Data Management for Non-Data Managers

Colleen M. Cox, CCDM
Manager, Data Management
PROMETRIKA, LLC

June 9, 2006

Definition

- Clinical Data Management is the process of ensuring that data collected during the course of a clinical trial is:
  - accurate
  - complete
  - logical
  - consistent

Where do data managers come from?

- Clinical Research Associates
- Life Science Majors
- Clinical Research Coordinators
- Programmers
- Registered Nurses
- Home Grown
  - Internal Training Courses

Educational Background

- United States
  - No current 4 year degree programs
  - Post Graduate Certificates Available
- Canada
  - Few 4 year degree programs

Educational Background

- International
  - Degree programs (BA/MS) in UK
  - Specialized Training/Certificate
    - Germany
    - France
    - Australia

Certification Process

- Released in 2005
  - Sponsored by Society for Clinical Data Management (SCDM)
  - 29 Core Competencies
    - Covers the spectrum
      - Protocol Review
      - Archival Procedures
  - 65 CCDMs
  - Number increasing

Regulatory Environment

- 21 CFR 11
  - Issued in 1997
  - Focus on ensuring:
    - data integrity
    - data accuracy
    - Ability to recreate

Regulatory Environment

- Guidance for Computerized Systems…
  - Released in 1999
    - Focus on Validation Processes
      - Design Qualification
      - Installation Qualification
      - Operational Qualification
      - Performance Qualification

Regulatory Environment

- Guidance for Computerized Systems…
  - Focus on End Users
    - Password Restrictions
    - Screen Guidelines
      - Red/Yellow/Green
    - Audit Trail
    - Ability to Comment

Regulatory Environment

- HIPAA
  - Privacy Regulation
    - Protection of Patient
    - Protection of Data
    - Being Implemented
    - Awaiting more FDA guidance

Professional Associations

- Drug Information Association (DIA)
- International Network of Clinical Data Management Associations (INCDMA)
- Society for Clinical Data Management (SCDM)

GCDMP

- Good Clinical Data Management Practices
- A product of the SCDM
- Version 4
- Chapters address each aspect of CDM
  - CRF Printing
  - Data Privacy
  - Laboratory and Other External Data
  - Measuring Data Quality
  - Metrics for Clinical Trials

GCDMP

- Chapter contents:
  - Introduction
  - Scope
  - Minimum Standards
  - Best Practices
  - Recommended SOPs
  - References
  - Other Related Reading

So Many Names…

- Data management is done different ways by different people
  - Difference in focus/emphasis
    - Sponsor
    - Academia
    - Clinical Research Organization
    - Clinical Trial Site

Organization of a DM Department

- Types of DM Personnel
  - Varies by organization
    - Data Entry Specialist
    - Clinical Data Coordinator
    - Data Manager
    - Clinical Data Manager
    - Database Manager
    - Programmer
    - CRF Designer
    - Coder
    - Tracker

Organization of a DM Department

- Therapeutic versus Functional
  - Therapeutic
    - Area of clinical expertise
      - Oncology
      - AIDS
    - Specific Development Project
      - Drug Approval (NDA)
      - Labeling Changes

Organization of a DM Department

- Therapeutic versus Functional
  - Functional
    - Grouped by Job Function
    - May work on multiple teams
    - Expertise at functional level

Basic Components of Data Management

- Receipt
- Entry
- Verification
- Validation
- Coding
- Clean Patient
- Clean Site
- Locked Database

