Comparison:
Oracle Clinical vs. Datafax

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STUDY SET UP

Design and Print CRFs

- Oracle Clinical
  - Uses 4 part NCR
- Datafax
  - Uses single sheet paper
- Time/Cost/Resource Issues
  - NCR paper costs more to print
  - NCR paper costs more to ship

Designing the Database

- Oracle Clinical
  - Entry screens are ‘modules’ or ‘views’ which represent CRFs
- DataFax
  - Entry screens are identical replicas of CRFs
- Time/Cost/Resource Issues
  - Database screens as exact replicas of CRF make entry more accurate, faster

Edit Checks

- Oracle Clinical
  - Edits are typically run in batch mode
- DataFax
  - Edits can be run interactively and in batch mode
- Time/Cost/Resource Issues
  - Running edits interactively allows for validation and discrepancy management to be done simultaneously

ENTRY / VALIDATION

Completing CRFs

- Oracle Clinical
  - Uses 4 part NCR paper
- DataFax
  - Uses single sheet white paper
- Time/Cost/Resource Issues
  - May be difficult to write data so it goes through to all copies of NCR paper
  - Paper CRFs may get lost or misplaced
  - Sites usually will not write data on ‘pinks’ but may add data to faxes and never fax in
  - Sites may be more familiar with using NCR paper

Retrieval of Data

- Oracle Clinical
  - Monitors pull CRFs and send (via overnight mail) to data management
- DataFax
  - Sites fax CRFs to data management as patient visits are completed

Retrieval of Data

- Time/Cost/Resource Issues
  - Shipping costs
  - Wasted monitoring trips
  - Monitor must complete submission sheets
  - Delay in receiving data

Logging of CRFs

- Oracle Clinical
  - CRFs are manually logged and filed
  - Casebooks are stored in a locked clinical records room
- DataFax
  - CRFs are automatically logged and filed
  - CRF images are stored within the system
- Time/Cost/Resource Issues
  - Storage space needed
  - Resources needed for manual filing, logging and tracking

Entry of CRFs

- Oracle Clinical
  - Casebooks must be physically signed out for entry
  - First pass entry occurs and CRFs are stamped
  - Casebooks handed off for second pass entry
- DataFax
  - Intelligent Character Recognition (ICR) ‘reads’ data
  - First level validation occurs – data is verified and queries applied
  - Second level validation occurs

Entry of CRFs

- Time/Cost/Resource Issues
- NCR copies can be difficult to read
  - Delays between patient visit and receiving data
  - Eye strain is less with vertical movement compared with horizontal movement

DISCREPANCY MANAGEMENT

Running and Reviewing Edits

- Oracle Clinical
  - Edits are typically run in batch
  - Discrepancies are reviewed & categories assigned
- DataFax
  - Edits typically run interactively
  - QC report is run & reviewed
- Time/Cost/Resource Issues
  - If edits are not run interactively, discrepancy management is a fully separate process

Printing and Sending Discrepancies

- Oracle Clinical
  - Print DCFs on 4 part NCR paper
  - Send (via overnight mail) DCFs to each site
- DataFax
  - Print QC report
  - Fax QC report to sites – automatically done by the system
- Time/Cost/Resource Issues
  - NCR paper is more expensive
  - Overnight mail is more expensive
  - Sending DCFs is more time consuming

Resolving Discrepancies

- Oracle Clinical
  - Pull casebooks and write resolutions on DCFs
  - Send back (via overnight mail) DCFs
- DataFax
  - Pull casebooks and make changes on CRFs
  - Fax back corrected CRFs

Resolving Discrepancies

- Time/Cost/Resource Issues
  - Overnight mail causes delays in receiving resolved DCFs
  - Overnight mail is more expensive
  - No easy way for sites to change data without a DCF

Applying Resolutions

- Oracle Clinical
  - Log returned DCFs
  - Sign out casebooks
  - Apply changes to database based on DCFs
  - File DCFs and return casebooks
- DataFax
  - Validate corrected CRFs received and resolve discrepancies

Applying Resolutions

Time/Cost/Resource Issues

- NCR paper can be difficult to read
- Paper DCFs may get lost
- More storage is needed for paper DCFs
- 'Key fields' are time consuming to change
- Paper DCFs create a paper trail to follow for data changes/corrections.

MONITORING

Source Verification

- Oracle Clinical
  - Monitors go to sites and pull CRFs
  - Conduct Source verification
- DataFax
  - Monitors can view CRFs via DataFax PDF builder prior to site visit
  - Go to site to conduct source verification

Source Verification

- Time/Cost/Resource Issues
  - Monitoring trips could be a waste of time if CRFs have not been completed
  - Monitoring trips could be time consuming if that is the first time monitors are able to review the CRFs

CLOSING THE DATABASE

Issuing Final Queries

- Oracle Clinical
  - Queries must be sent (via overnight mail) to sites and sent back with resolutions
- DataFax
  - Queries can be faxed to site and faxed back with resolutions
  - If necessary, queries can be reviewed over the phone while both site and data management personnel look at the same data

Issuing Final Queries

- Time/Cost/Resource Issues
  - Using overnight mail, queries can take over a week to be resolved and changes applied to the database

QC'ing the Database

- Oracle Clinical
  - Sign out CRF
  - Ensure all CRF pages/DCFs are contained within file
  - Compare SAS datasets to CRFs and DCFs
- DataFax
  - Compare SAS datasets to CRFs (all changes are contained on single sheet of paper)

QC'ing the Database

- Time/Cost/Resource Issues
  - Following a paper trail can make the QC process time consuming and difficult
  - Lost/misplaced CRFs/DCFs can be time consuming to find

Questions?

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