Good Documentation Practices for Clinical Research

How to implement Site Data Management to produce research-quality data

athn™
american thrombosis & hemostasis network

ATHN 2 Factor Switching Study

Secondary Objective

- Proof-of concept for collecting research-quality data through the ATHN infrastructure
  - ATHN 2 is the first ATHN project utilizing a large number of ATHN–affiliated sites and its infrastructure for an observational, prospective study of several hundred patients

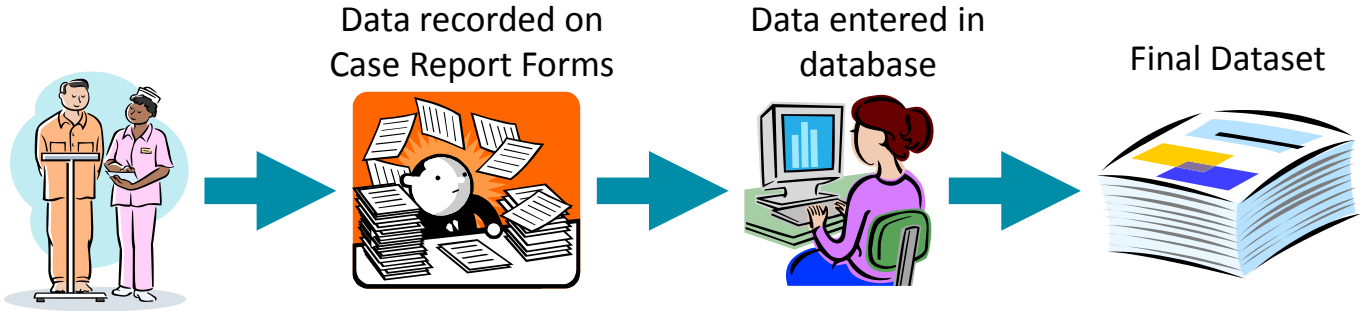
- Today's Training Objective
  - Provide Site Data Management tips and Good Documentation Practices training to ATHN affiliates and staff new to research to ensure ATHN 2's success as a study

Good Documentation Practices

For Clinical Research

- Flow of Research Data as ‘Site Data Management’
- Elements of Research Quality Data
  - Principles of ALCOA
  - Proper Error Correction
- Practical Tips for Success

Flow of Research Data



- Source Documents must support all research data as submitted
- eCRFs minimize the transmission of data several times by several people
  - Sources of error and bias
- Good Documentation Practices can minimize errors, maximize efficiencies to promote data quality

Source Documents and Case Report Forms

In 2015 'Hybrid' Electronic Systems & Paper-based Documentation

Electronic Medical Records (eMR)

