The Evolving Role of Decentralized Clinical Trials and Digital Health Technologies.

Q & A

CDER Conversations HERE

Interviews with CDER experts on priorities, projects, and initiatives

1. What are decentralized clinical trials and digital health technologies?

Location

- Clinical trial activities occur at locations other than a traditional clinical trial site.
- E.g. Participant's home, a local health care facility, or a nearby laboratory.

Use digital health technologies (DHTs)

- Use systems that capture health care information directly from individuals to the investigators.
- DHTS: e.g. activity trackers, glucose monitors, blood pressure monitors, or spirometers.
- Can be wearable, implantable, or ingestible.

2. Why are DCTs and DHTs becoming a larger component of the clinical trial landscape?

Advancement of available technologies

- Easier to collect, transfer, and store electronic data.
- Use of telemedicine to improve associated travel restrictions and physical distancing precautions.
- Improving recruitment and retention rates.
- DHTs enable frequent and continuous data collection,
- DCTs can reduce the time and expenses associated with traditional clinical trial sites.

3. We hear a lot about the underrepresentation of racial and ethnic minority populations in clinical research. How might DCTs and DHTs be part of the answer?

Reducing barriers to participation by these:

- ❑ **Traveling** - Older individuals and people with disabilities
- ❑ **Scheduled time** - People with household and childcare responsibilities
- ❑ **Clinical research facilities** - individuals from racial and ethnic minority groups.

4. We've discussed the benefits of DHTs and DCTs. What are the challenges?

Implementation challenges in transitioning to a digital clinical trial space

- ❑ e.g. storing electronic data securely, transporting treatments safe, data management skills, and data management platforms.

Technical hurdle:

- ❑ People uncomfortable with wearable sensors, without access to technology, or unfamiliar with electronic instruments may opt out of participating.

5. What is the FDA doing to address these challenges and continue the conversation about DCTs and DHTs?

- ❖ Support for development
- ❖ Guidance
- ❖ Digital development
- ❖ Stakeholder engagement

READ MORE HERE!

6. How do we expect DCTs and DHTs to evolve?

Hybrid models, where some trial activities take place at clinical trial sites and others at patients' homes or other convenient locations, are expected to be more common than entirely remote settings for clinical trials.