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ADaM IG v1.1 & ADaM OCCDS v1.0

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Agenda

- What‘s new in Analysis Data Model Implementation Guide Version 1.1
- The new ADaM Structure for Occurrence Data (OCCDS) Version 1.0
- Q&A

Release Dates

- Analysis Data Model IG v 1.1 was released 12th Feb 2016

- ADaM OCCDS v 1.0 was released 12th Feb 2016

Analysis Data Model IG v 1.1 - Analysis datasets

- A analysis dataset is defined as a dataset used for analysis and reporting
  - ADaM datasets:

    compliant with one of the ADaM defined structures and follows the ADaM fundamental principles
    - ADSL
    - BDS (e.g. ADLB, ADVS, ADTTE, ADPD)
    - OCCDS (e.g. ADAE, ADCD, ADMH)

    follows the ADaM fundamental principles defined in the ADaM model and follows as closely as possible the ADaM variable naming and other conventions
    - Other (e.g. ADMV)
  - Non-ADaM datasets

    does not follow the ADaM fundamental principles, created according to a legacy company standard, not starting with “AD”

Analysis Data Model IG v 1.1 – General Variable Conventions

- add ”*w*” as index for the wth variable with a single digit [1-9]
- expand “*y*” as index for the yth grouping to an integer [1-99, without leading zero]
- indexed variables must not be in a sequence
- length of SDTM variables traced over to ADaM can differ between SDTM and ADaM
- ADaM relative days (ADY, ADSTDY…) need not be anchored to SDTM.RFSTDTC
- Label change from „date/time“ to „datetime“ in ADLS and BDS, but not in OCCDS
- Errors in variable types are corrected e.g. ANRLO, ANRHI, …

Analysis Data Model IG v 1.1 – General Variable Conventions

- Added table for naming fragments:

  - **GRy/FL/ML/DT/TM/DTM/DTF/TMF/DY**

  any variable that ends with one of these fragments must follow the fragment convention

  - **CHG/BL/FL/OT/RU/SC/TA/TI/WA**

  any variable that ends with one of these fragments should follow the meaning of the variable but it is not mandated

Analysis Data Model IG v 1.1 – ADSL

- Only ADSL variables needed for analysis has to be traced over to the other ADaM datasets
- SITEID and SUBJID required in ADSL, permissible in other datasets
- Some new variables like:
  - Grouping for region (REGIONy/REGIONNyN)and age (AGEGRy/AGEGRyN), analysis age (AAGE)
  - ACTARM as permissible
  - Dosing variables (DOSExxP,DOSExxA,DOSExxU)
  - Subject-level sub-period and phase timing variables (PHwSDT, PxxSwSDT)
  - Subject-level trail experience variables (EOSSTT,EOSDT,DCTREAS,TRCMP,TRTDURY)

Analysis Data Model IG v 1.1 – BDS

- TRTP or TRTA not longer required, treatment variable(s) must either be from ADSL or TRTP/TRTA -> at least one required
- Some new variables like:
  - ASEQ (for traceability purpose)
  - Record-level dose variables (DOSExP,DOSCUMP,…,DOSEU)
  - Sub-period and phase timing variables (e.g.ASPER/subperiod within a period)
  - Analysis multi-response variables (MCRITy, MCRITyML, MCRITyMN)
- Notify that PARAMTYP will be retired in next version

Analysis Data Model IG v 1.1 – BDS

- For ADDTTE: - origin datetime and imputation flag (STARTDTM, STARTMF)
  - description of censor date (CNSDTDSC)
- For ADLB: - variables for toxicity correction of type for numeric normal range variable and adding the corresponding character variables.
- Data point traceability variables/SRC variables could point to ADaM datasets and variables
- Clarify the differences between PARAM and –TEST and AVAL/C and –STRESN/C :

  In contrast to SDTM --TEST, no additional variable is needed to further qualify PARAM. PARAM describes what is in AVAL/C.

  In SDTM –STRESN and –STRESC is needed, in ADaM only one of AVAL and AVALC is needed.

ADaM OCCDS v 1.0

- Combination of input data and analysis needs:

  Input data: usually events and inventions SDTM datasets

  - Data content typically not modified for analysis needs

  Analysis needs: subjects counts analysis, where a subject may be more than one time in a category

  - No need for AVAL or AVALC
  - Dictionary used for coding the occurrence

- Common used case:

  Adverse Events, Concomitant Medication, Medical History, Other like Clinical Events, Lab Events etc.

ADaM OCCDS v 1.0 – ADAE

- Only minor changes from the CDISC ADaM Data Structure for Adverse Event Analysis Version 1.0 document
- Dictionary terms according to MedDRA
- Indicator flags:
  - ONTRTFL (On Treatment Record Flag)
  - PREFL (Pre-treatment Flag)
  - FUPFL (Follow-up Flag)
- Occurrences flags:
  - AOCCFL (1st Occurrence within Subject Flag)
  - AOCCSFL (1st Occurrence of SOC Flag)
  - AOCCPFL (1st Occurrence of Preferred Term Flag)
  - AOCCIFL (1st Max Sev./Int. Occurrence Flag)

ADaM OCCDS v 1.0 – ADCM

- Most variables are from CM, SUPPCM and ADSL
- Dictionary terms adapted to WHO Drug
- Indicator flags:
  - ONTRTFL (On Treatment Record Flag)
  - PREFL (Pre-treatment Flag)
  - FUPFL (Follow-up Flag)
- Occurrences flags:
  - AOCCFL (1st Occurrence within Subject Flag)
  - AOCCxxFL (1st Occurrence of ATC Level xx Flag)
  - AOCCPFL (1st Occurrence of Preferred Term Flag)

Questions?

THANK YOU

