# COVID-19 Accelerates the Adoption of Decentralized Clinical Trials

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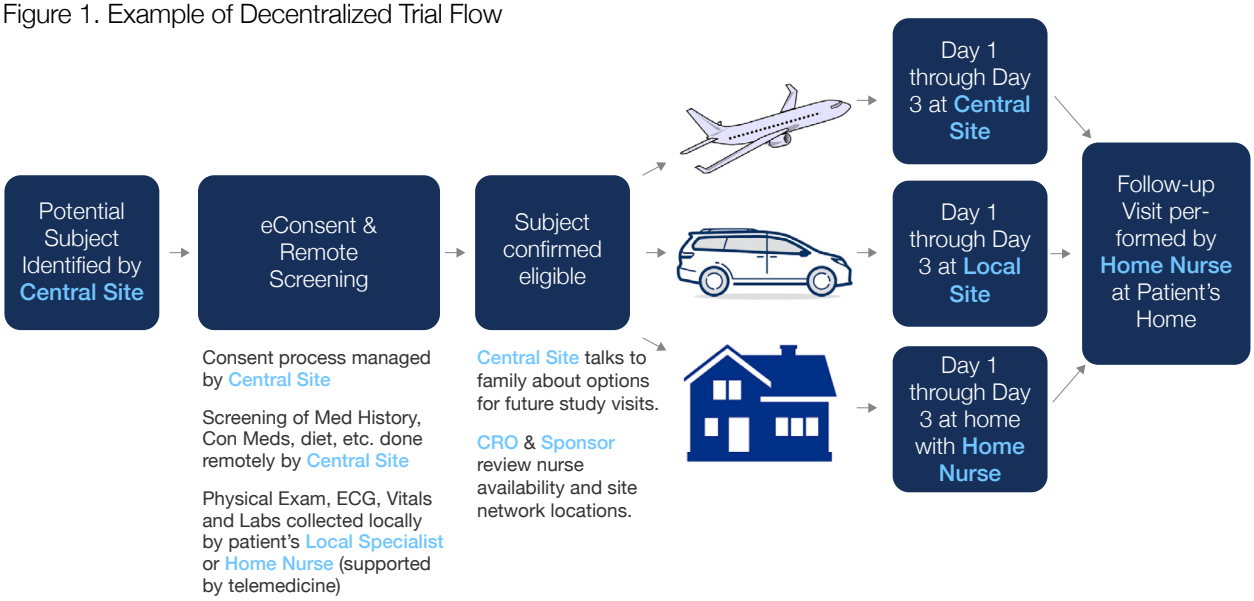
As the global COVID-19 pandemic continues to make all aspects of clinical trial conduct a challenge, many study sponsors have turned to decentralized clinical trial (DCT) strategies and tools as a solution for keeping studies moving forward. DCTs, which may be entirely virtual or a hybrid of on-site and off-site visits, offer a more patient-centric approach by reducing burden to both patients and their caregivers. To achieve this, DCTs leverage a wide range of digital technologies to collect safety and efficacy data from study participants, from the comfort of a patient's own home or from a convenient location of their choice. Ultimately, the goal of every DCT is to safely and effectively give the trial—and the study participants—the best chance for success.

### Case Study: Keeping a Pediatric Rare Disease Trial on Track During a Pandemic

#### Background

At Precision for Medicine, we have encountered and addressed firsthand the obstacles of clinical trial conduct in the setting of COVID-19. Recently, we assisted with a rare disease study involving children age 2-18 years that was facing challenges with recruitment and retention due to the public health emergency.

Figure 1. Example of Decentralized Trial Flow



### Solutions Implemented

- Collaborated with a patient advocacy group to identify more than 20 interested and eligible patients prior to the start of the study
- Implemented technologies for electronic consent and remote patient screening to be performed by sites
- Arranged for physician exam, vitals, ECG, and labs to be performed by a patient's local physician or a home nurse, with the support of telemedicine
- Offered the patient and their caregivers the option of off-site visits
- If off-site visits were selected, arranged for IP delivery and identified a nurse for home visits, with the same nurse assigned to the patient for the duration of the study
- When on-site visits were required, facilitated all travel arrangements including flights, hotels, and ground transportation

By implementing these solutions, we were able to successfully screen and enroll patients in this trial via DCT at the height of the pandemic.

### Benefits of a Decentralized Approach

Decentralization may not be appropriate for all studies based on existing trial design and the patient population being studied, Sponsors may need to consider adapting their primary endpoints to "de-risk" their studies during the pandemic; for example, by changing the primary endpoint so the data can be collected remotely via home healthcare or a wearable technology. When a study is suited for decentralization, there are several potential benefits:

