The Investigator as the Custodian of the Data Chain

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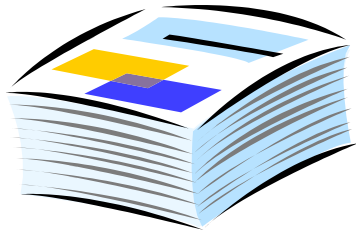
Agenda

- The investigator as the custodian of the data chain

Data Chain



Clinical Trial Data supports safe and efficacious medications for patients

What does good look like

- Understand and carry out the **protocol** precisely as written
  - identify and correct issues early
- Understand and follow **GCP**
- Report to sponsor
  - **accurate**,
  - **complete**, and
  - **timely** data

Carry out protocol as written

- **Plan**
  - Ensure study is consistent with your practice
  - Ensure adequate site infrastructure
    - personnel
    - processes/procedures
    - tools
- **Control**
  - Provide study oversight
  - Monitor site's performance
- **Improve**
  - Identify issues early and prevent from happening again

Following GCP and regulations

- **Patient safety**
  - Ensure IRB review and continuous approval of protocol and consent
  - Obtain consent prior to any protocol procedures
  - Report all adverse events
- **Data Integrity**
  - Create and maintain accurate source document
  - Maintain study documentation and medical records
  - Maintain investigational product disposition records
- **Protocol Adherence**
  - Inclusion/Exclusion
  - Conduct required procedures
  - Control of investigational product

Accurate and Complete Data

- **Accurate**
  - Data points in CRF must be substantiated by source documents
    - Subject diaries
    - Lab reports, EKG
    - Medical record (including electronic)
    - Worksheets
- **Complete**
  - Solicit information about AE's and *report* them
  - Avoid "Lost to Follow-Up"

Timely Data

- **Report data at time of visit or other event**
  - Higher likelihood of accuracy and completeness
  - Prompt data entry reduces lag between when information is known and available to sponsor
    - allows sponsor to detect safety signals as soon as possible to better protect patients
    - allows sponsor to trend site's performance for early detection and correction of issues