Session IV: Optimizing Protocol Design & Execution

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Session IV Relevant Materials

Watch Session IV – Optimizing Protocol and Design Execution from Mobile Technologies Event

Optimizing Protocol and Design Execution handout

CTTI recommendations and resources:

- Recommendations

- Related Resources
  - Decision Support Tool: Real Time Data Sharing with Study Participants
  - Framework of Approaches for Safety Monitoring and Managing Safety Signals

- Related Case Study
  - Sharing Data to Promote Patient Engagement

Glossary: Definition Technical & Regulatory Terms
Protocol Design & Execution

CTTI recommendations & resources support sponsors seeking to:

- Develop protocols that optimize the benefits of mobile technologies.
- Identify the logistical requirements for executing these protocols.

Overarching principles:

- Engage patients in trial design from the outset.
- Scientific principles for protocol design are unchanged when mobile technologies are used for data capture.
Session Overview

Protocol Design Considerations
- Presentation: Sharing data in real-time
- Presentation: Real-time safety monitoring
- Discussion

The Logistics – how can sponsors optimize:
- The patient experience?
- The investigator experience?

Questions from the audience
Sharing Data with Participants in Real-Time

Abby Bronson, PPMD
Sharing Data in Real-Time

- Study participant safety is paramount.
- Preserving trial quality and efficiency is critical.
- Regardless of whether data is shared in real time, participants should be offered the opportunity to:
  - Review summarized data at the end of their enrollment.
  - Learn the overall results of the study at the completion of the trial.
Sharing Data in Real-Time

Only 2% of potential clinical trial participants feel it is “not important” to see information collected by a mobile technology they are asked to wear.

67% of respondents preferred to see their information at least weekly.

Conclusion: Sponsors should include some mechanism of data sharing into protocols using mobile technologies.

* According to a 2017 CTTI Survey of 193 individuals in research database.
Decision Support Tool: Real Time Data Sharing with Study Participants

- Is sharing and/or displaying data in real time part of standard care?
  
  *Example:* Use of a CGM in T1D

- Can participants, without clinician support or contextualizing information, understand the data?
  
  *Example:* An EKG wave vs. step count

- Are there clear instructions for and support available to participants who may notice nontypical or unexpected data?
  
  *Example:* An elevated heart rate

- Can this threat to internal validity be mitigated through study design?
  
  *Example:* Double-blind design to equalize any impact of behavior modifications across arms

- Are participants able and likely to modify their behaviors as a result of viewing snapshots or data in real time?
  
  *Example:* Low activity data motivating increased movement

- Does the target participant population expect that the data be shared with them in real time?

  - NO
  - YES

As long as trial integrity can be preserved, it is likely appropriate that data be shared in real-time with participants.

It is unlikely that it would be valuable to share data in real time with participants.
Real-Time Safety Monitoring

Michele Russell-Einhorn, Advarra
Communication & Transparency is Critical

Use of mobile technologies raises two new potential issues related to safety signals:

- Detection of safety signals not previously observed using traditional protocol design and monitoring.
- Data collected and observed by the study participant, in the absence of context provided by clinicians, may lead to difficulty distinguishing between normal data and a possible adverse event.

Study participants should be well informed regarding the level of safety monitoring, if any, that will occur when they use/wear their mobile technology.

The information about the level of safety monitoring must be described in the informed consent.†

†For more information, see 21 CFR 50.25(a)(1).
Framework for Safety Monitoring & Managing Safety Signals

CTTI framework supports the management of atypical data, including data captured outside of the intended use of the mobile technology.

- Defines a variety of options for addressing unanticipated data.
- Describes the implications and applications of these options.
- Provides illustrative examples of how these approaches may be applied in practice.

Framework addresses cases when the mobile technology:

- Is not intended for safety monitoring.
- Is capable of accurately and reliably measuring pre-specified, valid safety measure(s) in the context of use of the trial.

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<tr>
<th>Technology/ Data Capability</th>
<th>Approach</th>
<th>Implications &amp; Applications</th>
<th>Illustrative Examples</th>
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CTTI
Real-Time Safety Monitoring

Regardless of the level of safety monitoring actually occurring when participants use/wear their mobile technology, this information should be clearly communicated:

- At enrollment
- Throughout the trial
Session IV: Optimizing Protocol Design & Execution

- Panel Discussion: Protocol Design
- Fireside Chat: Logistical Considerations Around Trial Conduct
- Questions from the Audience
Recommendations Recap

1. **Data sharing** decisions should be driven by safety and trial integrity.

2. **Communication & transparency with participants regarding safety monitoring** is critical.

3. **Define & test processes** for the implementation, operation, & maintenance of mobile technologies in the field prior to launching the trial.

4. Have a plan in place for mobile technology failure.

5. **Considerations** that inform adaptive designs in a trial using mobile technologies are the same as for traditional studies.
New Supporting Resources

- **Decision Support Tool:** Real-Time Data Sharing with Study Participants
- **Framework of Approaches for Safety Monitoring & Managing Safety Signals**
- **Case Example:** Feasibility Testing to Promote Successful Inclusion of Mobile Technologies for Data Capture
- **Case Example:** Sharing Data to Promote Patient Engagement
THANK YOU.

https://www.ctti-clinicaltrials.org/projects/mobile-technologies

www.ctti-clinicaltrials.org