tcs ADD™

Building on belief

TCS ADD™ Metadata Repository Platform

Life sciences industry routinely face inconsistencies and challenges in managing diverse data standards and output templates, leading to process inefficiencies. Across the entire study build process — protocol, data collection, and submission — 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 solution that is easy to configure and provides compliance to industry clinical and regulatory standards.

TCS ADD™ Metadata Repository provides a single source of truth for any type of metadata (i.e., SDTM, ADaM, C-DASH, non-CRF, etc.) and assures standards compliance. 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 SDTM setup even before trial starts.

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.

TCS ADD™ Metadata Repository Platform 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 SDTM, ADaM, C-DASH, non-CRF, etc., This facilitates real-time availability of data for downstream processing.

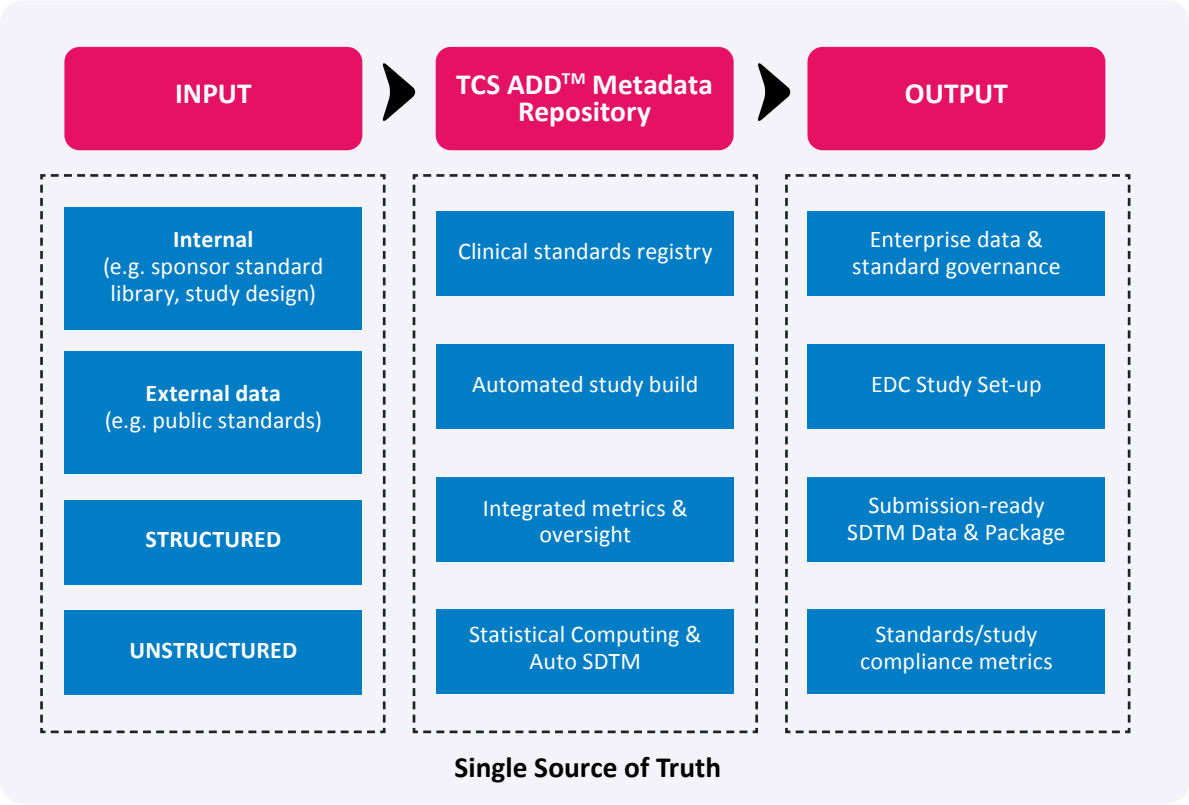
Who we are?

TCS ADD™ Metadata Repository Platform is a ready to use, interoperable metadata solution 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

TCS ADD™ Metadata Repository Platform comes equipped with the following key components:

- **Clinical standards registry:** Offers a repository of multiple templates and standards, enabling cross-study and product reusability. Enterprises can leverage its workflow and smart governance capabilities to handle evolving standards with ease.
- **Automated study build:** Automates creation of ready-to-use submission packages and provide a controlled environment for biometrics.
- **Integrated metrics and oversight:** Offers intuitive metrics to assess usability of standards, allowing consistent governance across the cycle.
- **Automated SDTM and statistical computing:** Automates creation of ready-to-use submission packages using artificial intelligence (AI), providing a controlled environment for biometrics. Data-Driven Feasibility



TCS ADD™ Metadata Repository Platform: Schematic Overview

Benefits

TCS ADD™ Metadata Repository Platform offers the following benefits:

- **Increased efficiencies & reduced workload:**

  Real time SDTM availability compared to 3-4 months typically taken, resulting in more time available for data cleaning

  Enhanced business agility by maximum reuse of standards

  Reduced Last Subject Last Visit to Data Base Lock timelines

  Increased efficiencies, productivity, and timelines across the product life cycle (study till commercial) by AI & automated analytics solutions

  Rapid retrieval of information due to a unified repository

- **Improved data quality & oversight:**

  Enhanced Quality of Standards

  Elimination of data inconsistencies across R&D and Clinical Trial processes

  Increased compliance with industry and sponsor standards

  Easily accessible audit trail across all activities

  Reuse of critical data and various industry level standards for other projects

  Cross-depth data lineage oversight

The TCS 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, 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
- **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.

TATA CONSULTANCY SERVICES

Awards and accolades

TOP 3
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FOR THE DECADE
2010 - 2020

About TCS ADD™ Platforms

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

Visit https://www.tcs.com/tcs-add on www.tcs.com

Email: add.platform@tcs.com

About Tata Consultancy Services Ltd (TCS)

Tata Consultancy Services is a purpose-led transformation partner to many of the world's largest businesses. For more than 50 years, it has been collaborating with clients and communities to build a greater future through innovation and collective knowledge. TCS offers an integrated portfolio of cognitive powered business, technology, and engineering services and solutions. The company's 469,000 consultants in 46 countries help empower individuals, enterprises, and societies to build on belief.

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