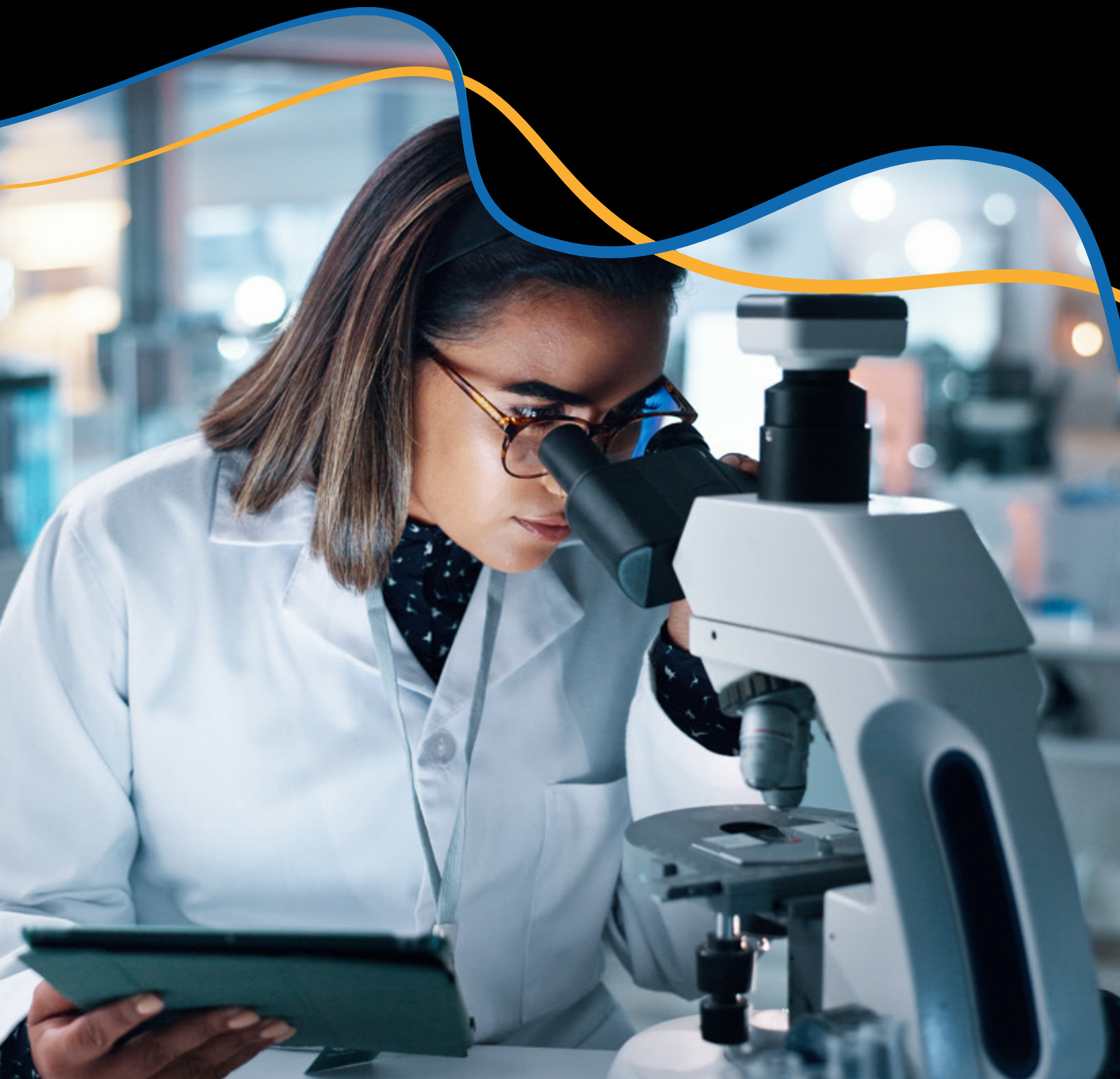
tcs ADD™

TATA

TCS ADD™ Clinical Data Repository

A foundation for modern clinical data sciences



Overview

Clinical trial monitoring is facing challenges due to the increased complexity of trials, and the increasing number of data sources, leading to inefficient operational and patient oversight and delayed signal detection. Siloed systems, a huge amount of time and effort taken to set up platforms and onboard studies, lack of required skill sets, and limited AI/ML capabilities are hampering conducting trials efficiently and impacting cost and quality adversely.

Firms need a secure, unified platform that aggregates clinical trial data from multiple sources (e.g., Electronic Data Capture (EDC), Electronic Clinical Outcome Assessments (eCOA), labs, imaging, wearables, Electronic Medical Records (EMRs)) across various systems and geographies. The goal is to providereal-time, harmonized, and accessible data to all stakeholders (Sponsors, Contract Research Organizations (CROs), Regulators, Sites) for improved decision-making and operational efficiency.

