Management of Imaging Data in Clinical Trials: Storage

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Overview:

- Data Storage: What You Need to Store

- Data Storage: How You Need to Store
  - 21 CFR Part 11 Compliance (Electronic Records)

- Software Solutions: Requirements

- Software Solutions
  - Commercial
  - Public Domain

- The Clinical Data Interchange Standards Consortium (CDISC) Paradigm

The Big Picture

- **DICOM:** We have a pretty good (not perfect), mature, and stable medical image transmission and storage standard. *But we do NOT have a standard method mandating how imaging data should be bound to related, non-imaging clinical trial data as part of a Clinical Trial Database system.*

- **Data Size:** Even imaging data from just a single patient can be **huge** (several GB) relative to other kinds of clinical trial data.

- **FDA's Role: FDA is the final arbiter** of the acceptability of Imaging Data collected in support of a clinical trial. The imaging community requires **GUIDANCE** from FDA to understand what FDA considers necessary and important.

Data Storage: What You Need to Store

- **DICOM Image Data** (In duplicate at different physical sites (21 CFR Part 11)
  - Should be deidentified PRIOR to transmission to storage.
    - Deidentification is non-trivial as identifying information is sometimes hidden in non-standard header fields.

- **Non-DICOM Image Data**
  - fMRI – When existing DICOM fails
    - Analyze, MINC, AFNI, **NIfTI (Neuroimaging Informatics Technology Initiative)**
  - 3D and 4D Ultrasound?

- **Associated Clinical Trial Metadata**

- **Raw Image Data** (Projection Data)?
  - Necessary? For how long? Burdensome for the imaging site.

Data Storage: How You Need to Store (21 CFR Part 11 Compliant Database)

- **Internal Security Safeguards**
  - Limited Access (passwords...)
  - Audit Trails
    - Additions, deletions, or alterations necessary to verify the quality and integrity of the data.
    - Computer generated, time stamped electronic audit trails are preferred.
  - Date/Time Stamps
    - Systems should be time and date synchronized.

- **External Security Safeguards**
  - Physical access to systems limited. Procedures and controls to prevent altering, browsing, querying or reporting data that do not enter through secure means.
  - Written records indicating authorized personnel with access privileges, must be available for FDA inspectors.
  - Controls to detect, mitigate effects of computer viruses, worms, and other potentially harmful software code.

- **Storage is a Process**, not just a service. SOPs must be defined and in place.

- **Separate "Storage Service"** must be implemented for each trial for sites that house data for multiple clinical trials.

Data Storage: Software Solution Requirements

- DICOM Image Storage
  - System should provide a standard means to attach relevant clinical trial metadata to imaging data. (No Standard)

- Programmable DICOM Header Scrubbing
  - All vendors and modalities have different deidentification issues. **DICOM standard is open for interpretation.**

- System should be able to track and document data from receipt, to interpretation, to analysis.

- Imaging Data & Metadata must be stored in a database in such a way that it can be seamlessly submitted and audited by FDA. (NEED FDA GUIDANCE).

Data Storage: Software Solutions?

- Commercial
  - "Oracle Clinical" - http://www.oracle.com/us/industries/life-sciences/046720.html
    - Integrated Clinical Data Management
    - Remote Data Capture

  - McKesson – 6-12 months from commercial release?
    - "Research Share"
    - "Horizon Study Share"

Data Storage: Software Solutions

- Some Non-Commercial Implementations
  - NCI caBIG – cancer Biomedical Informatics Grid
    - SciPort –Open Source
  - ACRIN – ACR Imaging Network
    - NCI-funded clinical trials cooperative group charged with conducting multi-center clinical trials of diagnostic imaging and image-guided treatment technologies
  - RSNA
    - MIRC (Medical Imaging Resource Center) Storage Service for Clinical Trial – http://mircwiki.rsna.org
      - Transmittal, Deidentification, Storage
  - ADNI
    - LONI - http://www.loni.ucla.edu/ADNI/Data/
  - XNAT
    - http://www.xnat.org/

The CDISC Paradigm

- **CDISC (Clinical Data Interchange Standards Consortium)**

  http://www.cdisc.com

  "CDISC is a global, open, multidisciplinary, non-profit organization that has established standards to support the *acquisition*, *exchange*, *submission and archive of clinical research data and metadata*. The CDISC mission is to develop and support global, platform-independent data standards that enable information system interoperability to improve medical research and related areas of healthcare."

- CDISC defined standards are commonly used and accepted in Clinical Trials regulatory submissions.

  However, to date, CDISC has not seen fit to directly address harmonization of DICOM with CDISC relative to their submission standards