METRONOMIA

ADAM IG V1.2

CONTACT DETAILS

Judith Köppert
Senior Statistician

Metronomia Clinical Research GmbH
Paul-Gerhardt-Allee 42
81245 München
www.metronomia.net

jkoeppert@metronomia.net
+49 89 829 265 231

AGENDA

- **ADaM introduction**
- **Changes from ADaM IG Version 1.1 to ADaM IG Version 1.2**

ADAM INTRODUCTION

- **ADaM = Analysis Data Model**

- **Analysis datasets must be analysis-ready**
  - 1-PROC-away principle
  - Categories, grouping variables or others that are needed for the analysis must be included in the respective ADaM dataset
  - Covariates or classification variables which are needed for the analysis must be included in the respective ADaM dataset

ADAM INTRODUCTION

- **ADaM data structure:**
  - ADSL – Subject Level Analysis Dataset
    1 entry per subject
  - BDS – Basic Data Structure
    1 or more entries per subject per parameter per timepoint
  - OCCDS – Occurrence Data Structure
    1 entry per coding path per analysis period
  - OTHER

ADAM IG V1.2

- **Section 1.5.1 General ADaM Definitions**

  New: „Scope – The extent or range within which an ADaMIG requirement applies (e.g. within a study, within a dataset, within a parameter, or within a specified subset of rows within a parameter). …“

- **Section 1.5.2 Basic Data Structure Definitions**

  Updated: Example added for ‚Parameter-variant‘ (AVALCATy)

- **Section 2.3.1 The ADaM Subject-Level Analysis Dataset (ADSL)**

  Changes of the text/ wording

  Following sentence added: „A variable in any ADaM dataset that has the same name as an ADSL variable must have the same values, type, and label.“

ADAM IG V1.2

- **Section 3.1.1 General Variable Conventions**

  „…When a secondary variable is included in the dataset, then the primary variable must also be included. …“

  CDISC Note updated for secondary variables (Core = Perm)

  ADSL variables: SITEGRyN, AGEGRyN, TRTxxPN, TRTSEQPN, TRxxPGyN, …

  BDS variables: TRTPN, TRTPGyN, AVISITN, ATPTN, APHASEN, APERIODC, ASPERC, PARCATyN, AVALCAyN, …

  Example of CDISC Note:

  „SITEGRyN cannot be present unless SITEGRy is also present. When SITEGRy and SITEGRyN are present, then on a given record, either both must be populated or both must be null.“

ADAM IG V1.2

- **Section 3.1.4 Flag Variable Conventions (Item 6 und 7)**

  Parameter-level (PFL) and record-level population flags (RFL):

  „N = no (not included in the population), Y = yes (included). Null values are allowed.“

  „0 = no (not included in the population), 1 = yes (included). Null values are allowed.“

ADAM IG V1.2

- **Section 3.2 ADSL Variables**

  Description added for pre-ADSL dataset

  „ … There may be situations where highly derived variables are to be included in ADSL yet the derivation of these variables may better be performed in another ADaM dataset. For example, consider the analysis need to include the baseline value of a derived parameter that is a composite parameter may best be created in a separate analysis dataset. Different programming processes can be employed to address this analysis need, and the ADaM does not dictate the process.

  One possible solution includes the creation of a „pre-ADSL“ dataset that is used as input into subsequent analysis datasets. The final ADSL is created and collates variables as needed from any analysis dataset including the pre-ADSL dataset. If this process is employed, the pre-ADSL dataset should follow ADaM principles but may not contain all required ADSL variables.“

ADAM IG V1.2

- **Table 3.2.8 ADSL Subject-Level Trial Experience Variables**

  Codelist/Controlled term „SBJTSTAT“ added to EOSSTT, EOTSTT, EOTxxSTT and EOPxxSTT

- **Table 3.2.9 ADSL Stratification Variables**

  New variables:

  STRATAR = Strata Used for Randomization
  STRATwD = Description of Stratification Factor w
  STRATwR = Strat Factor w Value Used for Rand
  STRATAV = Strata from Verification Source

ADAM IG V1.2

- **Table 3.3.3.1 Timing Variables for BDS Datasets**

  Description (CDISC Notes) for APHASE, APHASEN, APERIOD, APERIODC, ASPER and ASPERC updated to emphasize the relation between each other and TRTxxP from ADSL

  APERIOD: Core = Cond

- **Table 3.3.4.1.1 Analysis Parameter Variables for BDS Datasets**

  PARAMTYP deleted

  SHIFTy: Description updated

  „A shift in values depending on the defined pairing for group y within a parameter. SHIFTy can only be based on the change in value of any of the following pairs (BASECATy, AVALCATy), (BNRIND, ANRIND) … . „

ADAM IG V1.2

- **Table 3.3.4.1.1 Analysis Parameter Variables for BDS Datasets**

  BASETYPE: Description updated

  „ … If used for any PARAM within a dataset, should be non-null for all records for that PARAM within that dataset.“

  New variables:

  BCHG = Change to Baseline (Calculation: BASE – AVAL)

  BCHGCATy = Change to Baseline Category y

  PBCHG = Percent Change to Baseline (Calculation: ((BASE – AVAL) / AVAL) * 100)

  PBCHGCAy = Percent Change to Baseline Category y

- **Table 3.3.7.1 Toxicity and Range Variables for BDS Datasets**

  New variables:

  ATOXGRL = Analysis Toxicity Grade Low

  ATOXGRH = Analysis Toxicity Grade High

  BTOXGRL = Baseline Toxicity Grade Low

  BTOXGRH = Baseline Toxicity Grade High

  ATOXDSCL = Analysis Toxicity Description Low

  ATOXDSCH = Analysis Toxicity Description High

New: Section 4.9 Examples of Bi-Directional Lab Toxicity Variables

Table 4.9.1 Example of Bi-Directional Lab Toxicity Variables

	USUBJID	PARAMCD	AVISITN	AVAL	BASE	ABLFL	ANRLO	ANRHI	ATOXDSCL	ATOXGRL	BTOXGRL	ATOXDSCH	ATOXGRH	BTOXGRH
1	001-0001	HGB	1	7.4	7.4	Y	11	16.1	Anemia	Grade 3	Grade 3	Hemoglobin increased	Grade 0	Grade 0
2	001-0001	HGB	2	20.5	7.4		11	16.1	Anemia	Grade 0	Grade 3	Hemoglobin increased	Grade 3	Grade 0
3	001-0001	AST	1	33	33	Y	5	25				Aspartate aminotransferase increased	Grade 1	Grade 1
4	001-0001	AST	2	55	33		5	25				Aspartate aminotransferase increased	Grade 1	Grade 1
5	001-0001	AST	3	60	33		5	25				Aspartate aminotransferase increased	Grade 1	Grade 1

ADAM IG V1.2

- **Section 3.5 Differences Between SDTM and ADaM Population and Baseline Flags**

  Description updated:

  „…Whenever population or baseline flags are needed for analyses, the ADaM variables must be used. “

- **Section 3.3.9 Datapoint Traceability Variables**

  Text adapted to resolve uncertainties of use

- **Section 4 Implementation Issues, Standard Solutions, and Examples**

  Examples adapted to resolve ambiguities

QUESTIONS

Thank you!

Do you have any questions?