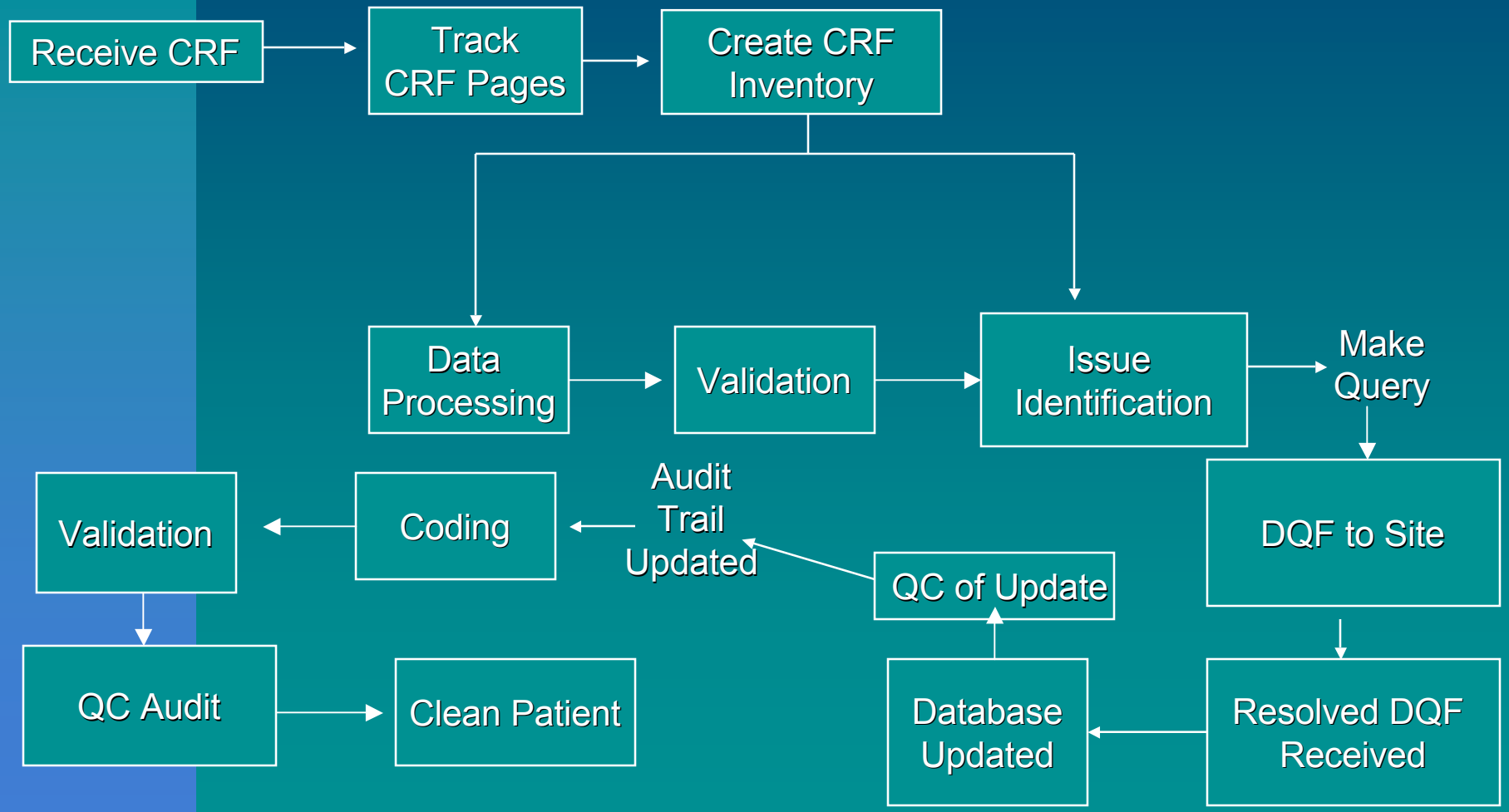
Data Management Plan

- DM equivalent of Statistical Analysis Plan
  - What
  - Who
  - How
  - When
- Proactive
  - Integration
  - Identify problems before they occur

