tcs ADD
Digital Advangage for Life Sciences

ADD Data Management

TATA CONSULTANCY SERVICES

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.

ADD Data Management is a one-stop solution 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 solution 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 solution that is easy to use and that accelerates its product lifecycle.

ADD Data Management 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 solution's non-CRF module ingests diverse data formats from different vendors/sources facilitating integrated query management, data reconciliation and discrepancy management. ADD Data Management also bundles a real-time automated digital document generation tool with component-based content that can be reused. The solution's integrated and automated terminology management capability enables easy up-versioning, customized drug groups, custom MedDRA queries and reference safety information.

Solution

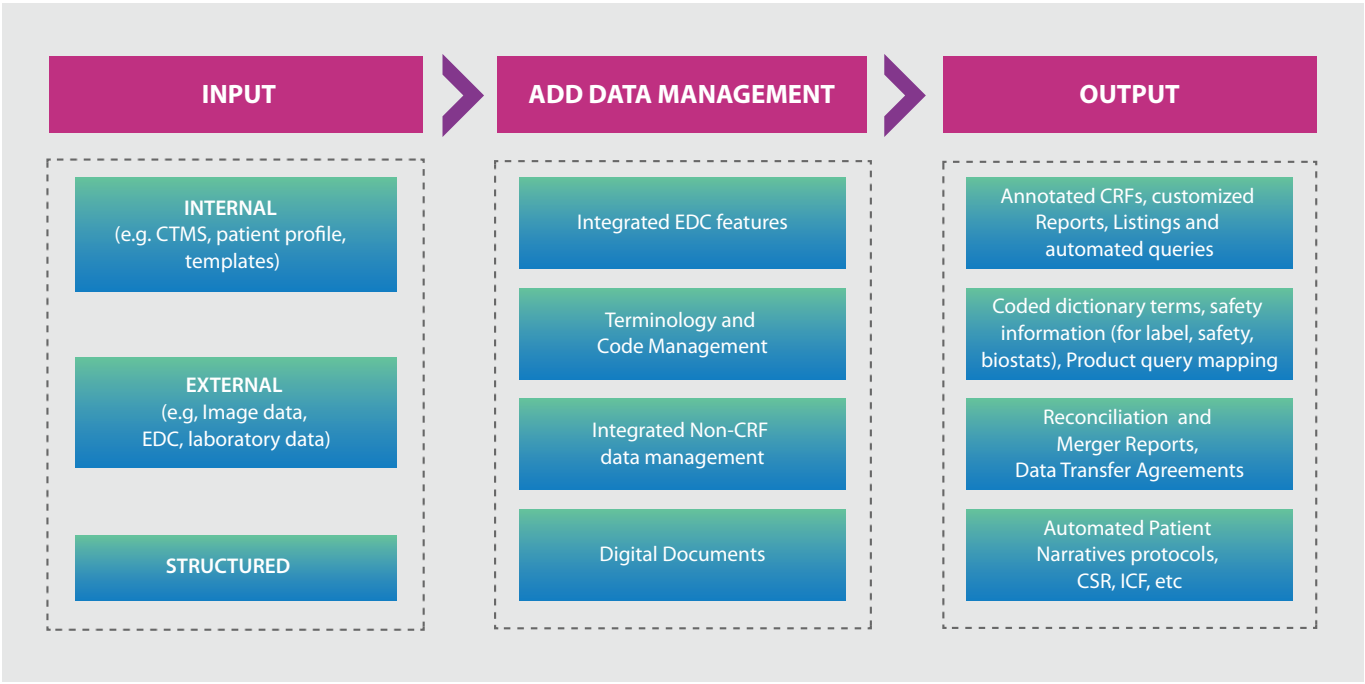
The ADD Data Management solution comprises the following three key components.

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.)



ADD Data Management: Schematic Overview

Benefits

With the ADD Data Management solution, 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 solution 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

The TCS Advantage

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

- **Open technology:** ADD Data Management solution provides a modern, open, fast and a user-first architecture.
- **Scalability:** Our solution 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:** 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:** 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 & Recognition

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 artificial 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 the **https://www.tcs.com/advanced-drug-development** page on **tcs.com**
Email: **ADD.Platforms@tcs.com**

About Tata Consultancy Services Ltd (TCS)

Tata Consultancy Services is an IT services, consulting and business solutions organization that delivers real results to global business, ensuring a level of certainty no other firm can match. TCS offers a consulting-led, integrated portfolio of IT and IT-enabled infrastructure, engineering and assurance services. This is delivered through its unique Global Network Delivery Model™, recognized as the benchmark of excellence in software development. A part of the Tata Group, India's largest industrial conglomerate, TCS has a global footprint and is listed on the National Stock Exchange and Bombay Stock Exchange in India.

For more information, visit us at **www.tcs.com**

IT Services
Business Solutions
Consulting

Corporate Marketing | Design Services | M | 02 | 21