SDTM/ADaM Implementation Considerations for Extension Studies - Experience Exchange

CDISC DACH User Network

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Extension Studies

Common Features

- Aim
  - To assess the long-term **safety** and/or efficacy of study drugs

- Continued observation/treatment of subjects included in a parent study under a new protocol

- Extension study protocol may allow for additional recruitment of new subjects

- Subjects from different lead-in studies may be followed-up under a new common protocol

- (Extended observation/treatment period may be introduced by a protocol amendment)

CDISC Implementation Challenges

- Subset of data collected for parent study is needed for analysis of extension studies

- Examples
  - Medical history
  - Previous concomitant medication / indication specific pre-treatments
  - Planned and actual treatment groups as used in parent study analysis
  - Timing information, e.g., start of study drug treatment in parent study
  - Baseline values from parent study
  - End of parent study data may be used as screening/baseline data for extension study
  - Other?

Possible SDTM/ADaM Implementation Options

Recollect relevant data in extension study?	Typically not

Parent Study SDTM > ADaM > TLF

Extension Study SDTM > ADaM > TLF

Parent Study SDTM > ADaM > TLF

Extension Study SDTM > ADaM > TLF

Discussion

- Pros and Cons of these implementation options

- Alternative approaches

- Traceability considerations

- Pinnacle21 Validation issues observed and their resolution

- Any specific experiences to be shared with the user community

- (Challenges of introductions of extension periods via protocol amendments when SDTM/ADaM implementation has already started)

Summary

- SDTM IG/ADaM IG focus on tabulation/analysis of a single study

- Document on ADaM for integrated data in progress

- Document for ADaM traceability examples in progress

- Until final document versions are published (and acknowledged by regulatory body):

  ➢ Agree with data recipient on implementation approach
  ➢ Sponsor-specific standards to be considered?
  ➢ Describe chosen approach to incorporate parent study data in the relevant RGs
  ➢ Describe specifics in define.xml

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