



Strategies for Clinical Investigators to Build Quality into Device Research

Presented by Donna Headlee, RN BSN CCRP

Consumer Safety Officer

Division of Bioresearch Monitoring

Office of Compliance

Center for Devices and Radiological Health



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

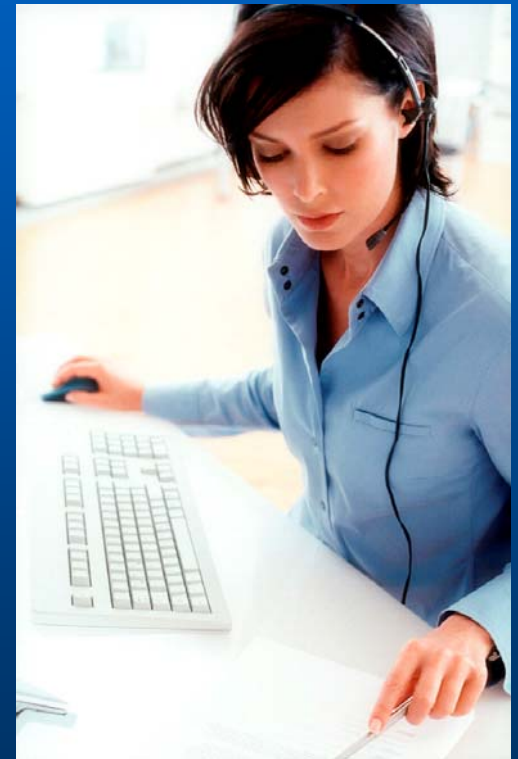


What are Source Documents?

- Hospital records
- Clinic and office charts
- Laboratory reports
- Memoranda
- Subjects' diaries
- Evaluation checklists
- Accountability records
- Automated instrument data
- Microfilm or magnetic media
- X-rays
- Subject files



What Format?





What are Elements of Quality Data?

ALCOOA

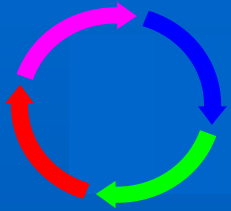
- Attributable
- Legible
- Contemporaneous
- Original
- Accurate



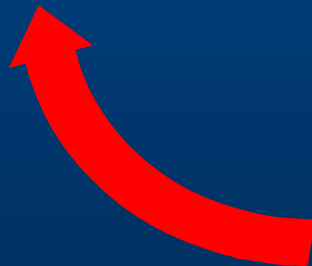
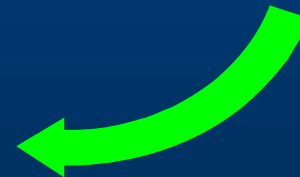
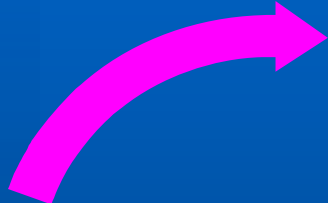
Quality Study



21 CFR 812.150(b)



Data Life Cycle





Clinical Investigators (CIs)





Clinical Investigator Strategies

- Obtain FDA/IRB approval
- Follow the signed investigator agreement, investigational plan and protocol
- Obtain Informed Consent
- Control investigational devices
- Document and report Unanticipated Adverse Device Effects (UADEs)



Obtain Approvals



- Obtain FDA/IRB approval prior to any subject's participation



Obtain Informed Consent

- Include all the basic elements and any applicable additional elements
- Allow adequate time for review of consent
- Document prior to subjects participation

21 CFR Part 50.25 and 50.27



Ensure Protocol Compliance

- Evaluate the protocol for feasibility
- Know the protocol:
 - Inclusion/exclusion criteria, study windows, study procedures, reporting criteria and timeframe
- Know each study staff member's roles and responsibilities



Ensure Qualified Study Personnel



- Sub-Investigator(s)
- Study Coordinator(s)
- Data Manager(s)
- Any additional study personnel



Provide Adequate Training



- Specific study expectations
- Procedures unique to the device or its use in the study
- Good Clinical Practice (GCP)



Develop Standard Operating Procedures

- Have written procedures:
 - Protocol evaluation
 - IRB communication
 - Informed Consent
 - Documentation and reporting UADE
 - Device accountability



Maintain Device Accountability



- Control investigational devices
- Keep all test article accountability records:
 - Shipping receipts, enrollment logs, dispensing logs

21 CFR Part 812.140(a)(2)



Document and Report UADEs



**UADE
REPORT**

- Report within 10 working days after first learning of the effect.
- Know:
 - Protocol and investigational plan definitions and reporting requirements
 - Sponsor's and IRB's requirements



Document

- Keep files organized at all times
- Keep ALL correspondence – sponsor, IRB, monitors, study subjects
 - letters, faxes, e-mails, memos, phone contacts



Documentation

If it is not documented, it did not occur!





What is Quality Assurance (Q/A)?

- All those planned and systematic actions that are established to ensure that the trial is performed and the data are generated, documented, and reported in compliance with GCP and Regulatory requirements



What is Quality Control (Q/C)?

- The operational techniques and activities undertaken to verify the requirements for quality of the trial-related activities have been fulfilled



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



Summary



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