The TCS ADD™ Clinical Data Repository offers a best-in-class data model that ingests data from multiple sources, such as the EDC, Interactive Web Response Systems (IWRS), central labs, safety portal, and others, applies robust harmoniza on, transforma on, and standardiza on processes to deliver a consistent and interoperable dataset. This equips companies with tailored insights, enabling smarter trial decisions.

Key Components

Interoperability

- The solution s industry-compliant Biomedical Research Integrated Domain Group (BRIDG)-based model framework provides faster interoperability and data structure-based Entry Attribute Value (EAV) model
- Subsequently, this enables seamless bi-directional integration with a variety of data sources across clinical, operational and scientific and including omics, biomarkers and real-world data, including Electronic Health Records (EHR)

Smart data ingestion

- Pre-built data ingestion module with flexibility for addition of newer sources
- A multi-format smart data ingestion framework with out-of-the-box connectors with 20+ sources
- Allows low-code configuration for faster source onboarding
- Allows scalability and parallel processing
- Ability to handle structured, unstructured data, and complex data such as imaging

Data-driven Architecture

- Handles and processes large data volumes and enables parallel processing.
- Its metadata-driven unified orchestration engine provides rich UI- led visualizations both at an aggregate level and drill-down facilitating predictive analytics

Data transformation

- Standard-based data transformation and harmonization to a common data model enabling simple as well as multi-step complex transformation
- Ability to handle inline transformation with cohesive data lineage
- Use of standards across clinical data flow
- Runs data transformation routines using languages like SQL, Python, or R

Data quality checks

- Automated conformance checks
- Ability to build custom quality checks
- UI to trigger and schedule quality checks on demand
- Transforms data from raw to trusted to refined
- Quality rules can be enforced hard or soft, based on business need

Data storage and review

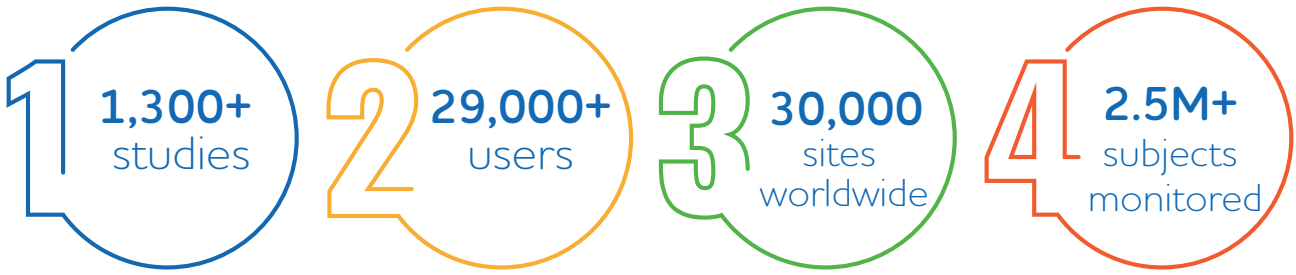
- Ability to store large data volumes
- Robust archival facility
- Enables AI-based visualizations or data analytic
- Enables holistic review of end-to-end clinical/operational data
- Enables safety/efficacy review with AI/ML-based analytic

Benefits

- Data standardization across formats (CDISC, HL7, FHIR)
- Real-time data integration and ingestion resulting in quicker data enablement to data management, clinical operations, and quality teams
- Faster onboarding of new sources with scalable cloud-native infrastructure role-based data access and permissions enabling efficient self-service reporting
- Audit trails and regulatory compliance (21 CFR Part 11, GDPR)
- Enables pluggable data science workbench for advanced analytics, AI/ML use cases such as workload forecasting, site feasibility and site narratives
- Accelerates clinical trial timelines
- Data quality checks enhance the quality and utility of business data by almost 20%
- Enhance patient safety monitoring and signal detection

Highlights

The Clinical Data Repository serves as the foundational layer for the AI/ML-powered TCS ADD™ Risk-Based Quality Platform implemented for a global top-three pharmaceutical company.



