Data Manager’s Role in Data Quality and KPI for Data Management Process

May 17th, 2011 | Beijing, China

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• Why is the Data Manager So Important for Data Quality?
• Roles of Data Manager
• Core Elements for Quality Data Management
• Key Performance Indicators (KPI) for Data Management Process
Why is Data Quality So Important for Society?

Reliable Data for Drug Approval

Drug Safety

Fit for Use for Meaningful Analysis
ICH GCP

Section 2 – Principles of GCP:

• **2.10** All clinical trial information should be recorded, handled, and stored in a way that allows its accurate reporting, interpretation and verification.

• **2.13** Systems with procedures that assure the quality of every aspect of the trial should be implemented.

Section 5 – Sponsor:

• **5.1.3** Quality control should be applied to each stage of data handling to ensure that all data are reliable and have been processed correctly.
Data Manager is the Key Person to Unlock the Value of Clinical Data in Clinical Research

Reaching the Goal of Quality Data is a Shared Process!
Why is the Data Manager So Important for Data Quality?

- Provides accurate, complete and “fit for use” data for medical review and statistical analysis, which is critical for final report and clinical data submission to FDA or other agencies
- Reduces or eliminates critical changes after Database Lock (DBL)
- Enables analyses to be conducted during the study that may drive key program decisions (e.g. Interim Analysis drives Go/ No Go decisions)
- Provides accurate data for updates to Data Safety Monitoring Boards
- Allows for timely drug/vaccine approval
- Provides accurate data for publications
Roles of Data Manager

Data Management Plan Preparation
Design and Data Review Specifications
  • CRF/Collector/DHG/DEG/Time&Event Schedule/Coding
  • Edit Check/Data Validation Plan
External Data Specification & UAT
Mapping Specification
Collector UAT & Deployment
Data Review Tool UAT & Deployment
Data Repository Dataflow UAT

Achieving Complete & Clean Data
Completion of Coding Quality Check
Resolution of Statistical Findings
External Data Verification
PI Signature
Database Lock
Data Repository Dataflow

Study Setup

Study Conduct

Data Integrity Review
Missing Visit Management
Query Management
Coding
Site DM Performance Management
External Data Processing & Loading
Post Production Change Management
  • CRF/Collector/DHG/DEG/Time&Event Schedule/Coding
  • Edit Check/Data Validation Plan

Study Closeout

Acronyms: CRF=Case Report Form; DHG=Data Handling Guideline; DEG=Data Entry Guideline; UAT=User Acceptance Test
Core Elements for Quality Data Management

Data Manager

Data Accuracy

Data Completeness

Data Consistency

Technology & Resources
- Standard Template / Library
- Check List / Job Aid
- Training & Mentoring
- Effective Tool Development

Operational Excellence
- DMP, DHG, DEG, DVP
- Cycle Time & Quality Metrics
- Good Project Management
- Communication & Collaboration

Control System
- Access Control/Audit Trail
- System UAT
- QA / QC
- Audit / Inspection

Industry & Company Standards
- ICH E6 (GCP) / 21 CRF Part 11 / MedDRA
- Company SOP, Procedure & Guideline Documents
Key Performance Indicators for Data Management

Operational Quality and Data Quality

**Study Setup**
- CRF Design Cycle Time
- Collector Development Cycle Time
- Data Review Tool Development Cycle Time
- Rounds of Changes in Specifications
- Rounds of UAT for Collector, Data Review tool
- No. of Post Production Changes
  - CRF/ Collector/ DHG/ DEG
  - Edit Check/ Data Validation Plan

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**Study Conduct**
- Data Entry and Review Cycle Time
- Query Resolution Cycle Time
- % Re-issue Queries (Poorly Written Queries)
- % Queries without Data Changes (Non-value added Queries)
- Coding Cycle Time
- Data Entry Error
- No. of Queries per Visit
- Coding Accuracy
- Data Review Quality Assurance*
- External Data Loading Assurance

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**Study Closeout**
- LPLV – Database Lock Cycle Time
- No. of Critical Deviation from DMP*
- No. of Critical Changes post DBL
- Mapping and Dataflow Error

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Critical Findings from Inspection, Internal Audit

*Also a KPI in Process Compliance

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KPI Example: “Study Setup”
Report Specification/User Acceptance Test (UAT) Quality

Request from Clinical/Statistics

Draft Report Specifications

Draft Report Specifications

Draft Report Specifications

Final Report Specifications

Test Data Preparation

UAT Round 1

UAT Round 2

UAT Round 3

UAT Passed

Release to Production

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Behind Operational Quality, Poor Specifications/Software Build Leads to Poor Data Quality!
KPI Example: “Study Conduct”
Data Review Quality Assurance (DRQA)

• DRQA is an activity to understand the quality of data review according to Data Validation Plan (DVP)
  – Base on the objective, it can be conducted at portfolio or protocol level

• Qualified reviewer could select a sample of data to perform the followings:
  – Review if data review is executed according to DVP
  – Review all review report outputs
  – Review all queries issued and handled
  – Identify missing datapoints
  – Any findings result in critical data change

Data Review Quality Assessment Cycle: May-Jun 2010

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Not Only Data Entry Quality is Critical, Data Review Quality is Equally Important!
KPI Example: “Study Closeout”
Database Lock Cycle Time (LPLV to DBL)

(Median Time for LPLV to DBL for Participating Pharmaceutical Companies)

Benchmark Data Can Help You to Understand How Well You Perform in the Industry!

‘Last patient last visit’ to ‘Database lock’. Source from CMR International. Data are shown for Phase Ib, Phase II and Phase III studies that were completed between 2007 and 2009. Extensions and terminated studies or studies associated with terminated projects have been excluded.
Summary

• Data Management is a critical step in Clinical Research

• Data Manager has important role in data quality from study setup until study closeout

• Key Performances Indicators (KPI) are effective measurements of timeliness, quality & compliance in Data Management Process
Thank You!
Study Setup

• Accountable for timely and quality delivery of Data Management deliverables that meet the requirements of the protocol and specifications set by Clinical/Statistics
  – Finalize Design & Data Review Specifications
    • Design: CRF/Collector/DHG/DEG/Time & Events Schedule/Coding
    • Data Review: Edit Check/Data Validation Plan
  – Finalize Data Management Plan
  – Collector UAT & Deployment
  – Data Review tool UAT & Deployment
  – External data specifications and UAT
  – Mapping programming and Data Repository dataflow UAT
Study Conduct

• Accountable for timely and quality management of Clinical Data
  – Data Integrity Review & Query Management
  – Coding
  – Routine follow-up on outstanding issues with sites
  – External data processing & communication with vendors

• Liaise with Clinical/Statistics for Protocol Level Data Management Concerns *(Found during Medical Review, Interim Analysis and Database Lock)*
  – Assessment and follow up on needs for Post Production Changes
Study Closeout

- Accountable for timely, quality and complete delivery of Clinical Data
  - Close communication with CRA and Sites
  - Clearance of missing data and outstanding queries
  - Complete coding and finish coding quality check
  - Clean all critical data points and resolution of statistical findings
  - External data verification
  - Obtaining PI Signature
  - Lock database