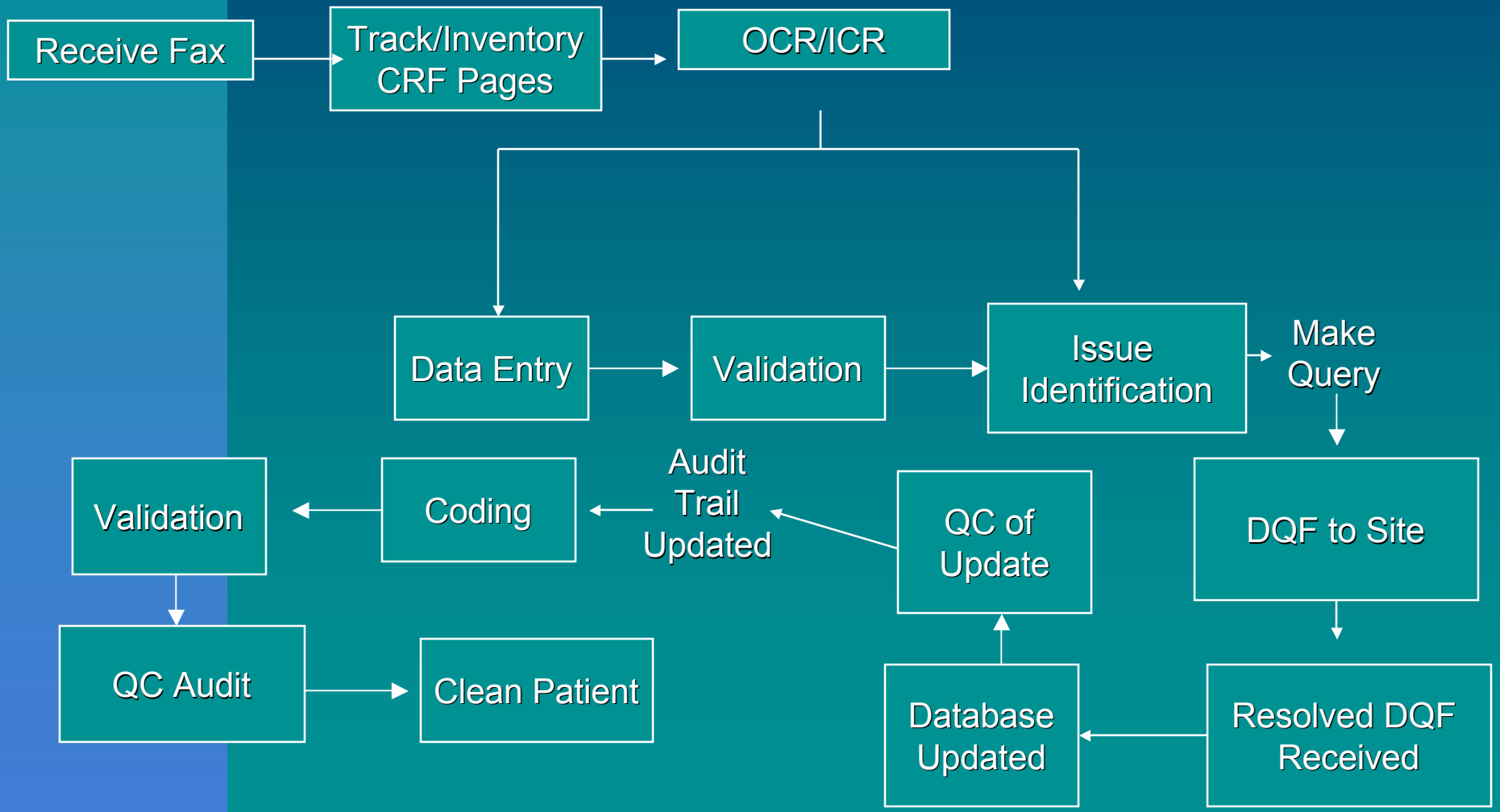
Data Management Workflow

- Paper
  - Case Report Form
  - Facsimile
- Electronic
  - Web Based
  - Web Enabled

