

tcs ADD™



TCS ADD™

Data Management Platform





Globally, life science industry is facing multiple complexities with archaic, disconnected and disjointed ways of handling data management activities. In a fast-moving technology landscape, the above challenge coupled with disjointed data sources operating with diverse data formats has led to organizations being unable to realize value from data and struggling to handle study timelines.

TCS ADD™ Data Management is a one-stop platform that caters to all needs of pharma including core electronic data capture (EDC) solution, terminology management, medical coding, non- case report form (non-CRF) data management and automated digital document generation. It offers an integrated, cloud deployed, self-service based platform that is modular, intuitive and ready-to-onboard with minimal training. Organizations, as a result, benefit due to increased efficiencies and reduced workload as well as improved data quality and oversight.

Overview

The challenges for the life sciences industry begin with manual and disparate data management activities such as data translation, source data verification and medical coding impacting operational efficiencies and increasing workload. In addition, disconnected and legacy data sources of diverse formats arising from different vendors require manual reconciliation and query management. The manual approach also extends to (1) terminology management due to absence of platform-led customizations and (2) document writing carried out cross-department leveraging multiple systems and lacking reusability of any kind. Thus organizations are looking for an integrated, intelligent, one-stop data management platform that is easy to use and that accelerates its product lifecycle.

TCS ADD™ Data Management Platform adds value to the life sciences industry with its novel, intelligent and cost effective solution that increases quality of data and simplifies the data handling process. Its integrated EDC solution possesses natural language processing (NLP) based analytics, automated data translation and multilingual capabilities, ML-based auto-coding, target source data verification and auto reconciliation capabilities. The Platform's non-CRF module ingests diverse data formats from different vendors/sources facilitating integrated query management, data reconciliation and discrepancy management.

TCS ADD™ Data Management Platform also bundles a real-time automated digital document generation tool with component-based content that can be reused. The platform's integrated and automated terminology management capability enables easy up-versioning, customized drug groups, custom MedDRA queries and reference safety information.

Solution

Integrated EDC

- Rapid study build and deployment
- Modular, multilingual, auto-translation, workflow-based design
- Rich dashboard and reports
- Harmonized, UI-based database lock features

Terminology & Coding Management

- Configurable and customized dictionary queries and reference safety information
- Integrated medical coding with in-built machine learning algorithm

Non-CRF Data Management

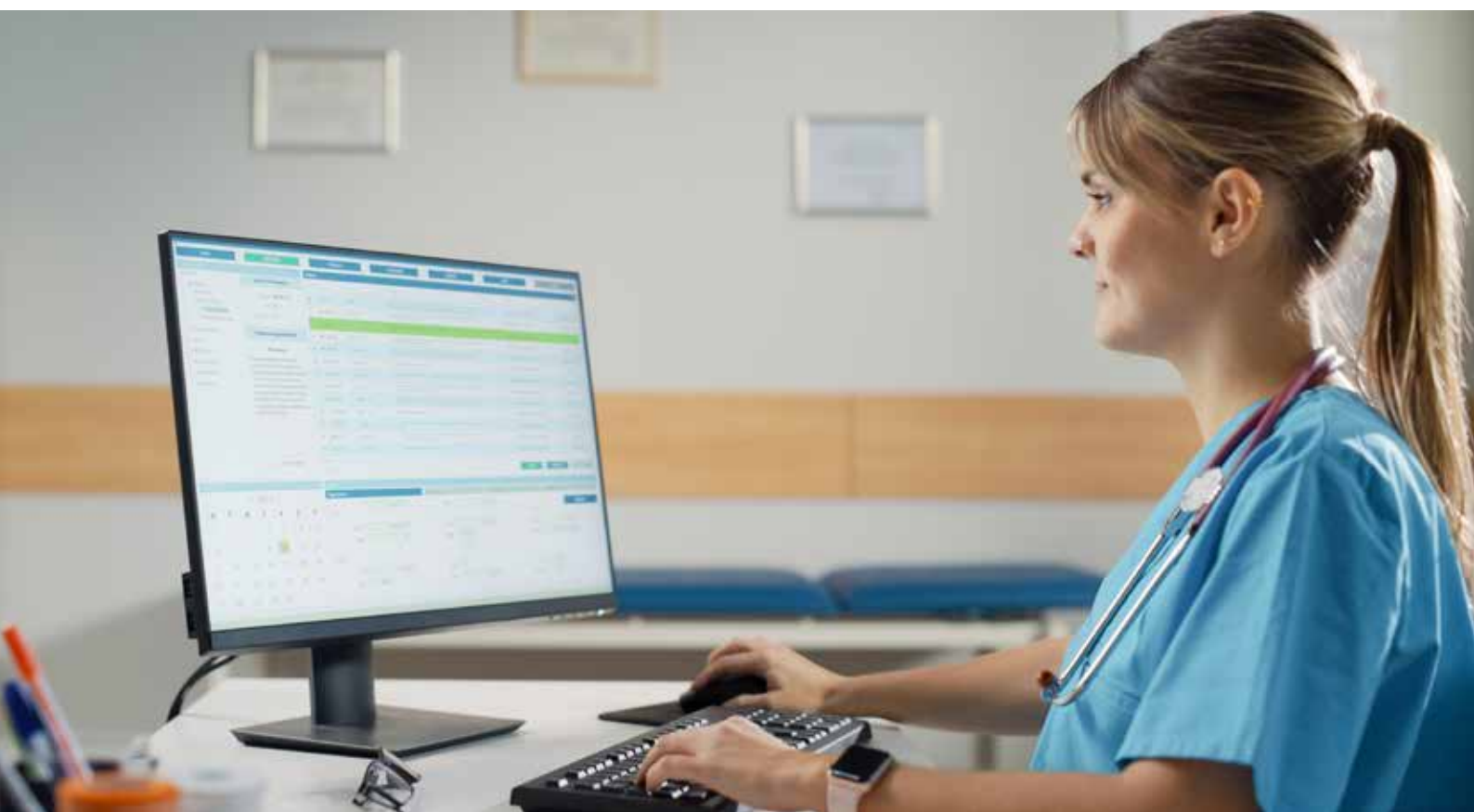
- Large data ingestion, reconciliation, merger reports with integrated vendor query management
- Inbuilt adaptors for various external EDC systems (e.g. Medidata)

