Session II: Data Collection, Analysis, and Interpretation

SUMMARY OF CTTI RECOMMENDATIONS ON DATA COLLECTION, ANALYSIS, AND INTERPRETATION

- 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.

CTTI RESOURCES DEVELOPED TO SUPPORT DATA COLLECTION, ANALYSIS, AND INTERPRETATION

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

TAKE ACTION: Visit https://www.ctti-clinicaltrials.org/projects/mobile-technologies to access CTTI’s Mobile Technologies recommendations and resources

TERMS USED IN THIS SESSION

Data Attribution – The process of establishing a particular individual/participant as the creator of a data point.

Data Epoch – A measurement of duration, the brief time interval during which data is collected and summarized.

High-Quality Data – Data strong enough to support conclusions and interpretations equivalent to those derived from error-free data.

Metadata – A set of data that describes and gives information about other data. Metadata is structured information that describes, explains, or otherwise makes it easier to retrieve, use, or manage data.

Mobile Technologies – Mobile applications and other wearables, ingestibles, implantables, and portable technologies containing sensors for the capture of outcomes data.

Raw Data – Output from physical sensor. If the sensor data is not accessible because it is processed by the firmware before being recorded, then the output of the firmware is often considered “raw” data.

Structured Data – Data that can be easily stored, queried, recalled, analyzed, and manipulated by machines.

A complete listing of all terms and definitions are listed in the glossary available at https://bit.ly/2uj5ZoW
SESSION SPEAKERS

Brian Bot  
Principal Scientist, Sage Bionetworks  
Mr. Bot is a Principal Scientist at Sage Bionetworks, a not-for-profit organization dedicated to exploring open source models in the advancement of biomedical research in Seattle, Wash. Previously, Mr. Bot worked in the Department of Biomedical Statistics and Informatics at the Mayo Clinic for seven years. He has extensive experience in working with clinical and genomic data and has a passion for exploring innovative ways to make science more open and transparent. Mr. Bot was an expert advisor to the CTTI MCT Mobile Technologies project team.

Aiden Doherty, Ph.D  
Senior Research Fellow, University of Oxford  
Dr. Doherty is a senior research fellow at the University of Oxford. His research interest is in the development of computational methods to extract meaningful health information from complex and noisy sensor data in very large health studies (e.g. over 100,000 UK Biobank participants). This builds on experience at Microsoft Research, Dublin City University (both in computing departments) and the University of Oxford (population health and biomedical engineering). In 2015, Dr. Doherty was one of only three Marie Sklodowska-Curie Actions COFUND Award winners (selected from ~9000 Marie-Curie fellowship holders between '07-'13) for his contributions to health sensor data analysis. Dr. Doherty is a member of the CTTI MCT Mobile Technologies project team.

Luca Foschini, MS, Ph.D  
Co-founder and Chief Data Scientist, Evidation Health  
Dr. Foschini is the Co-founder and Chief Data Scientist at Evidation Health, responsible for data analytics and research and development. At Evidation, he has driven research collaborations resulting in numerous publications in the fields of machine learning, behavioral economics, and medical informatics. Previously, Dr. Foschini held research positions in industry and academic institutions, including Ask.com, Google, ETH Zurich, and UC Santa Barbara. He has co-authored several papers and patents on efficient algorithms for partitioning and detecting anomalies in massive networks. Dr. Foschini provided expertise throughout the CTTI MCT Mobile Technologies project, participating as a key informant during evidence gathering and attending the expert meeting.

Nina Mian, MSc, MBA  
Head of Biomedical Informatics, Advanced Analytics Centre, AstraZeneca  
Ms. Mian leads the Biomedical Informatics Group, part of the Advanced Analytics Centre at AstraZeneca. This global team pioneers the use of novel visualization methods and advanced analytical tools to improve drug development decision-making. Ms. Mian’s research interests include initiatives focused on creating patient-centered insights. She holds degrees in Biochemistry and Informatics, and an MBA from Manchester Business School, UK. Ms. Mian helped to determine the direction and scope of the different projects within the CTTI MCT program.

Ken Skodacek, MS  
Policy Analyst, Clinical Trials Program, Center for Devices and Radiological Health, FDA  
Mr. Skodacek has been working with medical devices for over 25 years, currently as a policy analyst for the Clinical Trials Program in the FDA’s Center for Devices and Radiological Health. He leads the development and implementation of policies intended to improve the investigational device exemption submission and review process. As a representative from FDA’s Center for Device in the Clinical Trials Program in the Office of Device Evaluation, he has presented FDA’s perspective on the topic in a large number of mobile and digital health forums. Mr. Skodacek works with review teams and sponsors across product areas to encourage communication in order to resolve FDA’s questions and concerns to expedite appropriate approvals of Investigational Device Exemption (IDE) clinical investigations. Mr. Skodacek was a member of the CTTI MCT Novel Endpoints project team.
A GUIDE TO USING MOBILE TECHNOLOGIES FOR DATA CAPTURE

Collecting, Analyzing, & Interpreting Data
- 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

To access the complete packet of recommendations and resources as a .zip file, please click [here](#).

CTTI’S JULY 16 MOBILE TECHNOLOGIES EVENT

- Download the presentation
- View related July 16 event materials