Session V: Supporting FDA Submission & Inspection

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Session V Relevant Materials

- Watch Session V – Supporting FDA Submission and Inspection from Mobile Technologies Event
- FDA Submission and Inspection handout
- CTTI recommendations and resources:
  - Recommendations
  - Related Resources
    - Data Availability for FDA Inspection
    - What Sponsors Should Include in Submissions to FDA

Glossary: Definition Technical & Regulatory Terms
Session Information

Planning & preparing for FDA inspection
- Source data, audit trails, and what’s needed for mobile technologies when the FDA knocks.

Planning for FDA submission
- Getting ready to submit—what goes to the FDA when you use mobile technologies for data capture?
CTTI Recommendations on Preparing for FDA Inspection

Jonathan Helfgott, Johns Hopkins University
Some Background: The FDA Inspection Process

Process for issuing GCP inspection assignments

- Work with review divisions
- Issued to and conducted by ORA
- Different entities
  - Sponsor vs. CRO vs. Clinical Investigator sites

Types of inspections

- Pre-approval
- Routine
- For-cause
- Follow-up

*Inspections should be something you plan for throughout study design and conduct, not an afterthought.*
When mobile technologies are used for data capture, sponsors should define *source data* as the first level of data that is both clinically relevant to the trial and interpretable.

*Example: In a trial using a heart rate monitor to capture data to assess heart rate variability, sponsors may choose to define heart rate (beats/min) as the source data.*

Applying this approach requires that sponsors select mobile technologies that have been appropriately *verified*, and that all algorithms applied to the raw data to generate the source data have been *validated*.
FDA Inspection: Audit Trails Reviews

- Audit trails should track the data (including any modifications made to the data) from the point of creation in the mobile technology to the **durable media**.
  - This audit trail information should be recorded in the durable media.

- The earliest practically retainable record of the data captured by the mobile technology be defined as the **source document**.

- Typically, this means that the source will be the mobile technology manufacturer’s servers, or the server of another electronic vendor or CRO.

- Do not use mobile technologies or their companion apps for long-term data storage in order to protect and promote data security.
Study team has read only access to an appropriate level of data through an API

CTTI Resource: Summarizing Data Availability for FDA Inspection

Note: FDA regulations, per 21 CFR Part 11, do not require data to be maintained in a specific format.
CTTI Recommendations on Preparing for FDA Submission

Matt Kirchoff, NIH, NIAID
Data Processes and Information to Provide to FDA

- **Endpoint & Evaluation of Endpoint**
- **Information to Provide FDA**
- **Include in Statistical Analysis Plan**

- Evidence supporting technology verification*
- Evidence to show that algorithm is appropriate for desired endpoint (validation†)
- Evidence to show clinical meaningfulness of endpoint‡

- Filters used to “clean” noise from data set
- Algorithm/statistical models used to interpret data
THANK YOU.

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

www.ctti-clinicaltrials.org