What is the “ADAM OTHER” Class of Datasets, and When Should it be Used?
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Outline

ADaM fundamental principles
ADaM dataset classes and standard dataset structures
The OTHER Class of ADaM datasets
ADaM OTHER in the universe of analysis datasets
When the OTHER class should and should not be used
Concluding thoughts
CDISC ADaM

- Clinical Data Interchange Standards Consortium (CDISC)
- Analysis Data Model (ADaM)
  - Model for observed and derived subject data enabling analysis and supporting review
  - Influenced by needs of FDA statistical and medical reviewers
  - Preferred by FDA
  - Will be required by FDA for new studies no earlier than Dec. 18, 2016
  - Transparent: Materializes and exposes derivation
  - Fundamental Principles
  - Standard data and metadata structures
    - standard variables
    - dataset and variable naming conventions
    - rules
    - etc.
The Evolution of ADaM

• First, there was a philosophy: **Fundamental Principles**
ADaM Fundamental Principles

• Analysis datasets and their associated metadata must:
  – facilitate clear and unambiguous communication
  – provide traceability between the analysis data and its source data (ultimately SDTM)
  – be readily useable by commonly available software tools

• Analysis datasets must:
  – be accompanied by metadata
  – be analysis-ready
Fundamental Principles have Practical Effects - A Few Examples

- **Analysis datasets and their associated metadata must:**
  - facilitate clear and unambiguous communication
    - Flag imputed dates
    - Keep all observed and derived records, not just those analyzed
  - provide traceability between the analysis data and its source data (ultimately SDTM)
    - Include traceability variables, e.g. --SEQ
    - Metadata traceability always required

- **Analysis datasets must:**
  - be analysis-ready
    - Ideally, “One PROC away” from results
    - Minimal or no data manipulation in analysis programs
The Evolution of ADaM

• First, there was a philosophy: Fundamental Principles
• Then there were standard data structures: Classes of ADaM Datasets
Four Classes of ADaM Datasets – But only Three Standard Data Structures

1. Subject-Level Analysis Dataset (**ADSL**)
   - only member of this class is ADSL

2. Basic Data Structure (**BDS**)
   - the Swiss Army Knife vertical structure

3. Occurrence Data Structure (**OCCDS**)
   - Generalization of ADAE, will be finalized in early 2015

4. Other (**ADAM OTHER**)
   - This class has no standard structure!

Note: the OTHER Class is called ADAM OTHER in the CDISC Controlled Terminology for CLASS
The OTHER Class

• Purpose is to support analyses that cannot be supported by the ADaM dataset structures that have been defined to date

• Datasets of the OTHER Class must:
  – follow the ADaM Fundamental Principles
  – follow all ADaM dataset and variable naming conventions, etc. as much as possible

• The OTHER Class shrinks as the CDISC ADaM Team defines new Classes and structures

• But the OTHER Class is unlimited and grows each time someone needs something that is not yet addressed
ADaM OTHER in the Universe of Analysis Datasets

Analysis Datasets

ADaM Datasets

ADSL Class Datasets
  - ADSL
  - ADL*B
  - ADTTE*

BDS Class Datasets
  - AD......

OCCDS Class Datasets
  - AD......

OTHER Class Datasets
  - AD......

Non-ADaM Analysis Datasets
  - No Class! 😊
  - ........
So What Have We Seen So Far?

• Not all analysis datasets are ADaM datasets
• “ADaM datasets” is not a synonym of “analysis datasets”
• Non-ADaM analysis dataset ≠ ADaM dataset of the OTHER Class

• There are standard ADaM data structures (ADSL, BDS, OCCDS)
• The ADaM OTHER Class doesn’t have a standard structure
The OTHER Class has no standard structure … so … can I use the OTHER Class to do whatever I like?

