Database Lock

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Things to Consider

- Participant visits
- CRF completion at sites
- CRF data entry
- Laboratory data
- Data queries
- Coding of text data (including AEs)
- Reconciling AEs, protocol violations
- Reports
- How can database be ‘unlocked’?
Participant Visits

- Are all participant visits completed?
- Will there be post-discontinuation visits needed to follow up on adverse events or other reasons?
- Have decisions been made about ‘lost to follow up’ status?
CRF Completion at Sites

- After visits are completed, there is sometimes a delay in CRF completion.
- How can you confirm that all CRFs have been completed and transferred to the data management center?
CRF Data Entry

- Confirm that all records have been double entered (how?)
- Confirm that all CRFs have been filed correctly (how?)
- Confirm that all CRFs have been entered into the database (how?)
Case Report Form Data

- Create table summarizing number of observations in each data set
- Include audit trail data sets
- Include format library
Laboratory Data

- Are all expected laboratory data present?
- Are all queries resolved with lab?
- Is lab data stored with central database?
Data Queries

- Have all double entered data gone through data cleaning programs?
- Are all queries resolved?
- Laboratory/other non-centralized data query status?
- Have data cleaning programs been re-run after the last query updates?
- What methods can be used to quickly resolve last minute queries?
Coding of Text Data

- Medical and in-house coding
- Are coded data part of central database or are they in other applications (e.g., Access or Excel)?
- This takes more time than you expect because other staff are involved
Reconciling AEs, Protocol Violations

- SAEs are usually managed outside the DM groups
- Compare “safety office” data with study data
- Reconcile during the course of the study with email alerts
Reports

- Total number of CRFs by CRF
- Total number of CRFs by participant
- Review of FINAL status form
- Printouts of each CRF, date by participant
- Summary of endpoints
Unlocking Database

- Criteria should be defined in advance

Possible reasons:
- New (serious) adverse events
- Changes to study endpoint data
Documentation

- Include a cover memo describing database lock
- Annotated Case Report Forms
- Record structures
- Clinical protocol
- Data Management Plan
- Data Cleaning Plan
Conclusions

- Formalize with a Standard Operating Procedure and Work Instruction
- Stick to your procedures even when there is pressure to lock the database
- Look at the database from many angles to judge completeness