- **Allowing studies to continue during the COVID-19 pandemic.** Patient and monitoring visits continue to be limited at some sites. Incorporating decentralization components can help overcome the current limitations of research due to the public health emergency by enabling assessments to occur via telemedicine or home nursing. Monitoring activities can be conducted remotely via monitor access to the Electronic Health Record (EHR) or other remote solutions
- **Enabling COVID-19 studies.** Sites may be reluctant—or unable—to take on studies involving patients with presumptive SARS-CoV-2 infection if on-site visits are required. Decentralization provides options for patients to remain at home while participating in the study, reducing potential exposure to site staff and patients
- **Providing increased flexibility and choice for patients.** The clinical trial landscape is competitive, particularly for rare and orphan diseases. Offering decentralization options to patients and sites can set studies apart and provide an edge when patients and sites are deciding which trial is the best for them. For patient groups who are not ambulatory, DCT services offers a valuable and cost-effective solution to enroll patients
- **Reducing patient and caregiver burden.** Traveling to sites can be inconvenient or difficult, particularly for patients who are ill. Pandemic-related travel restrictions have made site visits an even bigger obstacle. Decentralization reduces this burden by allowing off-site visits to occur at the time and location of the patient's choice
- **Improving retention.** Reducing patient and caregiver burden has the secondary benefit of improving retention, which limits dropouts and delays
- **Future-proofing.** In these uncertain times, proactively planning for decentralization options now—rather than trying to retrofit studies later—can help mitigate risk

### Decentralization Strategies

A range of services and capabilities may be needed to effectively conduct DCTs, from eConsent, electronic patient reported outcomes (ePROs) and wearable technologies to home nursing, telemedicine, and direct-to-patient investigational product (IP) shipments. The precise solutions required will vary from study to study and should be customized to the specific needs of the trial and the circumstances surrounding the patient.

### eConsent

Utilizing an eConsent solution allows patients to remotely consent to the study using a simple app on their smartphone. Therefore, screening procedures can either take place remotely or begin prior to the first site visit. Certain electronic data capture (EDC) vendors offer eConsent modules that are easily integrated into the site's existing EDC system.

### Electronic Patient Reported Outcomes (ePROs) and Direct Data Capture (DDC)

ePROs enable sites to capture patient reported outcomes such as pain scales or quality of life questionnaires using a smartphone, tablet, or computer. ePRO systems may improve data integrity as they typically include input validation to check that patient entries are valid and complete. They also have the benefit of being less time consuming for patients to fill out and for investigators to analyze. As with eConsent, certain EDC vendors offer ePRO modules.

Direct Data Capture (DDC), which eliminates the need to transcribe data into the EDC system and reduces the need for on-site monitoring, is now offered by several vendors. With DDC, data are collected via computer or tablet by the clinician directly into the database. Some DDC platforms can capture not only data, but also documents, audio, video, and even handwritten notes. The data entered into the database can be printed and scanned into the site's EHR system or medical record.

### Wearable Technologies

Depending on the data that need to be collected, there may be sensors or wearable devices that can be used for automatic data capture and reporting. Data types vary from vendor to vendor, but often include movement, vital signs, activity, posture, and sleep. Some vendors also offer integration with the EDC system. Innovative examples of FDA-cleared wearables include the MC-10 BioStamp nPoint®, a device designed to collect biometric, physiological, and electronic clinical outcome assessment (eCOA) data, and the BioIntellisense BioSticker™, a device that provides up to 30 days of continuous vital sign monitoring, gait analysis, and fall detection. Precision works with a vendor that can help sponsors choose the best wearable technology for their study.



### Telemedicine

The COVID-19 pandemic has also spurred an increasing number of healthcare providers to expand their use of telemedicine. During this public health emergency, the U.S. Department of Health and Human Services has issued guidance that provides HIPAA flexibility for telehealth services. Currently, HIPAA-covered healthcare providers may, in good faith, provide telehealth services using remote communication technologies such as FaceTime and Zoom, even if the technology is not fully compliant with HIPAA rules. While this flexibility is not expected to be permanent, it does enable study sponsors to leverage telemedicine for certain assessments, but may require a protocol amendment for existing trials.

### Home Healthcare

Home healthcare providers can be used to perform physical examinations, study procedures, IP administration, and drug accountability. The benefits of home healthcare go beyond just meeting the logistical needs for study visits in accordance with the protocol. Home healthcare providers can also provide personal support to patients and caregivers, building a rapport and sense of trust that keeps

study participants engaged. If possible, utilize the same nurse for each patient throughout the study to provide coaching and education to inspire adherence.

Alternatives to home healthcare include arrangements with a local laboratory or the patient's primary care physician for sample collection.

### Direct-to-Patient IP Shipments

This decentralization option allows IP to be delivered directly to the patient's home. Depending on the complexity of the study protocol, the IP may be administered by the patient, a caregiver, or a home healthcare provider. Implementation of direct-to-patient IP shipments requires a well-planned logistics strategy to ensure supply chain integrity and patient confidentiality.

### Key Takeaways

DCTs offer benefits to patients, caregivers, sites, and study sponsors alike, but require careful planning and coordination of sites and vendors. Working with a partner that has already vetted and qualified a diverse pool of decentralization vendors can help facilitate a seamless transition to decentralization. At Precision for Medicine, we have been conducting DCTs for rare and orphan diseases since 2014, with global projects across more than 80 disease conditions. We have built and qualified a network of more than 30 DCT vendors across the spectrum of patient services, enabling study sponsors to customize their trials based on their specific needs.

The COVID-19 pandemic has accelerated the adoption of decentralization strategies and added momentum to the broader trends of increased digitalization and patient centricity in clinical trials. As we continue to experience waves of rising and falling COVID-19 infections rates and prepare for the possibility that the colder months will bring additional spikes, building decentralization into trials from the outset may provide a level of future-proofing that helps ensure smooth, successful study completion.

**Precision for Medicine** has been working on the leading-edge innovation described in this article, as well as our other COVID-19 projects and services. Learn more below.