

# TCS ADD™ Connected Clinical Trials



Bringing continued innovative pharmaceutical products to the market in the future will demand improvements in the clinical trial process, including personalized engagement with trial participants, high-quality data capture, effective patient monitoring, and increased operational efficiencies – aspects that are key to the incorporation of decentralized clinical trials.

With these goals in mind, Tata Consultancy Services (TCS) has developed a comprehensive decentralized trials suite of platform - the TCS ADD™ Connected Clinical Trials (CCT). This modern, scalable, and modular platform can be used by pharmaceutical companies to significantly transform the way clinical trials are conducted today— making them patient-centric, site friendly, and ‘digital by default.’

The platform integrates with various smart technologies, alleviating the burden on patients and sites, and enables decision making by investigators and sponsors in real time. The desired result is complete transparency, increased patient engagement, improved medication adherence, efficient trial supplies, and a highly automated clinical trial process.

## Overview

Digital technologies are increasingly being embedded in the daily lives of patients and on-site but are not yet integrated seamlessly into trials. Because of this, participating in clinical trials is often cumbersome, providing inefficient patient-engagement and achieving compliance with protocols sometimes becomes difficult. Pharmaceutical companies are striving to reduce the trial timelines to bring drugs to patients in need faster 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.

The TCS ADD™ CCT platform aims to connect patients, sites, and sponsors —key stakeholders in any clinical trial with a variety of innovative sensors, smart medication packages, and mobile devices. CCT enables the collection of patients’ health outcomes using mobile apps, wearables, engagement tools, and smart, connected devices, thereby reducing the need for site visits and making the trials more accessible to patients. With real-time data integration, analytics, and tailored patient support, CCT is designed to foster seamless connection between patients, sites, and sponsors and is intended to ensure full compliance to regulatory norms.

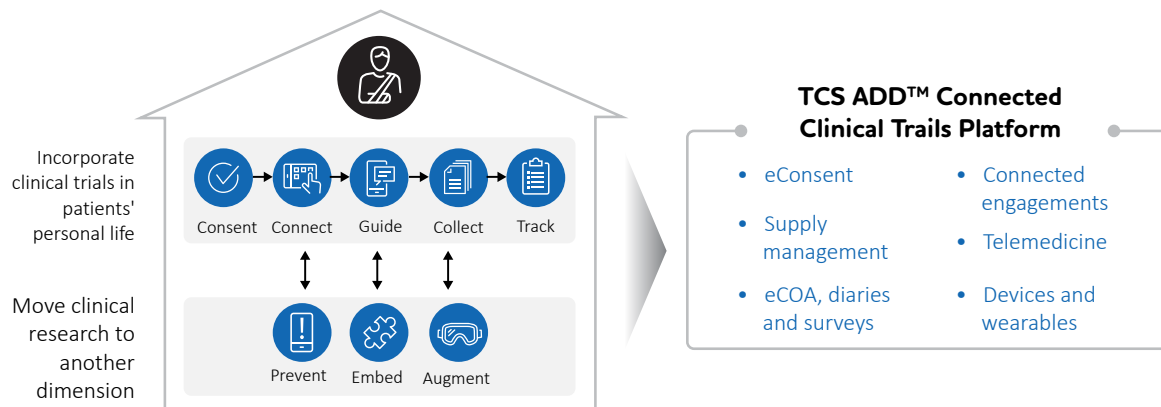


Figure 1: Schematic Overview of the TCS ADD™ Connected Clinical Trials platform

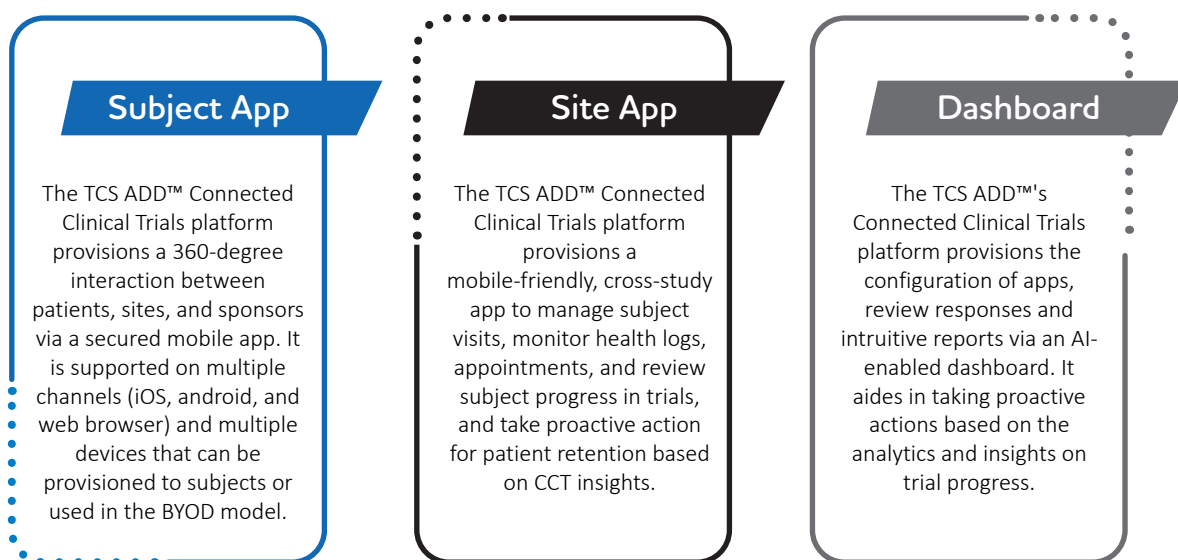
## Our solution

TCS ADD™ Connected Clinical Trials Platform Offerings:

- **Supply Management**
  - **Kit tracking:** Automated and real-time tracking and verification (e.g. receipt, processing, handout, and return) of kits accessible via site portal/site app supporting direct-to-patient and traditional supply models
  - **Digital label:** Personalized, easily accessible digital label and label updates in patient's preferred language delivered via patient app and site app/portal
  - **Pill/Unit dose tracking:** Automated and real-time tracking of individual pill/unit dose intake via sensor-enabled packages (barcode, NFC, Bluetooth) and accessible via site portal/app and patient apps



- **eConsent** – Patient-centric, flexible, and secure end-to-end informed consent solution with advanced digital experience
- **eCOA , diaries and surveys** - Unified, fast, and one-click approach to data collection and oversight for patients, sites, and sponsors, either entered electronically or uploaded in the paper form
- **Telemedicine** - Seamless and feature-rich audiovisual interaction between patients, sites, and sponsors across web and mobile apps
- **Devices and wearables** - Biometric sensors with connected medical devices for timely and accurate health insights through automated data collection and remote monitoring
- **Connected engagements** - Personalized patient and site support throughout the trial process via portals, apps, and multimedia literature



*Figure 2: Key components of the TCS ADD™ Connected Clinical Trials platform*



# Benefits

The TCS ADD™ CCT platform has been developed in close collaboration with pharma and multidiscipline stakeholders (Clinical, regulatory, supply chain, privacy etc) putting the patient at the center. Pilot feedback, collected from patients and sites via surveys and interviews, have been taken into consideration while enhancing this platform. All efforts have been considered so that the CCT platform may enable pharmaceutical and bio-pharmaceutical companies to realize the following benefits::

## Increased efficiencies and reduced workload

- Up to 50% reduction in dropouts linked to drug or protocol non-compliance
- Up to 30% reduction in eCOA cost due to device non-provisioning
- Increased site response to feasibility questionnaires and higher subject study participation and compliance due to integrated services
- Up to 80% reduction in on-site drug monitoring activities, data entry, and reconciliation
- Up to 100% reduction in wrong kit dispensing and high reduction in drug waste
- Up to 50% reduction in drug non-compliance related dropouts

## Enhanced data quality and oversight

- Up to 60% reduction in drug-related inspection / audit activities
- Up to 5% reduction in data management queries related to drug accountability
- Reduced consent-related audit findings such as missing names, etc.



### Meaningful insights and prevention

- Behavioral insights to predict dropouts and non-compliance
- Reminders to keep patients engaged throughout the study duration
- Direct insights into medication intake and behavioral changes at home
- Potential to develop drug medication intake models and novel insights

### Increased patient and site engagement

- Increased understanding and access to complete drug information
- Reduced administrative burden and increased patient safety
- Higher patient engagement due to personalized, easy-to-understand study information
- Enhanced site engagement with a single, unified solution

**Quicker go/no-go decisions** - Reduced assumptions of actual medication intake enabling faster decision making to continue with a compound

**Faster drug registration process** - Ability to combine individual studies, support adaptive trial designs, and alter medication intake on-the-go



# The TCS advantage

With CCT, you will be able to explore the use of the following differentiators:

## Developed for industry needs:

- Developed in alignment with cross-industry initiatives and outputs from ISPE, DTRA, TransCelerate, and such organizations
- Face-to-face workshops and events with industry-wide stakeholders from trial sponsors, medication and technology suppliers, patients, and sites
- Thought leadership shared via articles, seminars, webinars, and event participation

## Connected and compliant:

- Demonstrated integration with RTSM, ERP, EDC, and smart medication packages (pill/unit dose tracking)
- Configurable, modular, scalable, and compliant (21 CFR Part 11 and GDPR/HIPAA)

## Unified and flexible:

- Delivering enriched patient journeys and site experience throughout the study duration
- Available as a standalone application or can be integrated with other TCS ADD offerings such as e-Consent, Smart Questionnaires, Educational Material, Smart Devices and Wearables and Telemedicine.



# 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 consecutive 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 increase 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 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 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



Email: [add.platform@tcs.com](mailto:add.platform@tcs.com)

### About Tata Consultancy Services Ltd (TCS)

Tata Consultancy Services is an IT services, consulting and business solutions organization that has been partnering with many of the world’s largest businesses in their transformation journeys for over 56 years. Its consulting-led, cognitive powered, portfolio of business, technology and engineering services and solutions is delivered through its unique Location Independent Agile™ delivery model, recognized as a benchmark of excellence in software development.

A part of the Tata group, India’s largest multinational business group, TCS has over 601,000 of the world’s best-trained consultants in 55 countries. The company generated consolidated revenues of US \$29 billion in the fiscal year ended March 31, 2024, and is listed on the BSE and the NSE in India. TCS’ proactive stance on climate change and award-winning work with communities across the world have earned it a place in leading sustainability indices such as the MSCI Global Sustainability Index and the FTSE4Good Emerging Index.

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