

Data Management for Non-Data Managers

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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

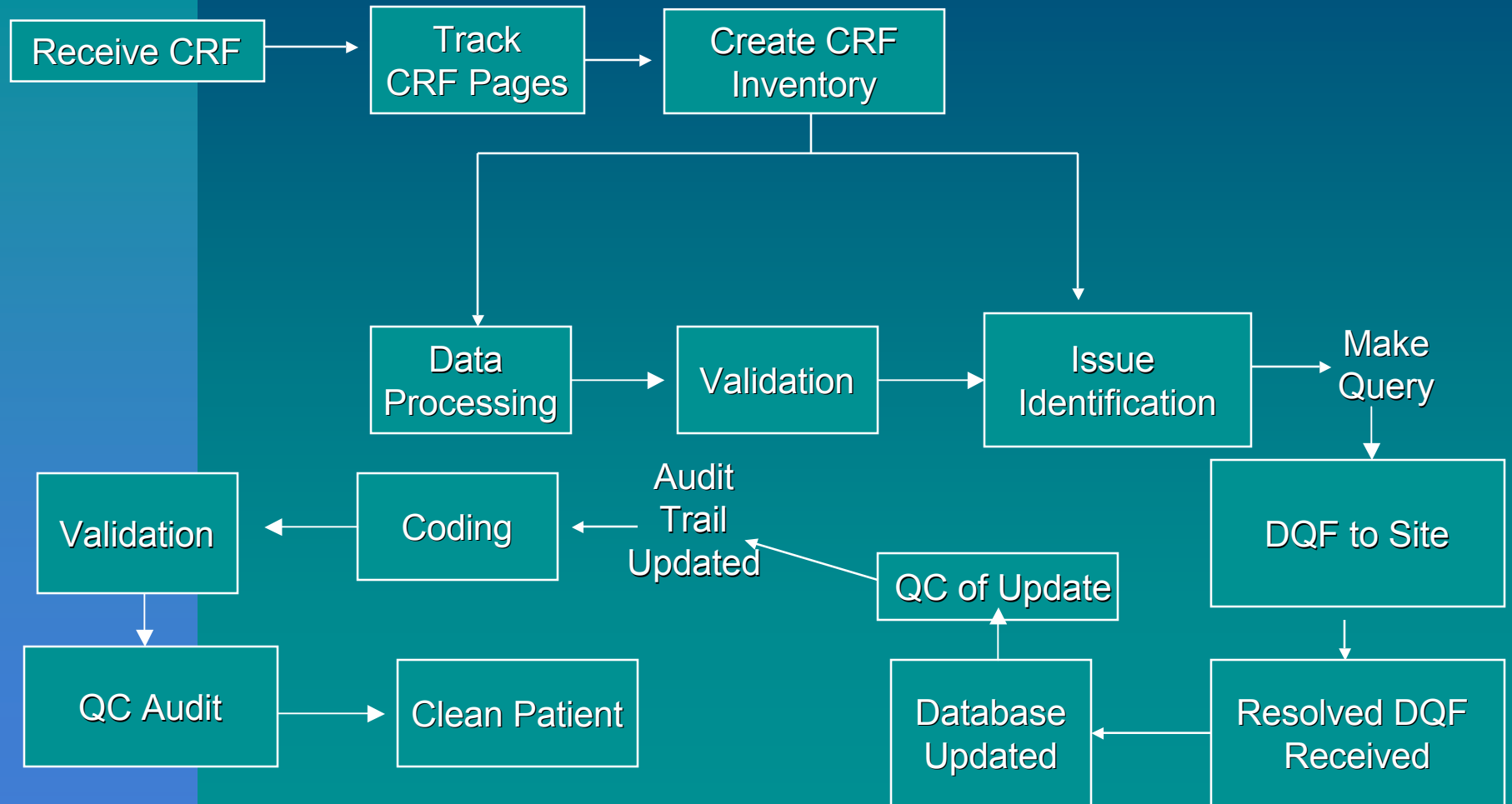
- Paper

- Case Report Form
- Facsimile

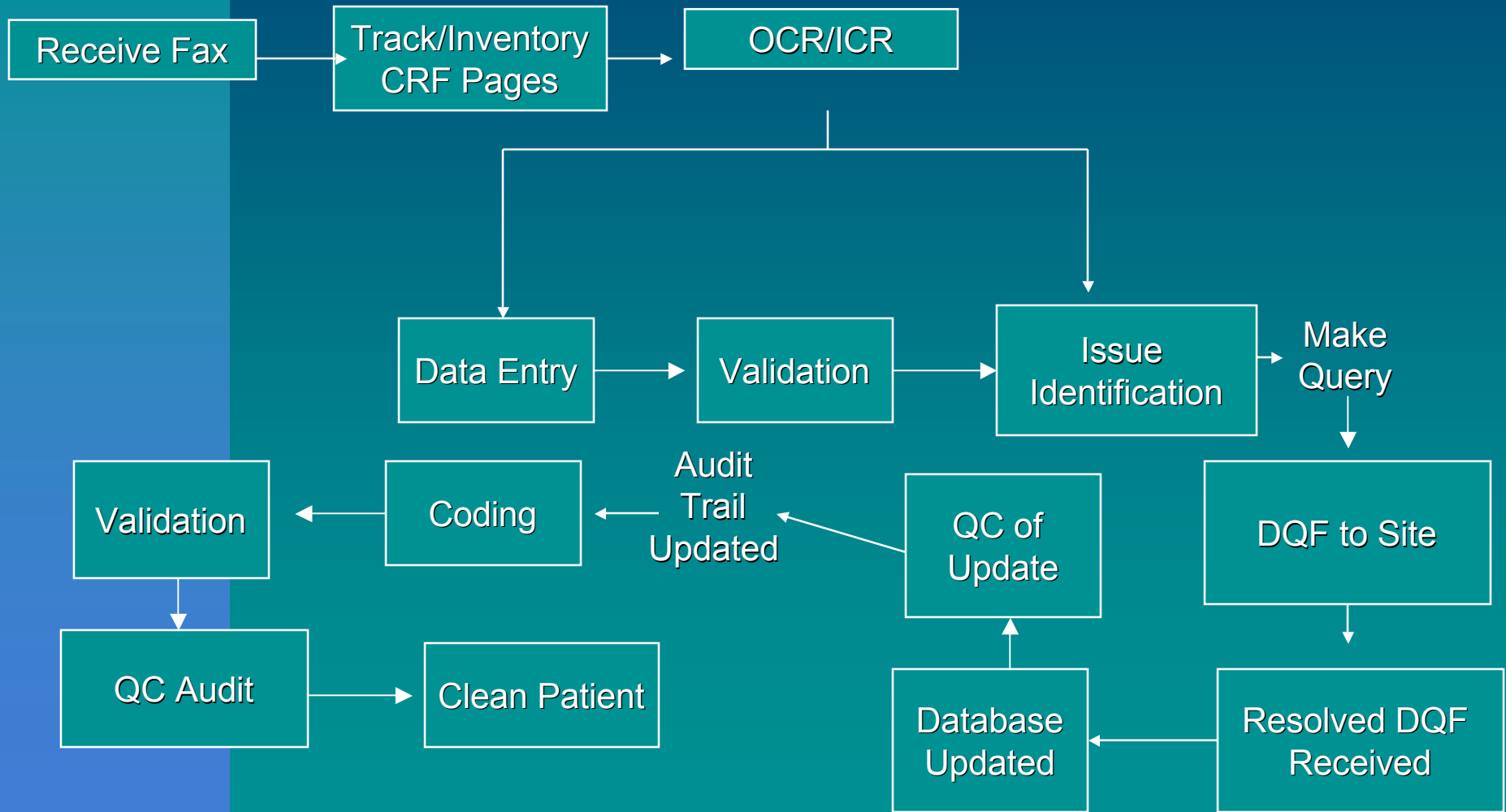