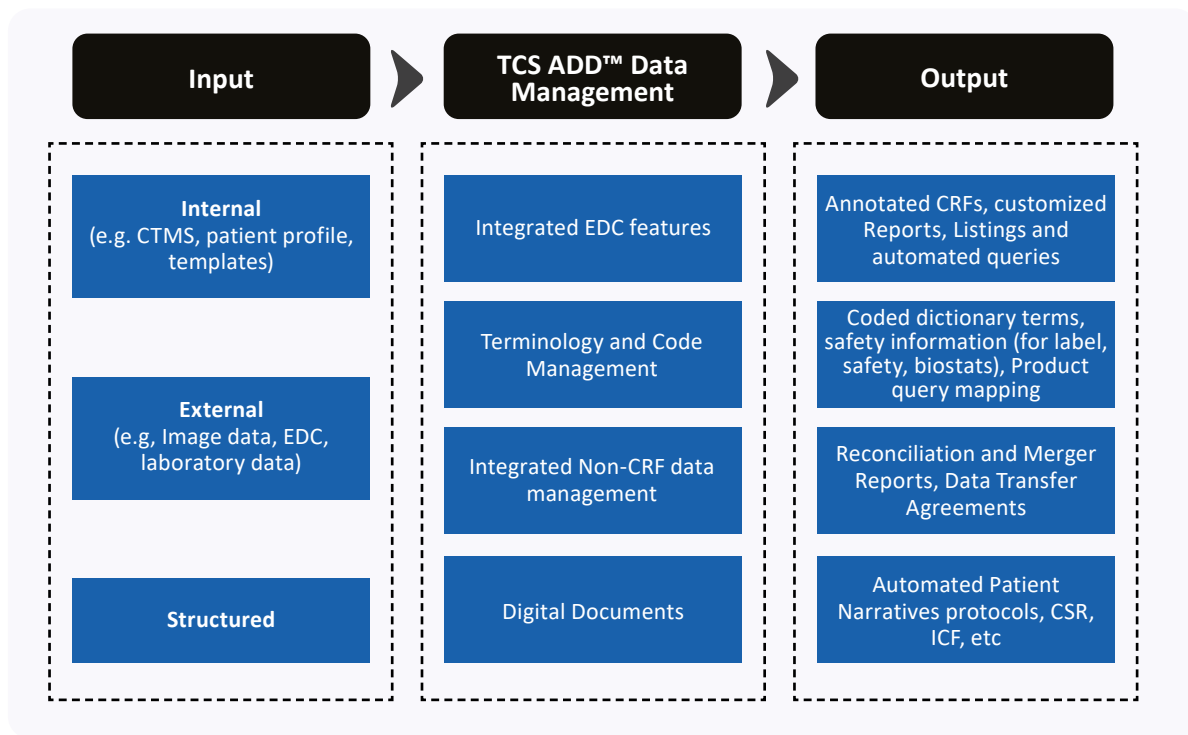
Digital Documents

- Template-based, automated document generation at study, product, and patient level
- Data ingestion from different data formats (SaaS data, .pdf, .csv, .xls, etc.)
- Workflow-based modular authoring and review capabilities
- Publishing in different digital outputs (PDF, Word etc.)

Medical Coding

- Configurable QC and SLA-driven workflows: Supports both one-step and two-step coding processes for coders and reviewers.
- Dictionary support: Built-in compatibility with the latest and previous versions of MedDRA, WHO-DD, and INN dictionaries, including up-versioning and impact reporting.
- Automation and integration: Designed to streamline coding with automation features and integration capabilities for external EDC systems.





TCS ADD™ Data Management: Schematic Overview

Benefits

With the TCS ADD™ Data Management Platform, life sciences companies can realize the following benefits.

Increased efficiencies & reduced workload

- Go-live in two weeks from study design, testing, validation, client user acceptance testing (UAT) and site training
- Up to 100% compliance in reporting severe adverse events using Non-CRF reconciliation module
- Over 50% time reduction for narrative generation
- Reduced data monitoring efforts, discrepancies and errors by using automated source data verification (SDV) module, intelligent alerts and queries
- Ready-to-use cloud hosted 21 CFR Part 11 compliant platform with zero programming for set up, simplified post-production changes and data verification

Improved data quality and oversight

- Up to 95% auto-coding
- Last patient, last visit (LPLV) to Database Lock within 7 days (vs average of 21 days)
- Advanced analytical intelligence to improve data quality
- Improved document quality by re-using custom objects (e.g. template scripts, codes)
- Automated workflow-driven framework across processes
- Improved accuracy and consistency of documents

Key features

Configurability & Scalability

- Customizable based on language preferences and local regulatory requirements
- Scalable to meet evolving business needs
- Intuitive and user-friendly interface requiring minimal training

Seamless Integration & Interoperability

- Cross-solution integration with other ADD platform offerings
- Plug-and-play orchestration with existing solutions
- Downstream integration with third-party safety systems
