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ADD Clinical Data Management

Life Sciences & Healthcare

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Pharmaceutical organizations are looking to optimize their processes with cloud based applications. The industry must optimize clinical development and reduce redundant data entry while reducing the drug's time-to-market. Conventional and rigid process models along with cost pressures are forcing the industry to look beyond available tools and models in the Electronic Data Capture (EDC) market.

Tata Consultancy Services' (TCS') ADD Clinical Data Management (CDM) platform is a robust EDC system that customers can use to conduct trials in a cost-effective manner. It improves study design, conduct, and reporting by integrating all the myriad CDM processes, delivering lower costs and robust solutions.

Overview

While procedures to manage different CDM processes have been established, pharmaceutical companies are still struggling to find the right platform. Rising research expenditure, regional demand, an evolving local regulatory environment and higher scrutiny regarding safety are causing an upsurge in regional trials, observational studies and post-launch studies. Most solutions are unable to integrate all the activities and are not adaptable enough to address constantly evolving regulatory requirements. Further, these platforms come with high acquisition and maintenance costs and long gestation periods.

Organizations need a web based platform to manage clinical trials – one that is easy to deploy, configurable and integrates effortlessly with downstream applications. ADD CDM leverages cloud-based platforms and mobility to improve study design, conduct and reporting. The solution enables rapid recruitment of more appropriate patients through mobile devices, resulting in improved engagement which leads to faster and more accurate information gathering and higher patient retention rates. Further, use of a cloud-based platform helps in the centralization of data, creating a single source of truth, while allowing simultaneous access from multiple locations. The integration of this data via EDC eliminates redundancies, reducing effort and errors.

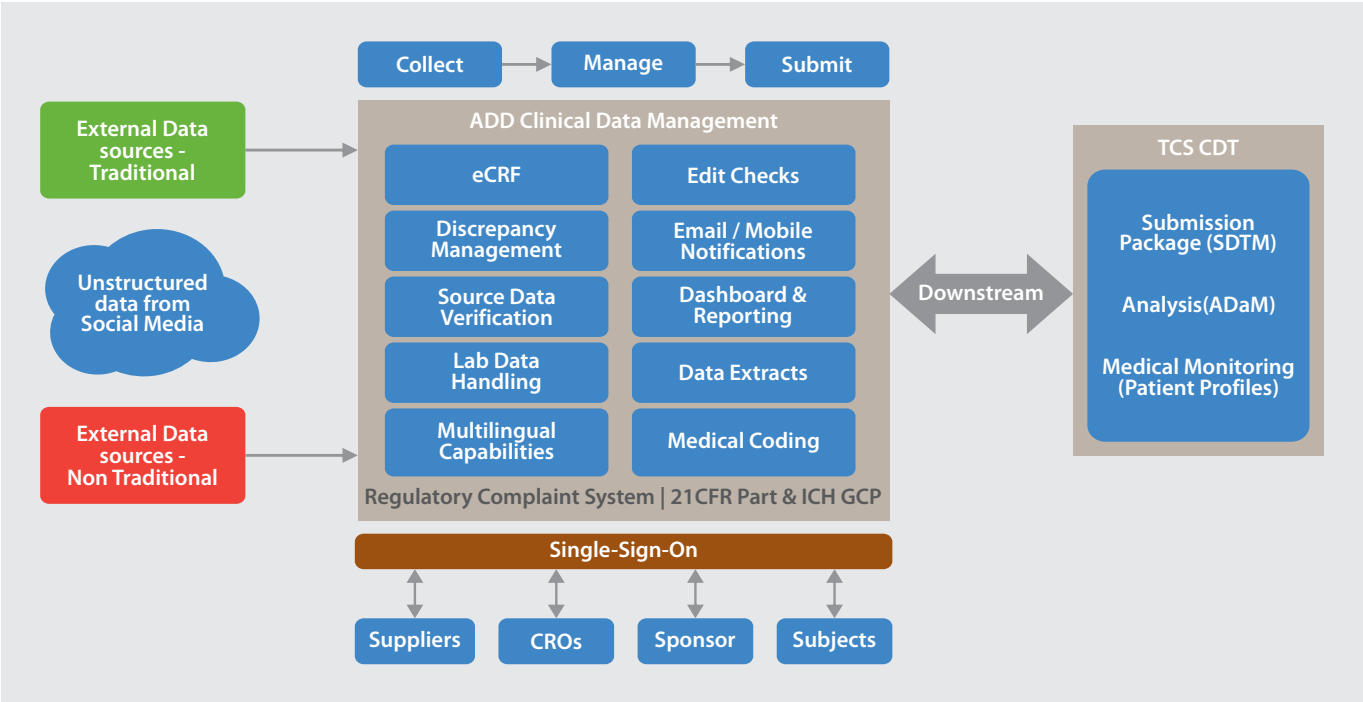
Our Solution

The ADD CDM platform is hosted on regulatory compliant datacenters which can be used to conduct trials cost effectively. The platform offers customers a range of services including infrastructure, applications, business services, help desk and user training—all bundled together with an attractive cost model. The system is designed to support multiple devices, which enables users to leverage its functionality from various locations. It covers all standard EDC functionalities to support all phases.

The ADD CDM Platform enables

- Creation of eCRFs & Rules
- Query management
- SAE Reconciliation
- Lab Data Management
- Integrated Dashboards with real time Integrated CDM analytics and reports
- Integration with external sources
- Global library with repository of eCRF drafts, enabling faster study setup
- Medical coding: comprehensive functionality covering MedDRA, WhoDD and synonym list
- Multilingual capabilities with translation workflows
- Randomization, blinding, and un-blinding
- Terminology Management
- Data transparency

TCS' Cloud-based Clinical Data Management Platform for End-to-End EDC Needs



Benefits

The benefits of implementing the ADD CDM platform are:

Reduced cost: Conduct trials involving a large number of patients—500-30,000—with a cost-effective solution.

Improved subject engagement: Improve patient retention and monitoring by leveraging the platform's ability to integrate mobile devices

Improved compliance: Enable accurate data collection and standardization, and thus achieve CDISC compliance

Geographic Presence: Provide multilingual support with wider geographic acceptability

Scalability: Provide built-in randomization with a solution that can handle Phase1/2/3/4 trials

The TCS Advantage

Organizations can leverage the following advantages by partnering with TCS to streamline CDM processes:

Industry trends adoption: The well-defined solution comes with a comprehensive roadmap considering future industry needs with several downstream solutions including auto narratives, patient profiles and visualization

Proven platform: It's a proven platform that is already being leveraged to deliver studies for a global pharmaceutical company in addition to local trials for an Indian Medical Research Center

Easy assimilation: The solution needs lower setup time and is easy to use with less user training effort

Domain-led solution: It is developed and owned by cross functional teams including practitioners and technologists

Roadmap agility: The platform roadmap is agile enough to enable collaboration with sponsors to evolve a solution based on a sponsor's current and future needs

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Awards & Recognition

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Visit the **Life Sciences & Healthcare** 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.

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