- Source 'Documents' may also be used for research

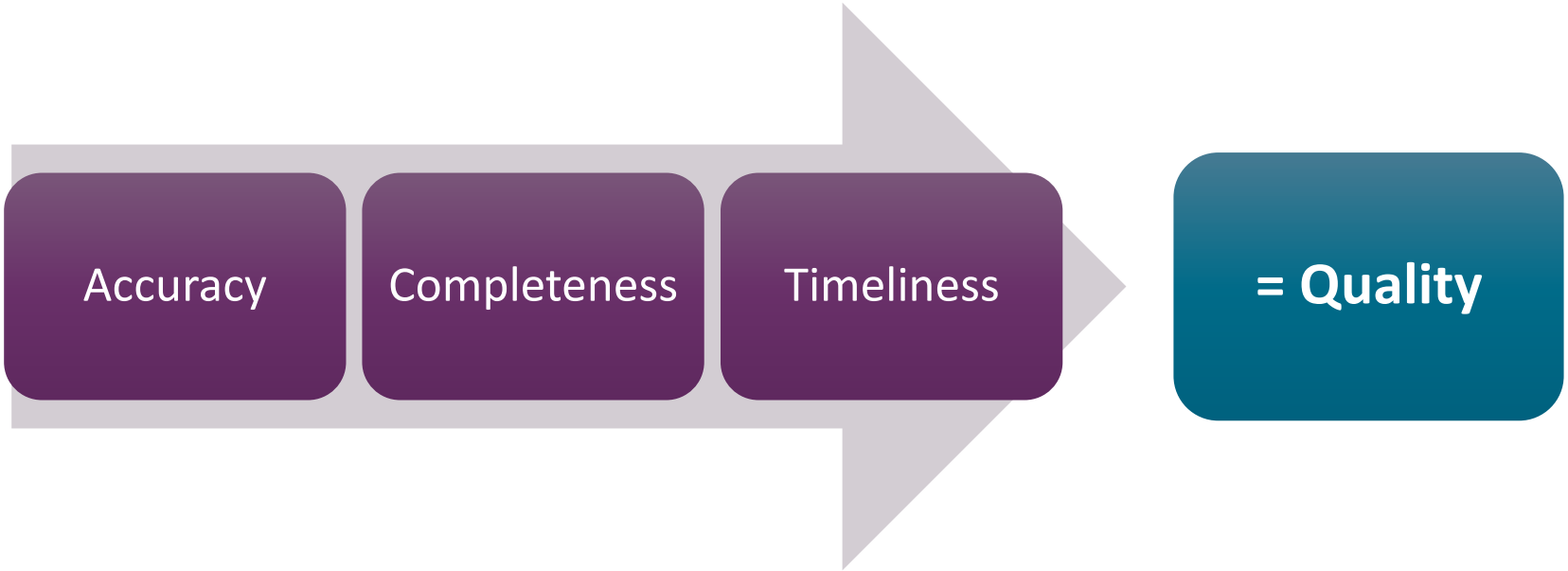
Electronic Case Report Forms (eCRF)

- Clinical Manager data populating Study Manager streamlines this dramatically but…

Paper-based Documentation

- A separate hard-copy file or 'Research Record' may still be needed for:
  - original, signed ICF
  - clinician visit notes or worksheets
  - laboratory results,
  - provider correspondence

What is research-quality data?



What is Site Data Management?

- Each site should have site-specific processes in place to ensure that high quality data are submitted as required for each research study, in accordance with the principles of ALCOA, an evidenced-based standard for data quality
- Evidence can be
  - Paper
  - Electronic
  - Hybrid

What is ALCOA?

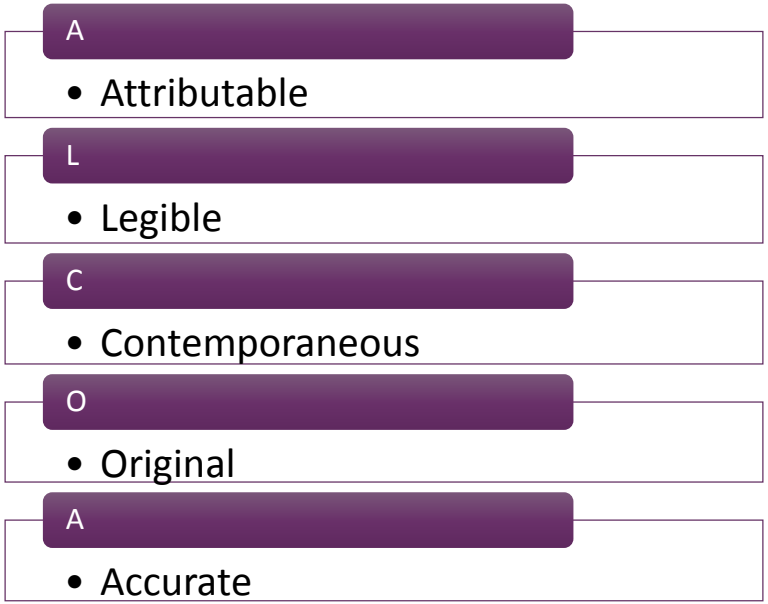
What is ALCOA?

