
Data Management Workflow

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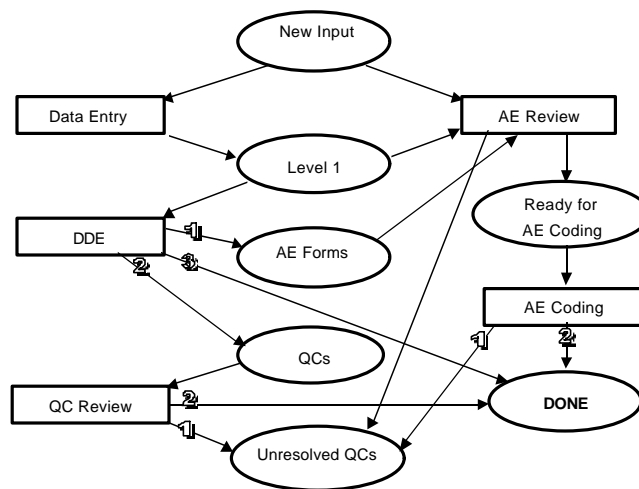
Demo Study - Tasks

1. Data Entry - first entry of new records
2. Double Entry - blinded real-time second pass
3. AE Review - immediate review of adverse events
4. AE Coding - adverse event coding
5. QC Review - review all records with data queries

Demo Study - Roles

- | | | |
|----|-------------------|-------------------------------|
| 1. | Data Entry | - data entry, double entry |
| 2. | Quality Control | - QC review, sends QC reports |
| 3. | AE Monitor | - immediate AE review |
| 4. | AE coding | - WHO/MEDRA coding |
| 5. | Study Coordinator | - random reviews |

Demo Study Workflow



DF4 DM tool: work flow status table

1. Similar to DF3 status table
2. Shows both task and storage nodes
3. Show tasks to be done and tasks completed
4. Shows tasks in progress
5. Allows user to launch a task
6. Customizable (what to display and order)

DF4 DM tool: windows

1. CRF Image - as in DF3
2. Data Entry - minor changes
 - New record sign off: user defined status & reason
 - QC color coding appears in the field corners
3. Record List - minor changes
 - Asterisk shows records for which task has been done
4. Data List - new
 - Easy to scan
 - Facilitates locating and jumping to a specific field
 - Facilitates QC review
 - Provides another data entry method
5. Message Bar -minor changes
 - Moved to bottom

DF4 DM tool: QC notes

1. Launched from QC menu or data list
2. User definable fields:
 - Problem types: missing, illegal, inconsistent, ...
 - Resolution types: fixed, accepted as is, ...
3. New fields:
 - Repeating or one-time query
 - Site role to which query is addressed: physician, surgeon, ...
 - Resolution method: refax, letter, DCQ, ...
4. New Features:
 - More than 1 QC allowed per field, but only 1 of each problem type
 - Linked fields - other fields to which QC is also attached
 - History - creation, modification, last transmission, resolution
 - Large Query window

DF4 DM tool: patient review

Quick access to data records for the current patient:

1. Shows visits performed and CRFs received.
2. Select one or more visits to build a new retrieval set (classified as an anytime work flow task).
3. After review, close and return to the current task.

DF4 DM tool: duplicate resolution

1. Main dialog shows the existing CRF image
 - Facilitates comparison and decision making
 - Bring data and QCs forward from existing record, or cancel and correct the keys to resolve the conflict
2. Compare Records
 - View history of conflicting records
3. View QC Notes
 - View data queries on conflicting records
 - QC resolution

Task Journaling

Data auditing records all data changes.

Task journals are separate and record:

1. Task Record Set Level
 - Who performed the task and why (for any-time tasks)
 - Start and end date-time
 - Number of records in the set
 - Work done: # of records for which the task was completed, # of pages reviewed, # of QCs added/modified/resolved/deleted
2. Record Level - for each record review
 - Start and end date-time
 - Task completed or record skipped
 - # of QCs added/modified/resolved/deleted

Work In Progress

- Legal range testing
- Edit checks
- Look-up tables
- Query by fields
- QC links to other fields
- Raw data entry
- ICR integration
- Visit Map
- Reports
- Data import
- DFsas?