Decentralized Clinical Trials

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We consider a decentralized clinical trial to be a clinical trial where some or all of the trial-related activities occur at locations other than traditional clinical trial sites.

Why is FDA interested?

Source: Duchenne Foundation Australia

Duchenne's drug evaluation-6MWD

Obvious questions

- Couldn’t the 6-minute walk test be supervised by someone close to the patient’s home?
- Could the measurement be made electronically using a digital health technology?
- Could the visit be changed to a virtual visit, using videoconferencing with the investigator?

DCT activities are not new

- We have seen over the years, and particularly during the COVID 19 pandemic that many trial-related activities can be done by patients at home:
- In outpatient trials, once patients leave their study visits, trial activities are effectively decentralized
  - Adherence to treatment regimens is left to the patients
  - Adverse events are treated in local clinics and emergency rooms
  - Participants may complete patient diaries
  - Long term follow-up may be a telephone visit

Strategies to Bring the Trial to the Patient

- Video and telemedicine visits
- Direct distribution of investigational products
- Electronic informed consent
- Use of local health care providers and facilities
- Home visits
- Digital health technologies
- When appropriate, hybrid trials can be designed where some trial related activities require a visit to a clinical research site and others can be done remotely

Remote trial visits

- DCTs may involve a network of locations where trial personnel and local HCPs work and where trial-related services are provided, all under the oversight of the investigator
- Investigator can supervise remotely using video conferencing, telephone as appropriated

Challenges

- Local regulations on telemedicine
- Physical examinations
- Video photography - may not fully capture the features of a lesion
- Patient engagement in absence of in-person contact
- Complex drug administration procedures
- Close medical supervision – e.g., for infusion reaction

Use of local healthcare providers and facilities

- There are resources and qualified healthcare providers in the clinical care environment who may be used in trials
- Delegation routine clinical activities to patient's local clinic or healthcare provider for routine procedures- e.g., X ray, clinical examination, laboratory tests)
- Ensuring appropriate qualifications
- Task logs allow investigators to keep a record of who is doing what
- Regular review of data

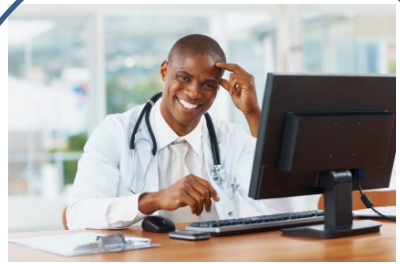
Home visits

- Novel approach
- Either dedicated or contracted trial staff
- Mobile trial units are being developed
- Extend the physical reach of the trial

Digital Health Technologies

- Access to continuous or frequent data
- Ability to detect sporadic events- e.g., seizures, arrhythmias, falls
- Patient reported outcomes “Ecological momentary assessments”
- Real world environment- work, exercise, sleep
- Objective record of functionality
- *Digital Health Technologies for Remote Data Acquisition in Clinical Investigations-guidance for industry*, January 2022

Oversight*



- Investigator
- Sub-investigator

FDA form 1572

- Local radiologist
- Local health provider
- Phlebotomist
- Visiting nurse

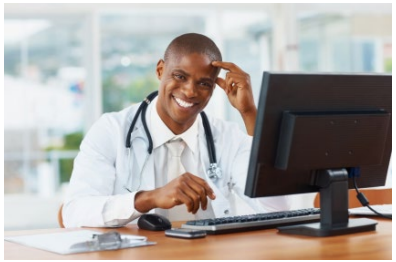
Task log

- Local emergency room
- Neighborhood clinic
- Pharmacy

Not part of study staff

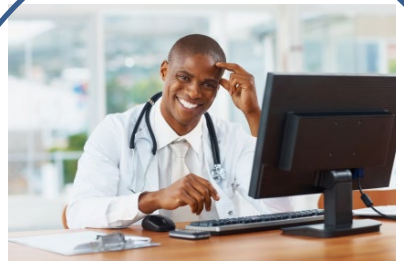
*Guidance for industry-Investigator Responsibilities — Protecting the Rights, Safety, and Welfare of Study Subjects, October 2009

Safety



- High risk products and severe diseases may not be suitable for DCTs
- Patients should be able to contact study staff
- Local medical facilities should be available for urgent care

Inspection



- Investigator
- Sub-investigator

Site inspection
- where the data are
- where study staff can be interviewed

- Local radiologist
- Local health provider
- Phlebotomist
- Visiting nurse

Local inspection
- may be necessary if problems are found

- Local emergency room
- Neighborhood clinic
- Pharmacy

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Conclusions

- Important opportunity to improve trial efficiencies, convenience for patients, access to diverse participants, rare diseases
- Electronic technology has broadened the scope of decentralized activities