Crowd-Sourced ADaM-Programming and Standardization: A Design Study

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Disclaimer

This presentation does not depict the current way of working at Roche.
The Components

- Specification Database (Global Level)
  - Specification Database (Project Level)
  - Specification Database (Study Level)

- Code Library (Global Level)
  - Code Library (Project Level)
  - Code Library (Study Level)

GUI

- Specification Compiler
  - Specifications

- Code Generator
  - Programs
Variable builder

Variable name: ADT    
Variable label: Analysis Date
Variable type: date    
Variable length: 8

Algorithm description:
Set to datepart of [ADTM].

Derivation algorithm:
- G01_01
- G02_03
- G03_02
- P01_01
- S01

Code:

data _OUTDATA_;  
set _INDATA_;  
  adt=datepart(adtm);  
run;

Program: adt_g01_01.sas

Previous variable  
Next variable
The GUI Variable View 2

Variable name: ADT
Variable label: Analysis Date
Variable type: date
Variable length: 8

Algorithm description:
<describe algorithm here>

Derivation algorithm: S01

Required program adt_s01.sas could not be found (yet)!

Program: adt_s01.sas

Previous variable  Next variable
The Data Model

Variables

Studies

Assignments

Datasets

Time Windows

Code Lists
Some Requirements for Contents in the Specification Database

- Prefer one-level variable references
- Prefer references to SDTM-variables
- Keep derivations as independent as possible
/* Header */

/*CODESTART*/
data _OUTDATA_;
   set _INDATA_
   adt=datepart(adtm);
run;
/*CODEEND*/
Requirements for Code Snippets

• Input must be a dataset

• Output must be the same dataset + 1 new variable + any number of additional records (exceptions apply)

• It must adhere to naming convention for replacement strings

• Depending on statistical computing environment: specific programming language
Example of a Compiled Program

/* Header */
data adxxxxxxx01;
   attrib /* ... */
       adt length=8 label="Analysis Date";
run;
/* ... */

* ADT -----------------------------------------------;
data adxxxxxxx08;
   set adxxxxxxx07;
       adt=datepart(adtm);
run;
/* ... */
Current State of Proof-of-Concept

- Specification Database (Global Level)
  - Specification Database (Project Level)
  - Specification Database (Study Level)
- Code Library (Global Level)
  - Code Library (Project Level)
  - Code Library (Study Level)
- GUI
- Specification Compiler
- Specifications
- Code Generator
- Programs
Doing now what patients need next