The TCS Advantage

- **Cross-industry collaboration:** We have been consistently partnering with pharma organizations and driving impact through several industry events and joint virtual engagements. As part of this ongoing effort, TCS ADD™ hosted a customer-partnered virtual event that provided insights into a science-led, data-driven approach to risk-based monitoring in clinical trials

- **Scalability:** Intelligent seamless pipeline catering to data processing, scaling to handle diverse sources, study volumes, and metrics at scale with optimized resource pooling

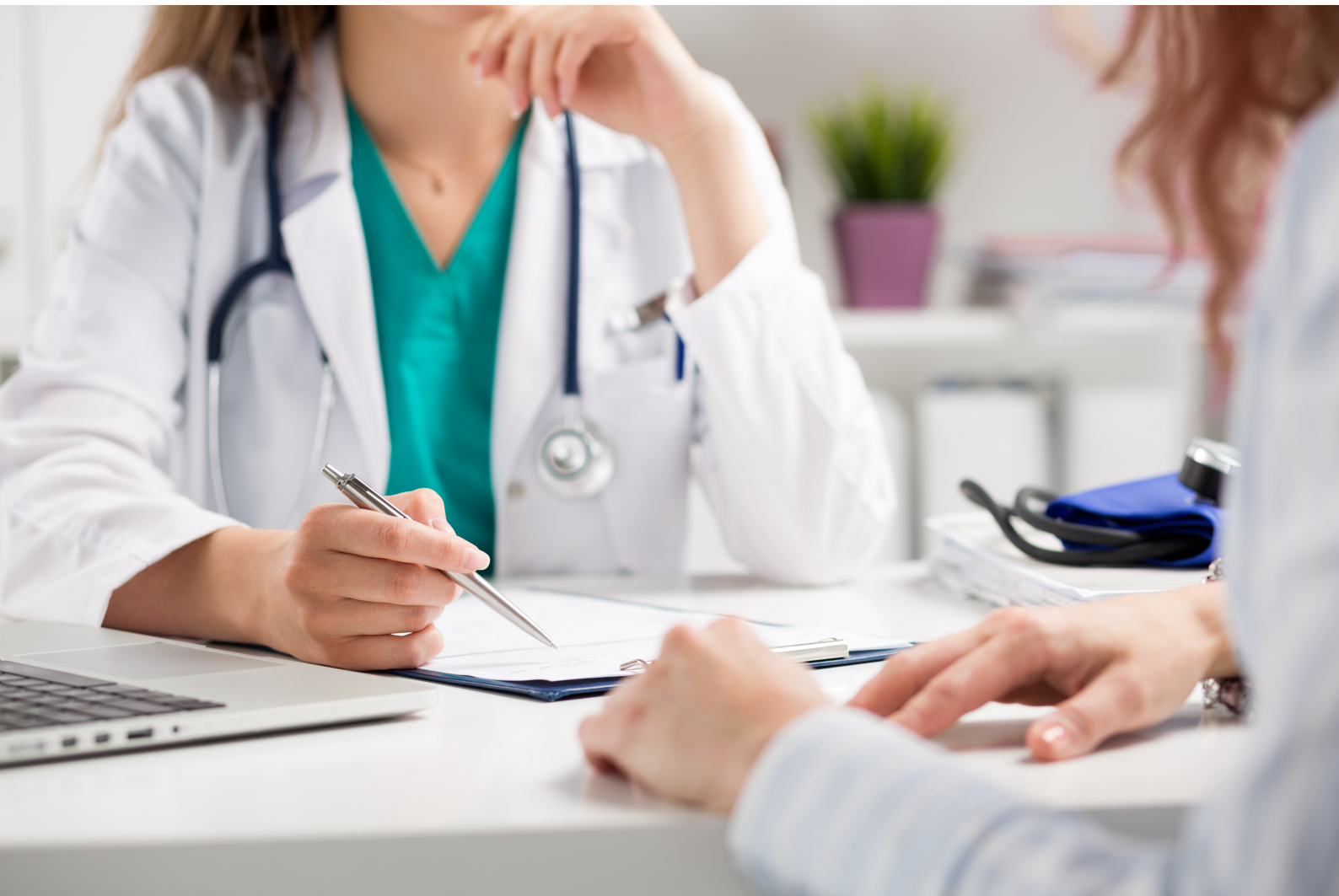
- **Flexible:** Companies can implement the platform as a standalone solution on top of the existing solutions or integrate with other TCS solutions for life sciences

- **Modular:** The platform is highly modular with its components capable of being implemented separately or in combination, mapped to the business requirement

- **Cross-solution integration:** The platform is modular and interoperable, seamlessly integrating with upstream and downstream systems, and horizontally with other TCS ADD™ offerings

- **End-to-end offering:** TCS provides IP-led solutions combined with clinical service capabilities helping life sciences organizations leverage a one-stop destination for serving their business requirements

- **Technology and domain expertise:** TCS-certified subject matter experts combine the capabilities of clinical research service providers, platform, solution providers, and global systems integrators to deliver strategic solutions fulfilling customer requirements



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 consecuti e 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 inc ease 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-clinical-data-repository-platform

Email: 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.

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