

Improving the Quality of Reports

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NOTE: No unequal values were found. All values compared are exactly equal.

Topics

- *Steps for developer and QCer*
- *Steps for QCer*
- *Consistency Checks*
- *Quality Gates*
- Areas of weakness in standard dual programming & QC processes

Developer and QCer Quality

- Therapeutic area knowledge
- Protocol familiarisation
- SAP familiarisation-check text not just templates/shells for guidance, make sure no inconsistency, else query
- aCRF
- Data familiarisation (don't just look at CRF)

Developer & QCer Quality

- Get to know data, you can develop macros that
 1. identify unique key variables in the input datasets-check structure is as expected
 2. Proc freq (all variables), proc means/univariate of numeric variables in your input datasets
- Let team/DM/DB programming know data issues early!
- Data familiarisation will help you with defensive programming

Developer & QCer Quality

The FREQ Procedure

Subject Reference End Date/Time

RFENDTC

Frequency

2009-08-05T13:30	1
2009-09-15T21:50	1
2009-09-30T11:00	1
2010-01-22	1
2010-02-12T11:31	1
2010-02-17T10:45	1

Frequency Missing = 34

Developer & QCer Quality

- Other examples
 - AESER="Y", "N", " "
 - AEREL=1, 2,3, .
 - AEOCCUR="Y" but AETERM and rest of variable blank

Developer & QCer Quality Defensive programming

- Programming that allows for unexpected values in raw data/unexpected results from proc/data step.
- Examples
 1. use if , then , else .. to output messages to log
 2. If upcase(varA)="QUALITY" ..
 3. If index(upcase(dsterm), "WITHDRAW") >0 then ..

Developer and QCer Quality-checking analysis datasets

- Checking your analysis datasets
 1. Checking unique key variables are ones expected
 2. Proc freq (all variables), proc means/univariate (numeric variables)
 3. Checking number of records, check a few subjects vs raw data
 4. Data consistency checks e.g. stop date is greater than start date.

Developer and QCer Quality -checking TFLs

- Before checking TFL, know the input data (analysis/raw) and data issues and let team know (including DM/DB Programming/Analysis dataset Programmer).
- Checking TFLs-check numbers coming of procedure (freq/univariate etc) step reflect numbers present in the report (they haven't been corrupted by further processing prior to final "proc report").

Developer and QCer Quality

- Checking a sample of the counts/stats against the raw/analysis dataset

Steps for QCer

- Check own log and Developer's log for issues
- Check proc compare clean for dual programmed analysis datasets
- Check proc compare clean for dual programmed TFLs
- Check cosmetics of TFLs against shells

Consistency Checks

- Good to do some consistency checks prior to sending reports to Statistician
- Once identified inconsistencies can
 - Addressed
 - Explained to statistician/sponsor up-front e.g. Inconsistency due to data issue

Consistency Checks

■ Overall Incidence of Treatment-Emergent AEs		
■	Wonder D	Comp A
TAES	1 (1%)	15 (50%)
■ Related TAES	0	13 (43%)
■ SAE TAES	0	13 (43%)
■ Grade 3 or 4 TAES	0	18 (50%)

Quality Gates Process

- Involves verification that all QC steps have been performed prior to sending an analysis deliverable to the sponsor
- Critical to ensure adequate time for Quality Gate review and remedial work
- Quality Gate must pass before proceeding

Quality Gates Process

- Raw dataset are most recent
- Developer and QCer Analysis dataset updated
- Developer and QCer TFLs updated
- Log check program (used at Parexel) has been run subsequent to analysis dataset and TFL output production
- Any warning/errors in log addressed. Any undesired log notes explained.

Quality Gates Process

- Logcheck output printed signed and dated.
- Proc Compares have “..All values compared were exactly equal” for all outputs, and outputs signed and dated by QCer
- Project Status Spreadsheet signed and dated to indicate all outputs passed QCed.
- Consistency review has been performed and has passed.

Areas of Weakness

- Analysis dataset specifications are not correct.
 - Adequate review upfront.
 - Changes in spec post-programming needs review
- QCer's opinion overrides original programmer opinion
 - QCer should be more experienced than developer
 - encourage developer to question/challenge the specifications and QCer assumptions
 - when there is a difference of opinion with QCer, get 3rd party (statistician's opinion)
 - ensure QCer and developer can adequately justify their decision when opinion is divided.

Areas of Weakness

- Pressure to meet timelines
 - When agreeing timelines take into account quality gates review and allowing enough time for remedial work
 - use of macros
 - 1. To get to know your data
 - 2. To create your deliverables
 - 3. To partly QC your deliverables
- This means less time on programming, more time on carrying out quality checks.

Areas of Weakness

- Data issues pre-database lock
 - important to be aware of the data issues on your project
 - Carry out consistency checks pre-statistician review, and explain inconsistency due to data issues (pass information to sponsor)

Areas of Weakness

- Lack of therapeutic area knowledge
 - e.g. need to know RACIST criteria in cancer trials
 - eye disorders-visual assessments
- Baseline1 ->Left eye 3.25 + Right eye 1.5 –
Visit 3->Left eye 3.5 + Right eye 1.0 +
right eye change from baseline, -0.5 or 2.5?

Areas of Weakness

- At kick-off meetings provide therapeutic area training
- Invite lead programmer not just the lead statistician to therapeutic area training
- Providing therapeutic area e-learning for any one programming on the study would be ideal!

Summary

- Quality is difficult when you have evolving data, SAP updates and time-pressures
- Companies have evolved good processes like dual programming to minimise error
- Quality issues still occur and need to be dealt with
- Knowing your data, SAP, protocol, therapy area will improve quality
- Macros can help with quality and time-lines

Summary

- Quality Gates process useful in ensuring a quality deliverable
- Applying these suggestions to improve quality means
 1. “NOTE: No unequal values were found. All values compared are exactly equal” seen much earlier

2. Client ☺

Questions?

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