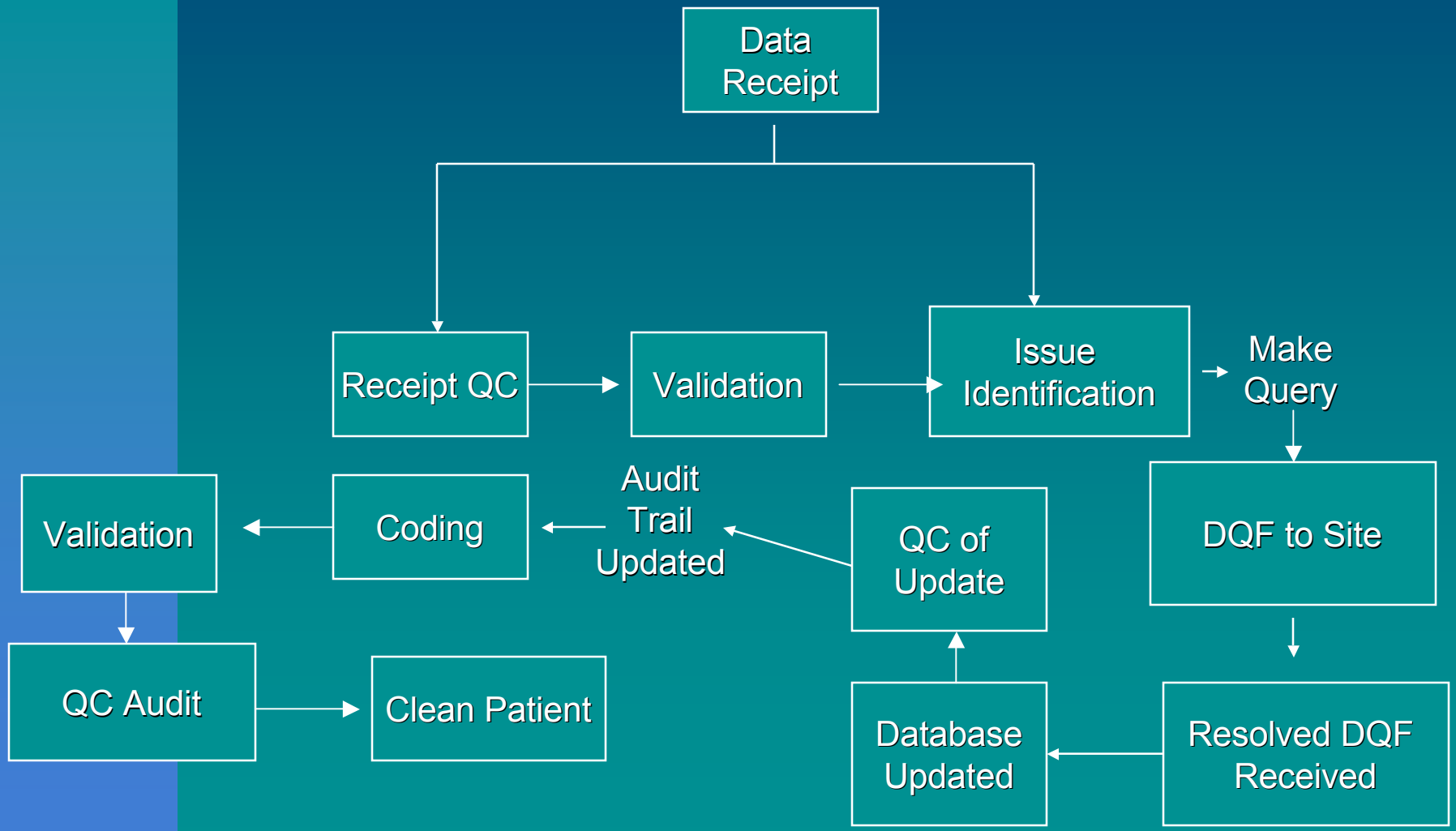
Case Report Form (Paper) Workflow



Case Report Form (Fax) Workflow



Electronic Data Collection (EDC)



Hybrid Studies

- Combination of processes
- Paper
  - Completed by site
  - Data entry by sponsor or CRO
- Electronic Data Capture
  - Entry completed at the trial site

Which Workflow to Choose?

- Type of Trial
  - Phase
  - Indication
  - Complexity
  - Level of Data Collected
  - Site Locations

Which Workflow to Choose?

- Resources
  - Sponsor
    - Personnel
    - Technological
    - Financial
  - Site
    - Personnel
    - Technological

Electronic Data

It is not just EDC anymore!

