ADaM – Our Experience

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Introduction

- Legacy Novartis Vaccines implemented CDASH and SDTM in 2011
- Mid 2014 a project team was formed to implement ADaM. Project team consisting of:
  - ADaM Lead
  - Project manager
  - Statistician
  - 3 programmers
  - Part time external CDISC expert

Design

- Elements considered in the design:
  - How many ADaM datasets
  - How to incorporate protocol deviations
  - Define.xml
  - Specification writing
  - Programs for ADaM dataset creation
  - Programs for TFL generation

Design elements

- How many ADaM datasets?
  - Only for primary analysis or all analysis?
  - Include support for listings?

- How to incorporate protocol deviation?
  - Re-specify deviations and exclusions based on SDTM?
  - Derive from a non-SDTM dataset?

- Define.xml
  - Directly built from specifications document
  - Coordination with team providing SDTM
  - Define version 1 or version 2?

Design elements

- Specification writing
  - Excel for now
  - Until a suitable metadata repository is in place

- ADaM dataset programs
  - Small set of standard programs
    - Metadata reading
    - Shell creation
    - Dataset finalization
  - Each dataset is programmed using a custom program (for now)
    - Initial setup of programs for a study takes between 3 and 10 days

Design elements

- TFL programming
  - Building blocks
    - Setup block
    - Denominator block
    - Counts and percentages block
    - Basic statistics block
    - Reporting block
  - Custom programming for non-basic statistics

Development

- Tool development
  - Building blocks and limited set of ADaM dataset program tools development effort relatively small
- ADaM standard development
  - Version 1 based on recreation 3 existing analysis
  - Challenges
    - Keeping number of population flags down
    - When to create records vs creating analysis flags
    - Application of CDISC standard to vaccines
  - After 6 studies still refining ADaM standard specially with respect to records vs flags

Training

- Classroom training
  - General principles of ADaM
- On the job training
  - Internal ADaM Center of Excellence provides
    - Support with specifications for statisticians
    - Programming of ADaM datasets
    - Support with use of building blocks
    - Maintenance of ADaM standard

Rollout

- Project manager manages rollout
  - Negotiates with clinical teams which studies to analyse using ADaM (in principle all)
  - Helps to adjust statistician to added tasks related to ADaM
  - Lessons learned session after each completed study

Conclusion

- Factors contributing to our successful ADaM implementation and rollout
  - At least one person with ADaM and vaccines experience in the team
  - Formation of ADaM Center of Excellence
  - Availability of project manager
  - Support from top level management
  - Building blocks approach for table generation

- Challenges
  - Making statisticians available earlier
  - Availability of extra resources to compensate for time needed to learn something new
  - Defining who should write the ADaM specifications
  - Training everyone in CDISC
  - Finalization of protocol deviations occurs at same time as ADaM specification writing
  - Application of CDISC to vaccine studies

Conclusion

- From the lessons learned
  - Over time the process is better understood and resources better managed
  - ADaM support group needs to have a good understanding of the studies
  - Quality of output has improved due to transparency/traceability of data
  - More examples are needed to accelerate TFL programming
  - Programmers pick up use of building blocks quick

Any Questions?

Thank you