• “I really don’t like the BDS vertical dataset structure. I prefer a horizontal structure. Can I make a horizontal dataset like I am used to and call it an OTHER class dataset?”
  – Probably not!
  – OTHER is not a loophole to drive a truck through
  – ADaM is a data standard
  – FDA wants sponsors to use the ADaM data standard
  – Use an ADaM standard structure when a standard structure is capable of enabling the analysis

• “Darn. Well then, when can I use OTHER?”
  – Let’s look at 4 situations where it may make sense
  – There may be others
Valid reason #1 for an ADaM OTHER Class dataset: No standard structure can enable the analysis

- If ADSL, BDS and OCCDS cannot support the analysis, then the OTHER class can be used
  - Must follow ADaM fundamental principles, naming conventions, etc.
- Example: Multivariate Analysis of Variance (MANOVA)
  - More than one dependent variable is needed on the same row
- Example: Correlation Matrix
  - The variables to be correlated must be on the same row
- Note: True statistical multivariate analysis is rare in Pharma
  - Virtually all hypothesis testing in Pharma involves univariate analysis (one analysis variable on the left hand side of the model statement)
  - BDS works great for univariate analyses (ANCOVA, CMH, TTE, …)
- Note: A horizontal OTHER Class dataset can often be created by transposing a BDS dataset, using BDS PARAMCD for the analysis variable names (but this is not always simple)
Valid reason #2 for an ADaM OTHER Class dataset: Listing view

• Someone wants/needs to see analysis variables side-by-side
  – This can be a legitimate need of statistician or reviewer

• An ADaM dataset of the OTHER Class, or even a non-ADaM dataset, can be created to support eyeball review of data
  – If it follows ADaM fundamental principles etc., can be ADaM OTHER Class

• However, such a dataset should not be used as the input dataset to the statistical analysis if ADSL, BDS, or OCCDS would suffice
Valid reason #3 for ADaM OTHER Class dataset: Pre-ADSL dataset

- Example: a pre-ADSL dataset that assembles facts to be used when deriving per-protocol population flag PPROTFL in ADSL, e.g.
  - Was the subject compliant enough with the prescribed therapy?
  - Did the subject take certain disqualifying concomitant medications?
  - Did the subject violate dietary restrictions?
- This dataset could be like a BDS dataset, with a parameter PARAM for each of these facts; but it probably won’t be BDS-compliant
  - It won’t have planned treatment
  - It won’t have variables copied from ADSL
  - If it follows ADaM fundamental principles etc., can be ADaM OTHER Class
- This dataset won’t be used for analysis
  - If these facts are needed for analysis, create ADSL variables to contain them
Valid reason #4 for an ADaM OTHER Class dataset: Intermediate dataset

• Example: an EX-plus (ADEX?) dataset is needed for statistician review
  – SDTM EX
  – Plus some SDTM EX supplemental qualifiers
  – Plus some columns copied from ADSL
  – Plus some derived variables
  – If it follows ADaM fundamental principles etc., can be ADaM OTHER Class

• Note: Renaming EXTRT to PARAM and some other variable to AVAL does not make this a BDS dataset

• This dataset should not be used for the statistical analysis

• A compliant BDS dataset (ADEXSUMM?) may be derived from this intermediate dataset
  – Parameters summarizing aspects of exposure for analysis
Not Valid Reasons for OTHER

• It’s going to cost us a lot to change to the standard ADaM structures
• I am used to a certain layout
• I don’t want to learn something new
• I want to do it my way
Concluding Thoughts

• CDISC ADaM has rules, but can still express the science

  – There is plenty of room for expression within ADSL, BDS, OCCDS
    • Designing ADaM datasets is a creative process

  – The ADaM OTHER Class is available for use when there is a need that can’t be met by the standard ADaM dataset structures
    • Don’t be afraid of it but use it only when necessary
References

- www.cdisc.org/adam
- http://www.fda.gov/ForIndustry/DataStandards/StudyDataStandards/default.htm
Questions?

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