Data Management and Good Clinical Documentation

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Learning Objectives:

• Distinguish between the Regulatory Binder and the Subject Binder
• Provide examples of source data and documents
• Define ALCOA and explain its importance to clinical research
• Describe how to correct recorded data, following Good Documentation Practices
• Define a “certified copy” of electronic data
Why is Good Clinical Documentation Important?

Inadequate/inaccurate case histories (subject records) are the second most commonly cited deficiency in US-FDA inspections of clinical investigator sites.

- FDA (21 CFR 312.2 (b)) requires that the investigator prepare and maintain accurate case histories designed to record all observations and other data pertinent to the investigation on each individual treated with the investigational drug or employed as a control in the investigation”.

Source documentation is also a common areas of concern during sponsor audits & monitor visits
Good Clinical Documentation is a requirement of GCP ICH E6 (section 4)

- Ensures the accuracy, completeness, legibility, and timeliness of CRF (case report form) data
- CRF data should be consistent with the source documents, or the discrepancies should be explained
- Prevents queries!

Bottom Line:
The quality of the documentation directly affects the quality of the data

In = Out!
Medical Record vs. Research Record:

**Medical Record**
- The collection of information concerning a patient and his or her health care

**Research Record** (includes the Regulatory Binder and Study/subject record)
- Collection of all pertinent study and clinical information, necessary for the reconstruction and evaluation of the study
- Research records are **NOT** part of the legal health record
- Should contain all the information necessary for an independent observer to reconfirm the data and reconstruct the entire trial
Research Records should demonstrate:

• that subject rights and welfare and safety were protected
• the accuracy, integrity and credibility of the collected data
• the study was conducted in compliance with the protocol, regulations, institutional policies

** Good Clinical documentation is the tool that ensures these fundamental principles are upheld**
Study/Subject Binder:

Collection of all pertinent study information for a single subject, necessary for the reconstruction and evaluation of the study:

- Original Informed Consent (*this is a requirement!)
- Completed source documents
- Certified copies of required study data
- Forms/evaluations completed by subject
- Reminder/reference worksheets
Source Data:

The original records of original findings, observations or other clinical trial activities necessary for the reconstruction and evaluation of the study findings

These will be found in...
Source Documents:

The records where data is **first recorded**.

Examples include:

- progress notes, lab reports, radiologic results, print-outs from point of care devices, operative reports, etc. (may even be a napkin!)
- Self-reported and self-administered assessments (aka Patient Reported Outcomes or PROs)
  - diaries or questionnaires completed by the subject
- Phone encounters

Maintained in the study/subject binder and transcribed into...
Case Report Form (CRF):

Primary data form where all study-required information is collected, for each enrolled subject

• May be paper or electronic
• Usually provided by the Sponsor, if Industry sponsored trial
• All required data elements included are defined and driven by the protocol

...not to be confused with CFR (Code of Federal Regulations)
Source Documents:

• Must contain the information that substantiates all data in CRFs
  • Does the data entered into the CRF match the source?
  • Is the data complete and consistent?
• Creates an audit trail
  • This is what a Monitor is confirming!
  • This also may be audited by others
Challenge Questions:

1. Is the copy of the signed Informed Consent, found in the subject’s medical record the source document?

2. Are printed Chest X-ray results a source document?
Source Documents: Creating your own

For the purpose of recording source data that is not typically found in the Medical Record

• Must include signature and date of person entering/recording information
• May want to refer to CRF Completion Guidelines to follow how data should be recorded

Examples:

Date: day/month/year or month/day/year
Time: 1:00pm or 1300
Hypertension at site = >140mm/hg
Hypertension per sponsor = >130mm/hg
**ALCOA:** Fundamental elements of quality data

**Attributable:** Is it traceable to the person responsible for recording visit with date, time and subject visit?

**Legible:** Is it clear enough to read?

**Contemporaneous:** Was it recorded as it happened, in real-time? *(NO post or pre-dating!)*

**Original:** Is this the first place data is recorded?

**Accurate:** Are the details complete and correct?
ALCOA: Fundamental elements of quality data

More recent additions:

**Enduring:** Long-lasting and durable

**Available and Accessible:** Easily available for review and/or retrievable in a reasonable time

**Complete and Credible:** based on real and reliable facts and complete to that point in time

**ALCOA is applied to both paper and electronic source data**
Good Documentation Practices:

Changes or Corrections:
- A single line through original entry (do not obscure!)
- Corrected data immediately adjacent to original data
- Date and initials

Never:
- Erase or record in pencil
- Scribble out, obscure, or obliterate the original information
- Use White-out

ICH GCP 4.9.3.
11/23/2016
11/24/2016 KO 11/24/2016
Monitoring Electronic Records:

**Certified Copy:** a copy of original information that has been verified as an exact copy having all of the same attributes and information as the original, as indicated by a dated signature.

21 CFR 11: Electronic Records and Signatures

Regulations that define when and how the FDA will accept electronic records and signatures as reliable and equivalent to paper
IMPORTANT:

If data or source documents must be sent off-site, it must be completely de-identified!

Example: If you need to send information to the Sponsor r/t and AE

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RATH-001

cc: Brian D. Fedchin, M.D.
    Mital P. Sheth, M.D.
    Shuwei Wang, MD

Dictation Date/Time: 05/19/2016 09:25 P
Date/Time Transcribed: 05/19/2016 11:04 P
Transcriptionist pcy/Job: [redacted]

CS # [redacted]

The discharge instructions that will be included as part of the medical record are the ones signed by the patient (or patient representative) and the appropriate staff (Practitioner and/or RN). Please see JeffNotes Signature Plus for this document.

Discharge Instructions Report (FINAL)
Name: [redacted]
MR#: [redacted]
Date of Birth: [redacted]
Discharge Date: [redacted]
Admission Date: [redacted]
Diagnosis
1) Chest Pain
2) Heart Failure, Systolic - (caused by decreased heart pumping power)
Take Home Points:

• If it is not documented, it didn’t occur
• The quality of the documentation directly affects the quality of the data
• All research documentation should create a clear, comprehensible and unambiguous audit trail
  • That mirrors the protocol requirements
  • That demonstrates regulatory compliance