- Integration with Rave via Non-CRF Rave Adapter

Advanced Data Management & Processing

- Centralized Query Management for streamlined issue resolution
- Dynamic eCRF Configuration, including image-based eCRF
- Dynamic Edit Check for automated data validation
- eDTA Management with vendor data ingestion
- Lab & eCRF Data Reconciliation for consistency and accuracy

Ontology & Dictionary Management

- MedDRA & WhoDD (B2/B3) Ontology Management for standardized medical terminology
- Automated Dictionary Versioning to stay updated with latest releases

Reporting & Insights

- 180+ Inbuilt Reports & Dashboards for real-time monitoring and decision-making

The TCS advantage

By partnering with TCS, life sciences companies can leverage the following differentiators.

- **Open technology:** TCS ADD™ Data Management Platform provides a modern, open, fast and a user-first architecture.
- **Scalability:** Our platform can be scaled up to any level commensurate to the business need. For example, digital documents can scale up to any document types and volume as per the business requirement.
- **Tailored solution:** The solution can be configured based on language preferences of the local enterprise users and local regulatory requirements.
- **Plug and play:** TCS ADD™ Data Management can be implemented either as a standalone solution or in addition to the existing solutions to increase the efficiency of the existing data capture system.
- **Technology and domain expertise:** Our certified subject matter experts have the capabilities of clinical research services providers, platform solution providers, and global system integrators and can deliver strategic solutions per all customer requirements.
- **Cost-optimized solution:** TCS ADD™ Data Management's open, mature and widely acclaimed solution offers a much higher return on capital investments by the life sciences industry and delivers a superior customer experience.



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 by **FORTUNE® Magazine**
- TCS recognized as a most valuable global brand 2023 by **Kantar Brandz**
- TCS ranked number one for tenth consecutive year in Customer Satisfaction by **Whitelane Research Survey 2023**
- TCS Europe Listed as a 2023 Top Employer 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 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.

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