Clinical Data Management

Quality Control & Quality Assurance

Module 10 Topic 11

Why Quality

Procedures for database finalization occur when the criteria for a "**clean**" study have been met

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Procedures for database finalization occur when the criteria for a "**clean**" study have been met

What is this criteria?

Quality to Clean Data

- **Clean** Database Criteria:
  - All CRF pages have been retrieved, entered and verified
  - Dictionary coding complete and reviewed by the Medical Monitor
  - All lab data loaded and reviewed
  - All queries resolved and applied
  - All subjects have a demographic and termination record
  - Enrollment reconciliation has occurred
  - All serious adverse events reconciled

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What's Next?

Quality Measure

Quality Assessment Components

- Quality Assurance (QA)
  " 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 the applicable regulatory requirements“

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Quality Measure (contd)

Quality Assessment Components (contd)

- Quality Control (QC)
  "The operational techniques and activities undertaken within the quality assurance system to verify that the requirements for quality of the trial related activities have been fulfilled"

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Control Measures

- Quality Control - Why perform quality control?

- To **quantify** data **quality** as a means of determining the **validity** of the data for analysis

Study Closeout

- **Why perform quality control?**
  To ensure compliance with GCP and applicable regulatory authorities AND verify that requirements for the quality of trial related activities are fulfilled.

- **HOW?**
  By implementing Quality Assurance and Quality Control Inspection processes

Study Closeout (contd)

- **Why perform quality control?**
  - To quantify data quality :
    - Use standard statistical sampling procedure e.g.
      - Subjects from different sites are randomly selected
      - 100% QC inspection of Critical Variables
    - Critical variables are checked for 100% of randomized subjects

Study Closeout (contd)

- **Why perform quality control? (contd)**
  - To quantify data quality :
    - Use standard statistical sampling procedure e.g.
      - Subjects from different sites are randomly selected
      - 100% QC inspection of Critical Variables
    - Critical variables are checked for 100% of randomized subjects

What are critical variables ?

Study Closeout (contd)

- Critical Variables:
  - Variables that impact primary efficacy and safety data
  - Driven by the protocol
- Critical Variables are:
  - Demographic Data
  - Adverse Event Data
  - Lab Normal Ranges
  - Study Termination Data
  - Primary Efficacy Data
  - Randomization Codes

Study Closeout (contd)

- Calculate and document data quality
  - Determine the percentage of errors
  - Make corrections to the database
  - Document all aspects of the review

Study Closeout (contd)

- Database Audit performed by Quality Control Group
  - Inspector must comprehend relevant trial-related data handling conventions and processing rules
  - Inspection report documents all findings
  - Corrections to the database made as necessary
  - Corrections to database verified and documented through SAS Compare process

Study Closeout (contd)

- Audit performed by Quality Assurance Group.
  - Conducted after Database QC Inspection is completed
  - QA Audit is to ensure that the Database QC Inspection Process is functioning
  - Also done to fulfill contractual obligations to sponsors that require audits of their studies.

Study Closeout (contd)

- Draft Tables and Listings:
  - Data presentation for review
  - Generated by the SAS Programmer and Statistician
  - Examined by members of the project team

Study Closeout (contd)

- QC Inspection completed
- Database declared ‘clean’
- QA completed
- Database corrections are complete
- Draft Tables and listings generated and reviewed

What happens next?

Study Closeout (contd)

- QC Inspection completed
- Database declared ‘clean’
- QA completed
- Database corrections are complete
- Draft Tables and listings generated and reviewed

What happens next?

Database Lock

QC Listing

The SAS System 10:03 Monday, January 26, 2009
STUDY NAME (SOME #)
Random Patients Selected for 100% Audit

SR. #	SITE	SUBJECT NUMBER
1	01	100:ABC

The SAS System 10:03 Monday, January 26, 2009
STUDYNAME(SOME #) Batch 001
Number of Observations Printed for QC (Batch Number 001)
Site= Site 01
Subject=500:SRG
Dataset=MH

SR.#	SITENAME	SUB_NUM	VISIT_NAME	QUALNAME	QUALREPEAT	DOMAIN
1.	Site 01	500:SRG	SCREENING	Page X	0	MH
2.	Site 01	500:SRG	SCREENING	Page X	0	MH
3.	Site 01	500:SRG	SCREENING	Page X	0	MH
4.	Site 01	500:SRG	SCREENING	Page X	0	MH
5.	Site 01	500:SRG	SCREENING	Page X	0	MH
6.	Site 01	500:SRG	SCREENING	Page X	0	MH
7.	Site 01	500:SRG	SCREENING	Page X	0	MH
8.	Site 01	500:SRG	SCREENING	Page X	0	MH
9.	Site 01	500:SRG	SCREENING	Page X	0	MH
10.	Site 01	500:SRG	SCREENING	Page X	0	MH
11.	Site 01	500:SRG	SCREENING	Page X	0	MH

SR.#	MHPID	MHTERM	MHSTYEAR	MHONG
1.	1	MYOPIA	1954	Y
2.	2	CATARRACT OF BOTH EYES	UNKNOWN	Y
3.	3	BASALIOMA OF THE SKIN IN PERIORBITAL REGION	1960	Y
4.	4	ARTERIAL HYPERTENSION	1967	N
5.	5	CORONARY ARTERY DISEASE	1988	Y
6.	6	ACUTE PERICARDITIS	2000	Y
7.	7	CILIARY ARRYTHMIA PAROXYSMAL	2001	N
8.	8	HEART FAILURE	2002	Y
9.	9	ACUTE URINARY INFECTION	2003	N
10.	10	TYMPANOTOMY RIGHT SIDE DUE TO CHRONIC OTITIS	2004	N
11.	11	CHRONIC OTITIS LABYRINTHICA	2005	N

Study Closeout (contd)

Database lock – What is it?

- Database has been approved as "**Final**"
- Users no longer have "rights" to access database to make modifications
- "Changes to data cannot occur unless sponsor project statistician request database to be unlocked for good reason"
- Once the database has been approved and locked, the study is un-blinded
- Transfer of an accurate database to appropriate recipient

Study Closeout (contd)

- **Archiving**
  "… all sponsor specific essential documents should be retained until at least 2 years after the last marketing approval or formal discontinuation of clinical development of an investigational product."

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