

Advance Drug Development Platforms for Clinical Trials

Life Sciences & Healthcare



Life sciences firms must meet the increasing demands for real time insights on the safety and efficacy of clinical trials from the patients, investigators, and stakeholders involved in these trials. Companies also face stringent regulations mandating standardization of clinical trial data, as well as publication of timely, error-free compliance reports. Drug makers can significantly improve stakeholder engagement, and ensure adherence to treatment norms, by migrating to an integrated clinical service platform that pools in patient information from disparate sources.

Tata Consultancy Services' (TCS') Advance Drug Development platforms help companies make informed, timely decisions concerning clinical trials, by provisioning an integrated platform for the entire value chain. The solution creates a comprehensive data source that fosters accelerated study setup and execution, eliminating redundant manual processes. This enables reduced time to market for new drugs, and generates substantial savings on account of associated costs.

Overview

Life science organizations need on-demand access to accurate clinical trial data in order to make swift, informed calls on drug studies. However, they face several challenges on this front, including inconsistent trial data, inefficient clinical development processes, and low visibility into treatment adherence.

Pharmaceutical companies' existing systems lack a compatible interface with new data sources such as the Internet of Things (IoT), mobile devices, patient diaries, and electronic clinical outcome assessments (eCOA). Suboptimal harmonization of trial data can hinder effective mid-course correction during actual studies, complicating the entire process and running up costs. Further, inefficient study setup and execution can pose a serious risk to patient safety, as well as lead to regulatory non-compliance.

TCS' Advance Drug Development solution provisions cost effective clinical service platforms, integrating key features of both commercial-off-the-shelf (COTS) and TCS' intellectual property (IP) offerings. The plug and play system empowers firms to minimize errors in drug studies by automating the entire clinical trial process. It enables companies to create a comprehensive and readily accessible data source for all of their analytical requirements during trials. The solution also provides real-time access to data for robust treatment adherence, and helps drug makers respond swiftly to regulatory queries with auto-generated compliance reports.

Benefits

TCS' Advance Drug Development solution helps pharmaceutical and biotechnology companies reap the following benefits:



- **Reduced time to market:** Significantly reduce the time to market for new drugs by streamlining workflows across the end-to-end clinical trial lifecycle; secure faster drug approvals through swift regulatory filings



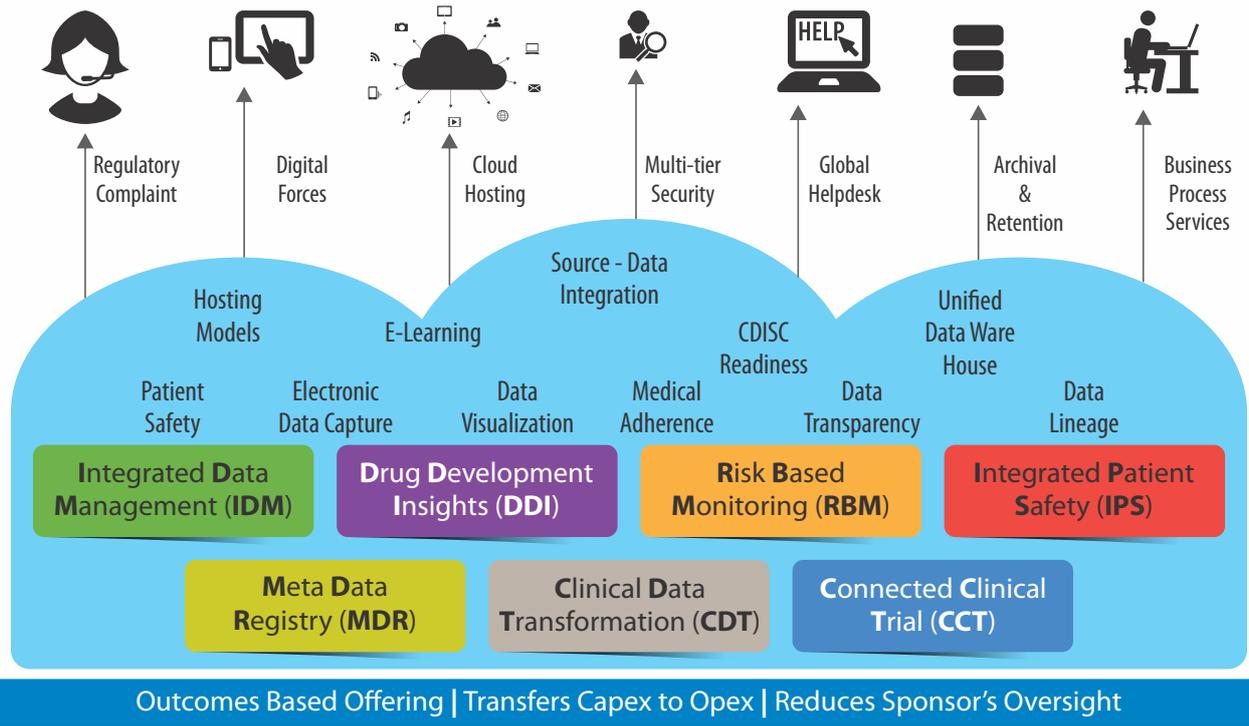
- **Regulatory compliance:** Fully conform to evolving regulatory requirements, without disrupting regular operations; respond swiftly to queries with autogenerated, submission-ready reports

Our Solution

Key solutions of our cloud-based platform suite includes:

- **Integrated Data Management (IDM):** Enables robust EDC functionalities to support study setup, conduct and closeout phases.
- **Drug development insights (DDI):** Aggregates clinical and/or operational data from structured and unstructured data sources into a clinical data warehouse enabling multiple business use-cases including Risk Based Monitoring (RBM), site feasibility, and so on.
- **Integrated patient safety (IPS):** Covers all aspects of pharmacovigilance in a predictable and cost effective manner.
- **MetaData Registry (MDR):** Enables management and governance of metadata standards at global, TA, project and study levels.
- **Clinical Data Transformation (CDT):** Transforms clinical data acquired from a variety of structured and unstructured data sources as per industry standards.
- **Connected Clinical Trial (CCT):** Improves patient engagement, enhances medication adherence and enables adaptive trial approaches.

Advanced Drug Development (ADD) Platforms



The TCS Advantage

By partnering with us, you can leverage the following differentiators:

- Domain expertise:** The Advance Drug Development solution has been developed by our cross-functional teams comprising practitioners and technologists with deep domain expertise. We have a team of over 200 professionals who have worked on a diverse range of clinical trial activities. Our pool of subject matter experts have an average experience of approximately 15 years in managing global clinical projects, site selection and clinical monitoring. TCS' application delivery teams leverage good clinical practices.

- Easy assimilation:** The platform can be set up in a short timeframe, and integrated smoothly with existing enterprise systems. The application is easy to use, and requires minimal user training.



- Improved patient safety:** Use the integrated clinical service setup to diligently track adverse events, and follow up with patients, thus boosting their safety



- Enhanced trial productivity:** Rapidly enroll appropriate patients for drug studies by harnessing mobile devices and associated data acquisition systems; reduce manual efforts and minimize errors in trial data to boost process efficiency

Awards & Recognition



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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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