Evidence-based Standard for Research

- Regulatory agencies, inspectors and auditors assess compliance with the ALCOA standards
- The FDA has been using the ALCOA acronym as a guide to their expectations regarding evidence
  - Paper-based
  - Electronic
  - Hybrid
- ICH defines Essential Documents as documents that individually and collectively permit evaluation of both the conduct of a clinical trial and the quality of the data produced in the trial

What is ALCOA?

Evidence-based Standard for Research



How to meet ALCOA Standards

- Attributable and Contemporaneous
  - One person should be responsible for submission of study data for each patient's study visit
  - In real-time, have clinicians sign any forms requiring signatures
  - Do not combine subjects' files
  - Promptly submit data

How to meet ALCOA Standards

- Legible, Accurate and Complete
  - Do a careful review of completed CRFs prior to entry
  - Don't guess
  - Minimize open text
  - Do not write in the margins of CRFs; This data does not get captured
  - Pay careful attention to dates
  - Correct errors properly

Error Correction

Good Documentation Practices

Error Correction

- Never obliterate entries that require correction
  - Errors must be corrected without obscuring original
- Never use correction fluid or tape (e.g., white out, liquid paper)

  Note: Redacting private information (e.g., patient names) is ok

- Never destroy original documents (even if they require error correction!)
- Do not alter past-dated notes and never back-date e.g., by writing alongside or adding to prior entries

