ADD Connected Clinical Trials Platform
Life Sciences & Healthcare
Bringing continued innovative pharmaceutical products to the market in the future will demand improvements to the clinical trial process, including effective patient monitoring, increased operational efficiencies, high quality data capture and personalized engagement with trial participants.

With these goals in mind, Tata Consultancy Services (TCS) has developed Connected Clinical Trials (CCT), an innovative ‘Software as a Service’ (SaaS) platform that can be used by pharmaceutical companies to automate the clinical supply process while also gaining real-time insights into adherence and trial data. The platform integrates with various smart technologies, alleviating burden on patient and sites, and enabling decision making by investigators and sponsors in real-time. The desired end result is complete transparency, increased patient engagement, improved compliance and adherence with study protocols, and greater operational efficiency during clinical trials.

Overview

Digital technologies are increasingly being embedded in the daily lives of patients and sites, but are not yet integrated seamlessly into trials. This results in clinical trial participation often being more cumbersome, deterring patient engagement and making compliance with protocols sometimes difficult to achieve. Pharmaceutical companies are striving to reduce the trial timelines in order to bring drugs to patients in need and are seeking new ways to facilitate adaptive trial designs and combine multiple studies. At the same time, regulatory requirements for patient health and data quality are increasingly becoming stringent, forcing pharmaceutical companies to rethink manual, paper-based, time consuming and error prone processes of managing clinical supplies. Besides, control over adherence to dosage norms is an important consideration in monitoring for patient safety during the course of the trial.

The CCT platform aims to connect patients and sites — the key stakeholders in any clinical trial — with features such as innovative sensors, ‘smart’ package and mobile devices that enable real-time data integration, analytics and tailored patient support. CCT is designed to provide end-to-end visibility on how clinical supplies are managed, both on site and at patient’s home, and address the challenges of current multilingual paper-based drug labels. The platform is designed to foster a real-time connection between patients, sites and sponsors and is intended to ensure full compliance to regulatory norms.

Our Solution

The CCT platform consists of three offerings and seven modules, which can be used separately or as a combination in a trial:

CCT Intelligent Trial Medication

- **CCT Adherence**: Enables registration and verification of individual medication intake via sensor enabled medication packages (smart packages) to eliminate guesswork for medication intake ensuring that the right pill is taken at the right time.

CCT Tracking: Uses medication scanners to track all medication kit transactions at the site to prevent dispensing errors, ensuring that the right medication kit is given to the right patient at the right time.


CCT Digital Patient and Site Engagement

- **CCT Subject App**: facilitates 360 degree interaction between patients, sites, and sponsors; supported on multiple channels (iOS, Android, and web browser) and multiple devices that can be provisioned to subjects or used in BYOD model:
  - Learn modules for patient education
  - Questionnaires that can be used by patients in BYOD model
  - Medication intake eDiaries
  - Patient survey
  - Digital visit cards and reminders
  - Motivational messages
  - Notifications

- **CCT Site App and Portal**: facilitates sites to use a mobile-friendly app to monitor and track all subject and medication related activities with features such as:
  - Alerts for subject compliance, medication recall, safety alerts
  - Tracking of trial supplies through barcode or NFC scanning
  - Verification of dispensed medication
  - Automated pill count on drug return
  - Site survey

CCT Virtual and Remote Trials

- **CCT Consent**: Supports electronic informed consent using patient-friendly multimedia content on mobile devices, both at site and remotely in users’ own language

- **CCT Digimarkers**: Provides end-to-end support for digital endpoints derived from smart devices, sensors, and wearables
Benefits

The CCT platform has been developed in close collaboration with a leading pharmaceutical company to reassess the entire clinical trial process, putting the patient at the center. Pilot feedback, collected from patients and sites via surveys and interviews, has been taken into consideration while enhancing this platform. All of these efforts have been considered so that the CCT platform may enable pharmaceutical and bio-pharmaceutical companies to realize the following benefits:

**Automated, paperless and self-controlling medication process (at site and at home):** Eliminate on-site monitoring for supply activities, addressing medication dispensation errors, transcription errors and discrepancies while also reducing site workload.

**Real-time access in treatment adherence (at home):** Reduces missed or incorrect dosage regimen increasing the potential to intervene faster and reduced safety risks or potential drop-outs.

**Personalized patient support and interactive multimedia communication:** Understand drug and study information with tailored support via personalized notification and how-to instruction videos. Leverage two way communication and real-time patient data collection (for instance, on adverse events etc.)

**Increased treatment and protocol compliance:** Reduce inspection findings on treatment adherence and study procedures. Gain complete oversight in medication handlings at site and at home with timely reporting of product complaints.

**Transformed labeling and packaging process:** Eliminate booklet label printing and label updates, with no manual label additions from a site, thus ensuring all labels are in a single label format. Improve readability, with only the latest label version accessible through the mobile app. This increases label flexibility resulting in time-effective trials. Automated tracking ensures reduced supply wastage.

**Enable Adaptive trial design:** Gain real-time insight with a possibility for immediate dose-adjustments (e.g. adding, changing, dropping a treatment arm). Additionally, conduct complex dosing designs and combined studies.

The TCS Advantage

With CCT pharmaceutical companies will be able to explore the use of the following differentiators:

**Software as a service model:** The CCT platform has been designed to be an open, cross-industry platform where all stakeholders can participate to create a new standard. The platform is offered in a SaaS model to support multi-tenancy.

**Domain expertise:** TCS has a vast pool of consultants, including physicians, pharmacologists and information technology professionals, with domain experience gained through diverse engagements with leading global drug manufacturers.

CCT’s subject matter experts have an average experience of approximately 15 years in managing global clinical projects, site selection and clinical monitoring.

**Integrated solution approach:** This comprehensive, patient-centric CCT platform combines trial supply administration, labeling management and patient engagement to harness synergies that help pharmaceutical companies advance new drugs in a cost-effective manner.

**IoT-powered platform:** The platform enables remote patient monitoring through ‘smart’ blisters, medication kits and mobile phones, addressing compliance and accountability throughout the course of the trial.
Awards & Recognition

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Visit the Life Sciences & Healthcare page on tcs.com
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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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