- Electronic

- Web Based
- Web Enabled

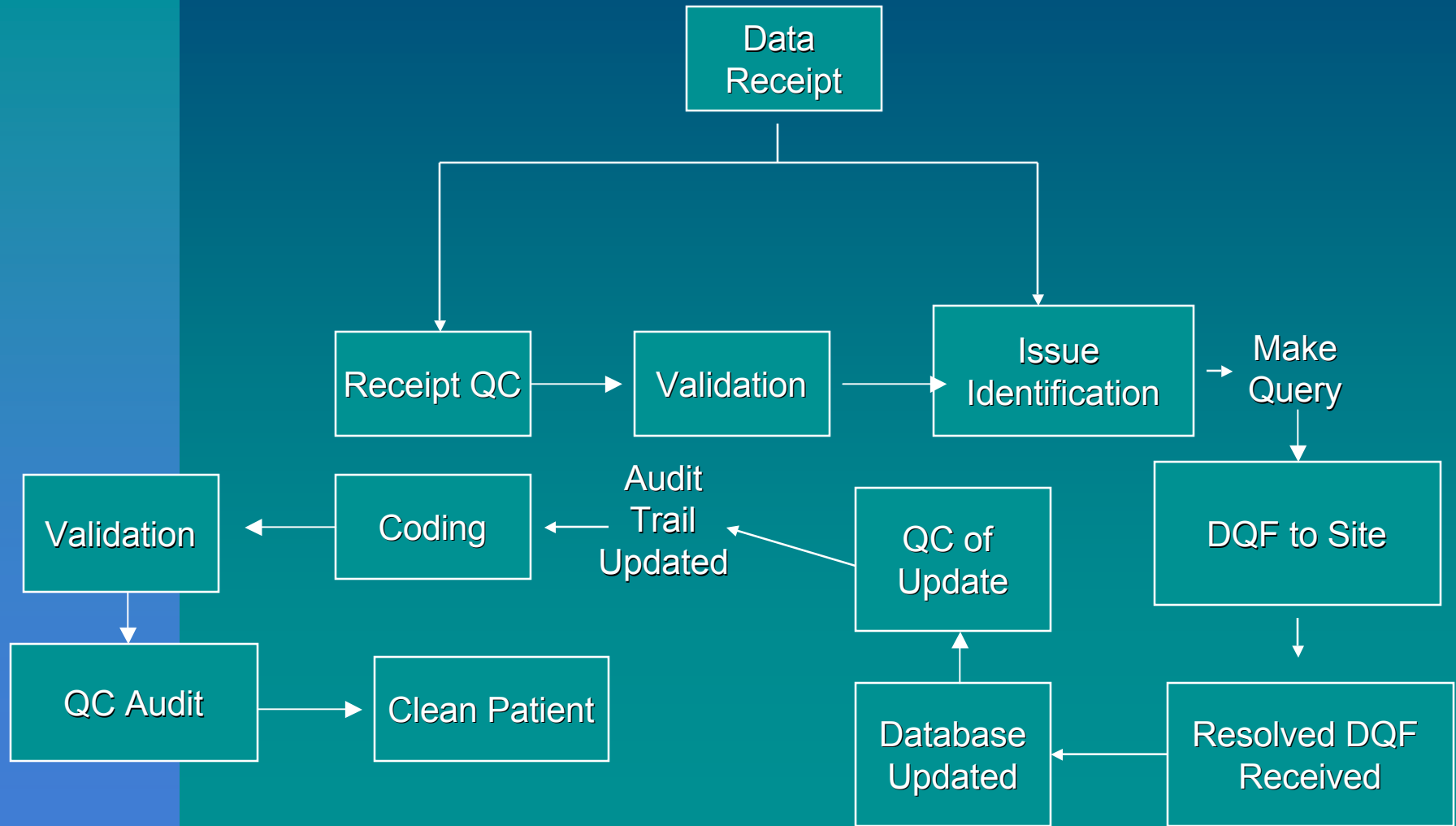
Case Report Form (Paper) Workflow



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 \times time to generate
- number of expected queries \times time to integrate

— Re-queries

- number of expected re-queries \times time to generate
- number of expected re-queries \times 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 Form
- 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

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