Good Documentation Practices

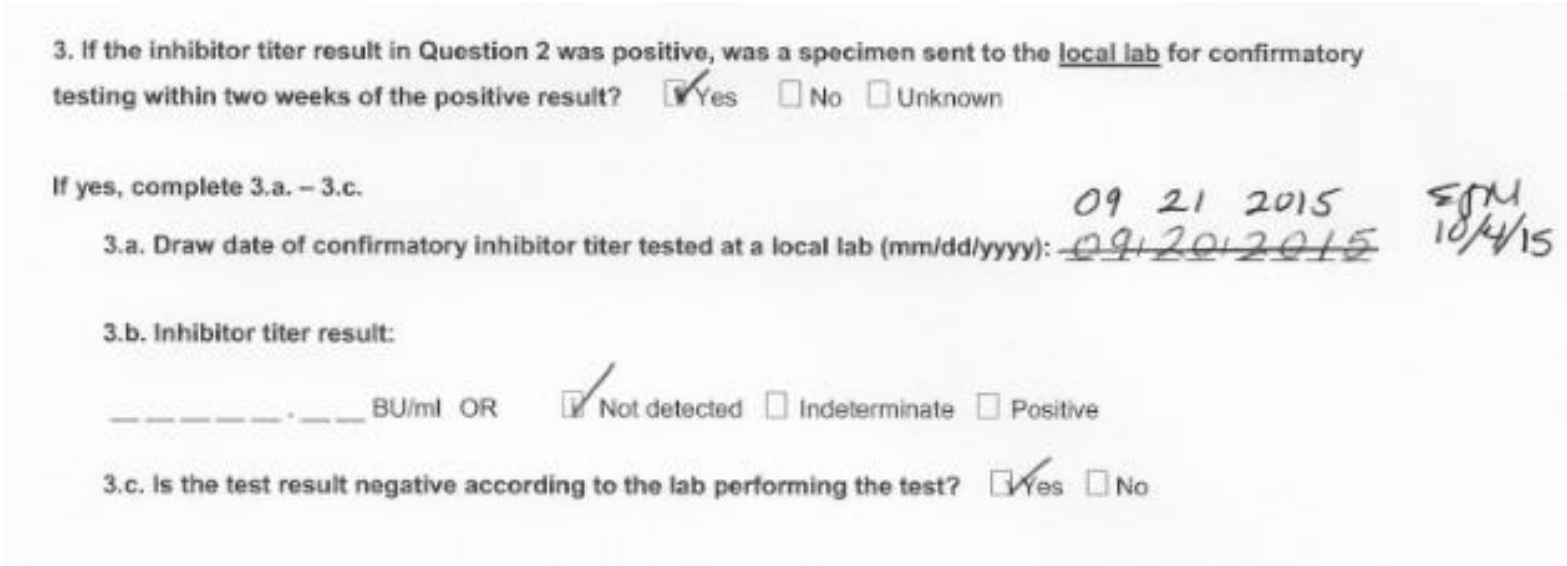
Error Correction

The original entry is still legible and it is known when the correction was made, and by whom.

1. Cross out the error with one line, leaving the original entry readable
2. Write the correct data next to or above the original data, now crossed-out
3. Sign/initial and date the cross-out
4. Indicate the reason for the correction, if necessary

Good Documentation Practices

Example of Error Correction



3. If the inhibitor titer result in Question 2 was positive, was a specimen sent to the local lab for confirmatory testing within two weeks of the positive result? ☑ Yes ☐ No ☐ Unknown

If yes, complete 3.a. – 3.c.

3.a. Draw date of confirmatory inhibitor titer tested at a local lab (mm/dd/yyyy): ~~09/20/2015~~ 09 21 2015 SM 10/4/15

3.b. Inhibitor titer result:

_____.__ BU/ml OR ☑ Not detected ☐ Indeterminate ☐ Positive

3.c. Is the test result negative according to the lab performing the test? ☑ Yes ☐ No

Good Documentation Practices

Error Correction

ATHN promotes a culture of compliance

- If you identify a problem
  - Notify a supervisor, manager, or trusted colleague
  - Report and resolve as appropriate
  - Don’t freak out

Practical Tips

Good Documentation Practices

Complete Records

- Proper documentation overall
  - Source documentation organized by Subject
  - Complete Files
  - Appropriate error correction
  - Gaps explained as necessary in Notes to File
    - Notes to File should be rare
    - Not routinely used to fix protocol weaknesses

Data Entry Best Practices

Physical Setup

- Set Up an Organizational System
  - Documents must be able to be accessible and easily located!
  - Files for each subject / study must be complete
    - Use ‘Notes to File’ to redirect as needed
- Physical Organization (Secure!)
  - Wall File (in limited access space/office)
  - Binders (on shelves, in office)
  - Files (in lockable drawers)

Data Entry Best Practices

"5 days to Clean Data"

- Organize and submit eCRFs by Subject Visit
- Enter data within 5 days of Study Visit if possible, and no longer than 2 weeks
- Maintain Forms by Status
  - eCRFs complete ready to be entered
  - eCRFs pending entry: due, incomplete, flagged
  - eCRFs to be filed
    - Paper forms/source documents returned to Subject File/Binder ('to be filed')
    - Good practice to initial and date bottom of each CRF to indicate that it has been submitted

Data Entry Best Practices

"Key What You See"

- Only enter what you see on CRF/Source
- Do not enter anything illegible or unclear
  - Follow available Data Entry Guidelines
- Clarify before entering
  - No guessing
  - Use sticky notes to flag any questions
    - Note: but do not use sticky notes as source documentation, such as for Vital Signs

Good Documentation Practices

Summary

- Study Team members are expected to
  - Follow the protocol!
  - Create and maintain complete documentation
  - Submit accurate data in a timely fashion
  - Correct errors according to ALCOA standards
  - Identify and acknowledge deviations or gaps

Good Documentation Practices

Summary

Adherence to best practice methods in the conduct of clinical research provides assurance that …

- ✓ Human subjects' rights, well being and privacy will be protected
- ✓ Data will be accurate and credible
- ✓ Methods and findings can be verified by sponsors and regulators (efficiently)
- ✓ Methods can be reproduced by other investigators

Securing Data.
Advancing Knowledge.
Transforming Care.