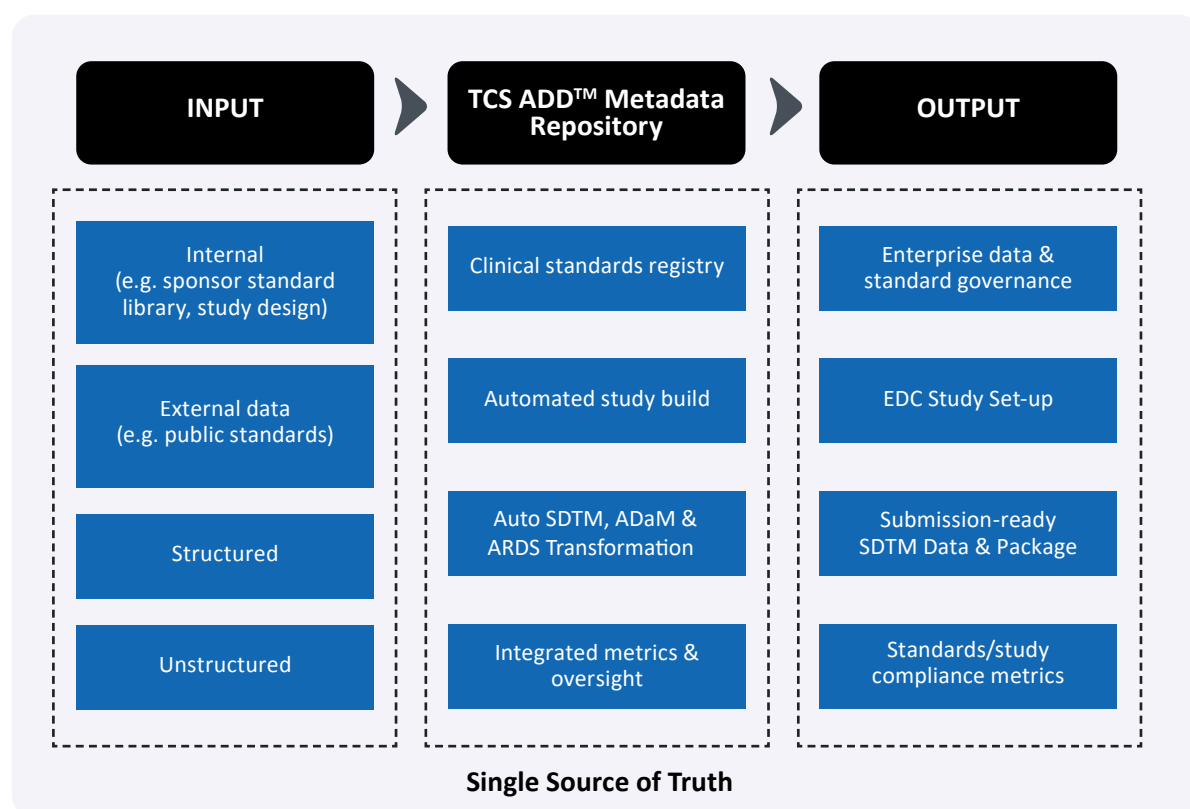
- Automated study design based on standards and templates via bi-directional integration to the EDC system
- This allows users to compare metadata set up in Metadata Repository (MDR) and EDC. The study snapshot feature enables to take snapshots of all the metadata elements of the entire study for future reference

### SDTM, ADaM and ARDS transformation metadata registry:

- Automates transformation metadata creation for new source collections using AI/ML
- Enables seamless API integration and standard-based metadata extraction
- Identifies target structures and predicts transformation metadata through AI-driven mapping
- Supports automated study setup with ready-to-use SDTM metadata
- Facilitates ADaM transformation using standard libraries based on analysis requirements
- Automates setup of domain/dataset metadata for both SDTM and ADaM

### Integrated metrics and oversight:

- Enables interconnected CRF, SDTM, ADaM, and ARS data models across the study lifecycle
- Visualizes relationships and dependencies between data elements
- Highlights CRF to SDTM linkages and their interactions



*TCS ADD™ Metadata Repository Platform: Schematic Overview*

# Benefits

TCS ADD™ Metadata Repository offers the following benefits:

## Customer technology landscape:

- **Technology simplification** - Reduced redundant tools, lowering IT maintenance costs by 20–30%
- **Data reusability** - Standardized metadata improved operational efficiency by 40%
- **Process automation** - Eliminated manual governance, reducing FTE effort by 25–30%
- **Scalability** - Enabled AI/ML-based metadata recommendations for future-ready trials
- **SAS to R code migration** - Acted as a key enabler for code transition
- **Version management** - Automated ingestion and comparison of new standard versions
- **Enables integration** - Integrated digital schedule of activities (SoA) and biomedical concepts for efficient data standardization

## Increased efficiency and reduced workload:

- **Standardization and reusability** - Centralized metadata management reduces duplication and improves consistency
- **Robust governance** - Centrally controlled change management for study-level standard updates
- **End-to-end automation** - Eliminates manual transformation/validation, cutting effort by 30–40%
- **Interoperability** - Configurable APIs enable seamless system integration
- **Proactive compliance** - Early regulatory checks reduce rework and submission delays
- **Faster decision-making** - Real-time metadata access speeds up study design approvals
- **Operational efficiency** - Global library sync and auto study build streamline processes
- **Exceptional SDTM efficiency** - Achieves study setup in just six person-days, far exceeding industry benchmarks

## People and organizations:

- **Empowered teams & reduced silos** - Unified metadata access enhances collaboration across clinical, regulatory, and IT teams
- **Skill transformation** - Shift from manual tasks to strategic roles in analytics, AI insights, and compliance
- **Robust governance** - Centrally controlled change management for both data collection and analysis standards
- **Faster onboarding** - Automated workflows cut training time, boosting new hire productivity
- **Reduced subject matter experts (SME) workload** - AI-driven recommendations enable self-service metadata access, freeing SMEs for high-value work
- **Greater agility** - Accelerated metadata management and study setup support efficient trial scaling

### Improved data quality & oversight:

- Enhanced standards quality
- 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 unstructured data arrives
- Unified Study Definitions Model (USDM) - aligned study design - Supports study setup in line with a defined USDM roadmap

## TCS Metadata Repository platform Advantage

TCS ADD™ Metadata Repository platform comes with these unique advantages:

- **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, and flexibility:** Our platform can be scaled to any level based on the business need and can be implemented as a standalone platform or on top of existing platform
- **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, platform, solution providers and global systems integrators to deliver a strategic platform



# 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 suite of modern and open AI powered suite of life sciences platforms 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 about platform, visit - <https://www.tcs.com/what-we-do/products-platforms/tcs-add/solution/tcs-add-metadata-repository-platform>



Email: [add.platform@tcs.com](mailto:add.platform@tcs.com)

### 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 14 of the world’s most prestigious marathons and endurance events, including the 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 \$30 billion in the fiscal year ended March 31, 2025. For more information, visit [www.tcs.com](http://www.tcs.com).

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