

Solutions for Decentralized Clinical Trials

Decentralized clinical trial (DCT) models enable patients to enroll and participate in clinical trials from home or significantly reduce traveling to a central investigator site. COVID-19 caused a significant disruption in clinical development and a strain on the entire health care system, factors that helped to accelerate industry's adoption of the decentralized strategy. DCTs require careful consideration on design and execution — from protocol development to technologies to enroll and monitor patients, collect patient data remotely, and manage clinical supplies.

Design and Execution of DCTs

DCTs pose unique challenges that could potentially increase the burden on patients, sites, and sponsors if not carefully considered and addressed. YPrime has the expertise to design and execute effective DCT strategies that take full advantage of the benefits of technology while meeting regulatory requirements and expectations.

- Our scientific experts help clients focus on those endpoints and timepoints that answer the most important research questions and meet regulatory expectations
- Our patient insights and engagement team develops trial strategies and tools to keep patients more informed, boost compliance, and improve retention
- Our data science team are leaders in building new protocol-specific integrations with other platforms, medical devices, and applications

Decentralized Clinical Trial Solutions



eCOA solutions for DCTs

- Remote ePRO data collection with multiple modalities to increase flexibility and convenience for patients including handheld devices, BYOD, and web-based back up
- Patient engagement strategies and solutions to keep patients more informed, boost compliance, and improve retention
- Tablets for sites exclusively designed for eCOA data collection, sites may access multiple studies on the same device and single sign-on technology eliminates multiple system logins
- App-based architecture allows for a single build for all modalities, including web-based back up, reducing development time, risk, and costs
- Web-based back up solutions provide continuous data collection in the rare event of device malfunction, loss or when patients cannot travel to investigator sites
- Scientific experts help clients focus on those endpoints and timepoints that answer the most important research questions, meet regulatory expectations, and reduce the burden on patients
- Data science team to help clients optimize eCOA technology to drive better outcomes and deliver cleaner data

IRT solutions for DCTs

- Flexible design can accommodate early phase studies through late-stage trials with complex protocol requirements
- Platform supports remote, hybrid, and onsite visit schedules for individual patients
- Patient workflow feature accommodates unique visit structures and dispensation needs
- Multiple direct-to-patient clinical supply shipping models within a single study
- Treatment return module allows treatment to be returned by the patient, or marked lost, for drug accountability
- Discrepancy management feature enables verification of returns without a CRA
- Standard site IP return-to-depot module enables any kit previously reconciled to be returned to the depot
- Reconciliation reporting feature makes it easy to monitor compliance on a site level
- Lifecycle accountability feature provides a clear history of when materials are moved from one status to another—allocated to the patient, returned to the site (or pharmacy or depot), ready for reconciliation, reconciled
- 24x7x365 global technical support for sites and patients

Global Patient Insights for DCTs

- Actionable insights from patients, care partners, healthcare providers, patient advocacy groups, and payers
- Data driven insights that support client messaging, outreach strategy, adherence modeling and patient support programs
- Inform patient-focused protocols, trial designs, enrollment, retention strategies and tools
- Insights to help select and develop PRO tools that are relevant to the patient population, delivery methodology, ability constraints