Strategies for Sponsors to Build Quality into Device Research

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Objectives

- Identify the elements of quality throughout the data life cycle of a clinical trial.
- Recognize best practices for implementing a quality study.
- Identify the elements of a corrective and preventative action plan.

Topics

- Data, quality data, data lifecycle, and quality studies
- Suggestions for the conduct of “Quality Studies”
- A quality systems approach to the conduct of a clinical study

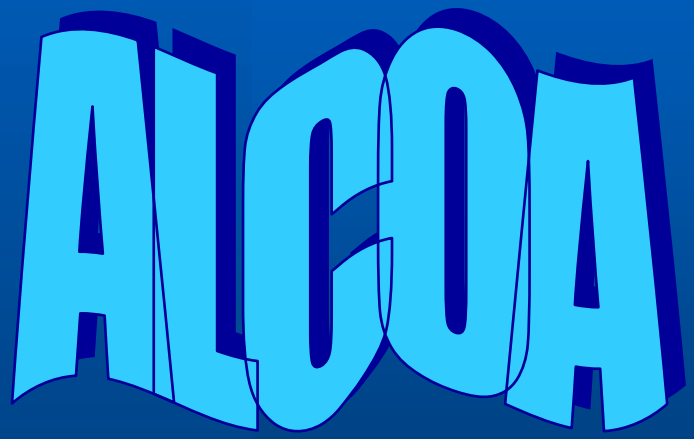
Source Data

- All information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the study

What are Documents?

- Hospital records
- Clinic and office charts
- Laboratory notes
- Memoranda
- Subjects' diaries
- Evaluation checklists
- Accountability records
- Automated instrument data
- Photographic negatives
- X-rays
- Subject files

What are Elements of Quality Data?



- Attributable
- Legible
- Contemporaneous
- Original
- Accurate

Guidance for Industry
Computerized Systems Used in Clinical Investigations

Quality Study

Data + Quality  Quality Study

21 CFR 812.150(b)

Data Life Cycle

Sponsor Strategies

- Obtain protocol feedback
- Select qualified investigators
- Select qualified clinical sites
- Provide adequate training
- Ensure adequate monitoring
- Secure investigator compliance

Obtain Protocol Feedback

- When planning a study, consult potential investigators, scientific experts and FDA reviewers
  - Inclusion & exclusion criteria
  - Testing appropriate for endpoints
  - Case Report Forms

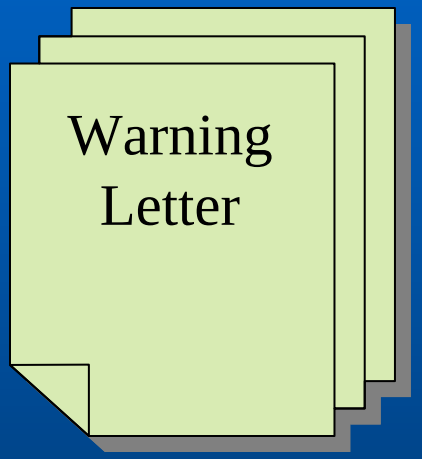
Select Qualified Investigators

- Knowledge, training, & experience
  - appropriate for the device
  - specific use in the study
- Commitment to research
  - clinician vs. researcher

21 CFR 812.43(a)

Select Qualified Investigators (cont)

- Compliance history
  - FDA 483
  - Warning Letters
  - Untitled Letters
  - IRB Suspensions



Select Adequate Study Sites

- Availability
- Personnel
- Resources
- Equipment

Ensure Qualified Study Personnel

- Sub-Investigator(s)
- Study Coordinator(s)
- Data Manager(s)
- Study Monitor(s)

Provide Adequate Training

- Before study & when essential staff replaced
  - Specific study expectations
  - Procedures unique to the device or its use in the study
  - Regulatory requirements
    - Importance of the informed consent process
  - Clinician versus Investigator

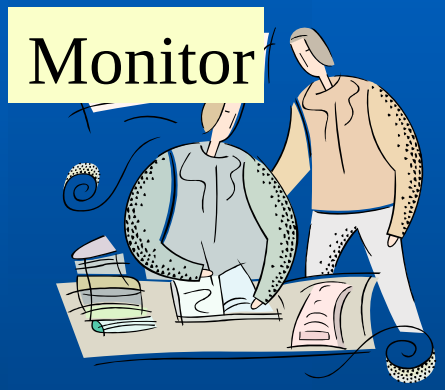
21 CFR 812.40

Provide Retraining

- Retrain when necessary
  - Significant changes in device or protocol
  - Monitoring reveals problems

21 CFR 812.46(a)

Ensure Adequate Monitoring



- Early & frequent enough for specific study
- Systemic issues can be corrected before study integrity is jeopardized
- Regular data audits avoid numerous queries and late database cleanup

21 CFR 812 40 and 812.46

Secure Investigator Compliance

- Predetermined strategy
- Expeditious review of monitoring reports
- Immediate actions to correct noncompliance
  - device shipments halted until evidence of compliance
  - terminate site's participation in study

21 CFR 812.46(a)

Quality Systems Approach

- Build quality into every step
- Evaluate the process at every stage in the data lifecycle
- Ensure accurate, complete, and current data at every stage in the data lifecycle

Corrective & Preventative Action Plan

- Develop and implement a corrective and preventative action plan (CAPA) to ensure quality data

CAPA Steps

- Assess the root cause of the problem
- Evaluate the extent of the problem
- Develop actions to correct the problem
- Implement preventative actions to avoid recurrence
- Incorporate timelines for implementation
- Document steps taken

Summary

- Incorporate the elements of quality throughout the data lifecycle
- Implement best practices for the conduct of Quality Trial
- Develop and implement a corrective and preventative action plan