- PDAs
- Other Devices
  - ECGs
  - MDIs
  - BP Measurements
  - Phase I Units

Integration of Data

- Pooling of data from various sources
  - Case Report Forms
  - Quality of Life Questionnaires
  - Central Laboratories
  - Randomization
  - Electronic Devices
- Create a complete profile of the patient

Integration of Data

- Pooling of data from various sources
  - Work closely with provider
  - Documentation
  - Need to ensure that data is:
    - accurate
    - complete
    - consistent

Queries

- Three Stooges
  - Training Issues
  - Lack of Feedback
  - Reference Tools Unavailable
  - Lack of Communication
  - Complexity
  - Level of Querying

Queries

- Three Tenors
  - Team Interaction
  - Feedback Loop
  - Support for Resolutions
  - Focus on Needed Data Points
  - Use of Self Evident Corrections

Interim Data Presentations

- DSMB/CEC/Updates/Interim Analyses
  - Blinding
    - Need to ensure that study personnel remain blinded
  - Data Cleaning
    - Work with project team to define level of cleanliness and timelines

Blinding

- What needs to be done
  - CRFs
    - Ensure no data points will break blind
  - DM Process
    - Ensure that no step reveals blind
  - Unblinding
    - Notification before breaking

Blinding

- The Exception
  - In the event of an SAE
  - Request by PI
    - Need to follow documented procedures

Database Lock

- What is a locked database?
  - All CRFs received and processed
  - All DQFs returned and integrated
  - All electronic data received and integrated
  - All data issues resolved
  - QC Audit completed
    - 10% and/or 100%

Archiving of Material

- Paper/Fax
  - CRFs
  - DQFs
  - Study Documentation
    - Data Management Plan
    - Validation of System
  - Final Datasets

Archiving of Material

- EDC
  - Media
    - How to Store
  - Period of Retention
  - Where to Store
    - Site
    - Sponsor
    - Off Site

Budgetary Factors

- Phase of Trial
- Complexity of Trial
- Number of Patients
- Number of Total Pages
- Number of Unique Pages
- Number of Queries
- Number of Terms to be Coded

Budgetary Factors

- Phase of Trial
  - I - IV
- Complexity of Trial
  - Study design
  - Data Points Collected
  - Type of Data Collected
  - Validated instruments
    - Efficacy assessment (RECIST)
    - QOL assessments (SF36)

Budgetary Factors

- Number of Total Pages
  - CRF logging and tracking
  - Data preparation
  - Double data entry
  - Data review

Budgetary Factors

- Number of Unique Pages
  - Unique pages=data sections
    - Panel/table/dataset
  - DMP development time
  - DVG development time

Budget Derivation

- Query Management

Queries

- number of expected queries *x* time to generate
- number of expected queries *x* time to integrate

– Re-queries

- number of expected re-queries *x* time to generate
- number of expected re-queries *x* time to integrate

Budget Derivation

- Medical Terminology Coding
  - Number of Terms to be Coded
    - number of expected AE's *x* time
    - number of expected medications *x* time
    - Consistency report review
      - Within study
      - Cross-study

Acronym List

- DIA - Drug Information Association
- SCDM - Society of Clinical Data Management
- ACDM - Association of Clinical Data Management
- IVRS - Integrated Voice Response/Randomization System
- QOL - Quality of Life
- CEC - Clinical Event Committees
- DSMB - Data Safety Monitoring Board
- SAE - Serious Adverse Event
- PI - Principal Investigator
- CDISC - Clinical Data Interchange Standard Consortium
- INCDMA – International Network of Clinical Data Management Associations

Acronym List

- CRF - Case Report From
- DMM/DMP - Data Management Manual/Plan
- VC/DC/CF - Validation Check/Data Check/Cross Form Checks
- DCF - Data Correction Form
- DQF - Data Query Form
- SAP - Statistical Analysis Plan
- EDC - Electronic Data Capture/Collection
- RDE - Remote Data Entry
- CRC - Clinical Research Coordinator
- OCR - Optical Character Recognition
- ICR - Intelligent Character Recognition
- DVG – Data Validation Guidelines

Web Sites

- www.scdm.org
- www.diahome.org
- www.fda.gov
- www.indcma.org

Contact Information

Colleen M. Cox, CCDM
Manager, Data Management
PROMETRIKA, LLC
725 Concord Avenue
Cambridge, MA 02138
ccox@prometrika.com