Remote Clinical Research: Promise Meets Reality

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Current Clinical Research Environment

- COVID-19 pandemic challenged research teams to continue with their protocols
  - —Converted protocols to remote (remote consent, remote study assessments)
  - —Often converted because there was no other alternative
- Number of active clinical research protocols (trials) are increasing
  - —Multiple protocols targeting COVID were started
- Recruitment into trials remains below pre-COVID era
- More of the population have become comfortable with communication through the Internet

What is remote clinical research?

- Remote consenting
  - —Have talked with research participants through email or over the phone for many years
- Is getting the research participant signature on a research consent the only clear definition of “remote consent”?

How do we Define Remote Clinical Research?

- Protocols that are 100% remote from consent to completion
- Mixed protocols with in person and remote
  - —Should we consider the percent of encounters that are remote?
  - —Is there a difference between synchronous and asynchronous assessments?
- Protocols that converted from in person to remote

How does remote research impact on research coordinators?

- Research Coordinators may have more to learn since we want to give research participants more options
- More choices equals more work
- Many different approaches to remote consenting that need to be mastered
- More choices generally means longer consent forms because need to describe the options

Polling Questions

Major concerns about remote research

- Does remote research lead to bias in who enrolls?
  - Vulnerable populations with less experience and access to electronic communication are left out
  - Adding LRAs and interpreters to remote consenting very complicated
- Accurate assessment of identity and characteristics of those who enroll
- Remote consenting
  - Is it all about the signature?
  - Who decides not to participate in study if consent is remote?
  - We do not have data on the extent to which remote consenting is equivalent to in person in terms of completing consent, understanding, and overall satisfaction
- Safety concerns related to remote studies
  - Older adults living alone asked to complete research exercises
- Loss to follow up may be higher
- Quality of the data collection conducted remotely
  - Privacy and attention of research participant

Promise for Remote Research

- Allows incorporation of new measurement
  - —Wearables and continuous monitoring
- Decreases burden of participation so overall enrollment in research studies increases
- Establishes easier communication channels between research teams and participants
  - —Increases partnership bond
  - —Facilitates communication about study results

Summary

- Implementing trials will need to adapt to environment and remote communication is a new channel
  - —Are research participants now ignoring emails?
  - —Is travel to research site a burden?
- Remote trials still need to be judged by usual clinical research principles:
  - —Is there bias to enrollment?
  - —What were the followup rates?
  - —What was the quality of the data?
- While there are some general principles, each study will also need to be evaluated in terms of risk/benefit and alternatives available