Session V: FDA Submission and Inspection

SUMMARY OF CTTI RECOMMENDATIONS ON FDA SUBMISSION AND INSPECTION

- Ensure that trials conducted using mobile technologies for data capture can be readily reconstructed (i.e., end-to-end traceability).
- Source data should be the primary data resource provided to FDA during inspection.
- Be prepared to provide supporting material for mobile technology-based claims to FDA as part of any marketing application.

CTTI RESOURCES TO SUPPORT YOUR FDA SUBMISSION AND INSPECTION

- Data flow diagram
- Schema illustrating the data and supportive information to provide FDA inspectors
- Schema depicting what sponsors should include in their submissions to FDA

TAKE ACTION: Visit https://ctti-clinicaltrials.org/our-work/digital-health-trials/ to access CTTI's Mobile Technologies recommendations and resources

TERMS USED IN THIS SESSION

Audit Trail – A process that captures details of information—such as additions, deletions, or alterations—in an electronic record without obscuring the original record; an audit trail facilitates the reconstruction of the course of such details relating to the electronic record.

Data Element – A recorded assessment of a single observation associated with a subject in a clinical study.

Durable Medium – Media that can be stored, accessed easily, and reproduced at convenience.

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.

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.

Source Document – Original documents, data, and records are source documents. The earliest practically retainable record should be considered as the location of the source data and therefore the source document.

Source Data – All information in original records and certified copies of original records detailing clinical findings, observations, or other activities in a clinical investigation used for reconstructing and evaluating the investigation.

Validation – The process of ensuring that the mobile technology is meeting its intended use by generating objective data that accurately represents the outcome assessment it purports to be measuring.

Verification – The assessment of accuracy (which may include routine calibration), precision, consistency across time, uniformity across mobile technologies, and possibly also across different environmental conditions. Verification also provides assurance that the relevant firmware /software that generates processed data is accurate, precise, consistent, and uniform.

A complete listing of all terms and definitions are listed in the glossary available at https://ctti-clinicaltrials.org/wp-content/uploads/2021/06/CTTI_Mobile_Technologies_Glossary.pdf

SESSION SPEAKERS

Jonathan Helfgott, MS

Coordinator, Regulatory Science Program, Johns Hopkins University

Mr. Helfgott is program coordinator in the MS in Regulatory Science program at Johns Hopkins University where he teaches and advises students. Additionally, he is the Director of Global Regulatory Affairs at Stage 2 Innovations. Prior to joining Stage 2 Innovations in early 2015, Mr. Helfgott was formerly the Associate Director for Risk Science, within the Office of Scientific Investigations at FDA's Center for Drug Evaluation & Research (CDER). Prior to joining CDER in 2010, Mr. Helfgott worked at the FDA's Center for Devices and Radiological Health (CDRH) within the Division of Bioresearch Monitoring (BIMO). Mr. Helfgott is a member of the CTTI MCT Mobile Technologies project team.

Matthew Kirchoff, PharmD, MS, MBA

Clinical Research Oversight Manager, Office of Clinical Research Policy and Regulatory Operations, NIAID, NIH

As NIH / National Institute for Allergy and Infectious Diseases (NIAID) Country Co-Lead in Liberia, Lt. Cmdr. Kirchoff provides clinical and operational leadership and support to the Liberian-U.S. Joint Clinical Research Partnership, which started with Ebola and is now progressing to other infectious diseases. Lt. Cmdr. Kirchoff also maintains his duties as a Clinical Research Operations Manager for International Research Pharmacy Operations with NIH / NIAID. He manages or has previously managed pharmacy operations in multi-site international clinical investigations, including recent Ebola-related vaccine and treatment trials in Liberia, Sierra Leone, Guinea, and Mali. Lt. Cmdr. Kirchoff previously developed policies related to the conduct of clinical investigations under the Associate Director for Clinical Methodologies in CDER's Office of Medical Policy, and worked in CDER's Office of Unapproved Drugs and Labeling Compliance within the Office of Compliance. Lt. Cmdr. Kirchoff is also a Commander in the United States Public Health Service, and has participated in several officer training courses, two domestic deployments, and many deployments to West Africa. Lt. Cmdr. Kirchoff is a member of the CTTI MCT Mobile Technologies Project Team.

Thomas Switzer, M.Ed.

Innovation Project Manager, Strategic Innovation, Genentech

Mr. Switzer is a principal project manager in the Roche PHC Center of Excellence supporting Digital Health Platforms. His current focus is on developing technology platforms supporting molecule teams across the Roche late-stage organization. Mr. Switzer has over 18 years of clinical development experience, including six years of experience in developing and deploying digital technologies in clinical trials. He has been at Roche since 2010 serving in a variety of roles within Clinical Operations and Innovation groups. An Exercise Physiologist by training, he has been continuously tinkering with the various digital widgets on himself before testing them on other people. Mr. Switzer is a member of the CTTI MCT Mobile Technologies Project Team.

A GUIDE TO USING MOBILE TECHNOLOGIES FOR DATA CAPTURE

FDA Submission & Inspection

- Recommendations

- Related Resources
  - Data Availability for FDA Inspection
  - What Sponsors Should Include in Submissions to FDA

- Glossary: Definition Technical & Regulatory Terms

CTTI'S JULY 16 MOBILE TECHNOLOGIES EVENT

- Access the recommendations and resources. (zip file)
- Download the presentation
- View related July 16 event materials