Session II: Data Collection, Analysis, & Interpretation

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Session II Relevant Materials

- Watch Session II – Data Collection, Analysis, Interpretation from the Mobile Technologies Event
- Data Collection, Analysis, and Interpretation handout
- CTTI recommendations and resources:
  - Recommendations
  - Related Resources
    - Strategies for Optimizing Data Quality
    - Appendix: Approaches to Promoting Correct Data Attribution
  - Related Case Study
    - Optimizing Data Quality & Participant Privacy

Glossary: Definition Technical & Regulatory Terms
Session Outline

Accelerometer-based tool
Evaluating physical activity
Subjects with heart failure
Number of active hours per day
Key Themes from the Recommendations

1. Minimum data set to fulfill endpoints
2. Monitoring and optimizing data quality
3. Proactive attribution with patient input
4. Identification of ranges and mitigation of variability
5. Minimize missing data
6. Appropriate planning for statistical analysis
7. Establish standards to support scaling acceptance
Recommendations in Summary

- Biostatisticians and data scientists, as appropriate, should be involved in all decisions regarding protocol design, data collection, analysis, and interpretation.
- Collect the minimum data set necessary to address the study endpoints.
- Include appropriate strategies for monitoring and optimizing data quality.
- Address data attribution proactively with patient input.
- Identify acceptable ranges and mitigate variability in endpoint values collected via mobile technologies.
- Minimize missing data.
- Plan appropriately for the statistical analysis of data captured using mobile technologies.
- Establish industry-wide standards to drive the successful scaling and more rapid acceptance of clinical trials using mobile technologies for data capture.
Supporting Resources

| Table outlining strategies for optimizing data quality |
| Case examples: |
| • Feasibility Testing to Promote Successful Inclusion of Mobile Technologies for Data Capture |
| • Optimizing Data Quality and Participant Privacy |
| Appendix describing technical approaches to promoting correct data attribution |
THANK YOU.

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

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