Building Quality into Data Management Practices

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Outline

- Data Management Center Overview
- Data Management SOPs
- Work Instructions
- Data Management Plan
- Database Selection

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Data Management Center

The DMC seeks to improve clinical outcomes and research by leading the development of state-of-the-art data management.

- Resides in the Division of Biostatistics and Epidemiology
- Acting Director – Eileen King, PhD
- Manager and 12 staff – Coordinators, Programmers, Specialists

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Services/Support

- Grant and protocol review
- Budgeting and resourcing for data management operations
- Case report form design and development
- Database design and development
- Data management plans and standard operating procedures
- Collaborate with TRTO/OCTR for IND studies
- Education/Outreach

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I. Develop Standard Operating Procedures (SOPs) for Data Management Activities

- SOPs should be written to cover all key elements of the conduct of a study
- Provide enough detail to ensure steps are consistently carried out
- Don't provide so much detail as to end up with violations due to normal variations in working
- Written at a high level to outline:
  - Required tasks
  - Sign-offs
  - Checks performed

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How can DMC help with SOPs

- Data Management SOPs drafted and out for review by institution.
- Final step is to have external review
- Final SOPs available for sharing July 2012

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SOP Titles

- SOP Violation
- CRF Creation, Approval and Release
- CRF Tracking, Storage and Archival
- Database Design and Set-up
- Data Entry
- Handling External Data
- Data Management Plans
- Medical Coding
- Data Exports
- Data Discrepancies
- Database Audit
- Database Lock
- Archiving Study Data & Documentation

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II. Develop Work Instructions

- Work instructions can be more specific to a particular division or study
- Can document in more specific detail how to do things
- Generally not formally audited by regulatory agencies on work instructions

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How Can DMC help with Work Instructions

- Drafting Work Instructions
- Will post on DMC Website
- Organizations can modify and adopt appropriately

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Work Instructions Under Development

- At least one Work Instruction for each SOP developed
- Templates and forms for use as guidelines

III. Write Data Management Plan

- Details how data will be:
  - Collected
  - Stored
  - Managed
  - Archived
- Describes and defines all data management activities for a study
  - What
  - Who
  - When
  - How

Timing of DMP

- Development begins after the protocol and Case Report Forms are drafted
- Should be written before the first patient enrolled
- Must be kept current
  - reflect important changes to the data management process and computer systems that take place during the study

DMP Table of Contents

- Protocol Summary
- Definitions And Acronyms
- Personnel Contact Information
- Case Report Forms
- Database Development
- Data Acquisition
- Data Cleaning
- External Data Sources/Reconciliation
- Medical Coding
- Interim Analyses
- Screen Failure Data
- Study Data Metrics
- Database Lock Procedures
- Database Unlock Procedures
- Database Audit Plans
- Helpdesk/User Assistance
- Database And Study Documentation Archival
- DMP Amendment Process
- DMP Training
- Other Processes

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How Can DMC Help

- Data Management Plan template out for review
- When finalized will be available on DMC website
- To get access to draft, contact Rachel.Akers@cchmc.org

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IV. Select Appropriate Database

Considerations:

- Paper vs Electronic Data Capture (EDC)
- Complexity of project design
- Budget
- Single- vs multi-site
- Regulated requirements
  - 21CFR Part 11 compliance indicated?
  - Collaborate with TRTO/OCTR Regulatory

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Database Options

- REDCap - CCTST
  - Cost covered by CTSA grant
- Biomedical Informatics
  - Custom builds
- TeleForm
  - Paper-based data collection
- Clinical Trial Management System
  - Coming Soon!

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Collaborate on Database Design

- Investigators, Coordinators, Data Managers, Biomedical Informatics, and Statisticians must work together
- Poor database design affects:
  - Data Entry
  - Data Cleaning
  - Extraction
  - Statistical Analysis

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How Can DMC Help

- Help with selection of appropriate database
- Build and/or Review database
  - Variable names
  - Formats/coding
  - Variable types
  - Range checks/logical checks

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