

# What is a Decentralized Clinical Trials?

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## CURRENT EVIDENCE!!

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“Decentralized Clinical Trials:”  
also termed “direct-to-participant trials” or “virtual” studies.

A separate side-effect of the pandemic has been the swift adoption of virtual interactions between physicians and patients to provide continuity of care while maintaining social distancing. This comes at a time of rapid advancement of technology permitting those interactions, such as enhanced internet connectivity, electronic health records, real-time video conferencing, smartphone health applications, and remotely connectable health monitoring devices that are becoming more accurate, practical, and affordable. Interest in decentralized clinical trials (DCTs) that use “virtual elements” like these has grown in parallel with acceptance of “virtual medicine,” accelerating shifts in clinical trial design that many feel are long overdue.” The concept of blockchain technology for healthcare applications and clinical trial data management is also briefly discussed.

### Advantages of DCTs:

#### Logistics and accessibility

DCTs improve logistics by enhancing:

- ✓ Subject recruitment and retention
- ✓ Remote monitoring and data collection
- ✓ Minimize obstacles to participants (travel costs, job absences, and medical comorbidities).

#### Individualized treatment effects

Development of individualized thresholds for measuring treatment effects.:

- ✓ Smaller studies
- ✓ Small sample sizes.

#### Precise assessment for treatment outcomes:

- ✓ Wearable devices provide more accurate, timely, and comprehensive real-time data.

#### Consistencies in trial management

Decrease site-specific inconsistencies:

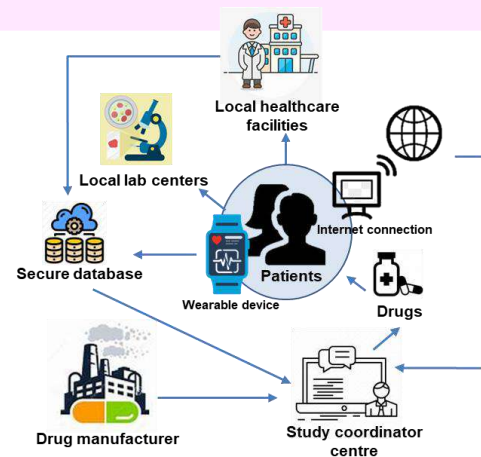
- ✓ Redundant applications, ethical submissions, and costs.

#### Remote patient/subject interaction:

- ✓ Occurs more frequently/at times
- ✓ Convenient locations for subjects,
- ✓ Improving compliance.
- ✓ Enhancing study safety.

#### DCTs rely on virtual tools and automation:

- ✓ Require smaller investigative teams
- ✓ Lower costs to sponsors.



Adapted from Gail A. Van Norman et al. *J Am Coll Cardiol Basic Trans Science* 2021; 6:384-387.

### Challenges of DCTs:

#### Drug distribution and management:

DCTs require shipping drugs to multiple coordinating sites, including potentially directly to patient homes:

- ✓ Drug stability, appropriate storage facilities, prevention of unauthorized access, and timely refills.

#### Technological challenges:

DCTs rely on technological advancements, such as wearable biometric devices, which are still in the early phases of development and require clinical validation.

#### Technical support and infrastructure:

Limited support and facility in remote locations or home:

- ✓ without internet connectivity
- ✓ Unavailability of technical support, troubleshooting, batteries, transmission methods, and internet infrastructure, which may be.

#### Patient privacy and cybersecurity:

Protecting patient privacy stored on connected devices and ensuring the security of transmitted information is a challenge in DCTs. Reliable cybersecurity systems are necessary to store and transmit private patient data securely