

ADaMIG v1.1 is Almost Final – Are You Ready?

PhUSE Single Day Event

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Nate Freimark

VP Clinical Programming and Data Standards – The Griesser Group

What was updated?

- More variables added
- Clarity added to notes for existing variables
- More examples added

ADaM 1.0

- **1) Study Identifiers**
- **2) Subject Demographics**
- **3) Population Indicator(s)**
- **4) Treatment Variables**
- **5) Trial Dates**
- **6) Subject Identifier Variables for BDS Datasets**
- **7) Treatment Variables for BDS Datasets**
- **8) Timing Variables for BDS Datasets**
- **9) Analysis Parameter Variables for BDS Datasets**
- **10) Analysis Descriptor Variables for BDS Datasets**
- **11) Analysis Visit Windowing Variables for BDS Datasets**
- **12) Time to Event Variables for BDS Datasets**
- **13) Lab Related Analysis Variables for BDS Datasets**
- **14) Flag Variables for BDS Datasets**
- **15) Data Point Traceability Variables**

ADaM 1.1

- **1) ADSL Identifier Variables**
- **2) ADSL Subject Demographics Variables**
- **3) ADSL Population Indicator(s) Variables**
- **4) ADSL Treatment Variables**
- **5) ADSL Trial Dates and Times Variables**
- **NEW - Subject-Level Period, Subperiod, and Phase Timing Variables**
- **NEW ADSL Subject-Level Trial Experience Variables**
- **6) Identifier Variables for BDS Datasets**
- **7) Record-Level Treatment Variables for BDS Datasets**
- **8) Timing Variables for BDS Datasets**
- **NEW - List of Record-Level Period, Subperiod, and Phase Timing Variables**

ADaM 1.1 (cont.)

- **NEW - Suffixes to Use for Timing Variables for BDS Datasets**
- **9) Analysis Parameter Variables for BDS Datasets**
- **10) Analysis Descriptor Variables for BDS Datasets**
- **11) Analysis Visit Windowing Variables for BDS Datasets**
- **12) Time-to-Event Variables for BDS Datasets**
- **13) Lab-Related Variables for BDS Datasets**
- **14) Flag Variables for BDS Datasets**
- **14) BDS Population Indicator(s) Variables**
- **15) Datapoint Traceability Variables**
- **NEW - Required Fragments for Use in Naming ADaM Variables**
- **NEW - Additional Fragments That May Be Used in Naming ADaM Variables**

1) ADSL Identifier Variables

- GEOGRy/GEOGRyN added
 - Geographic region
 - No controlled terminology at this point in time
 - US vs ROW
 - Based on continent

2) ADSL Subject Demographics Variables

- AGEGRy/AGEGRyN added
 - Multiple versions in the same study
 - <65 vs >=65
 - <75 vs >=75
 - MDR design (definition remains the same regardless of study)
 - AGEGR1 used in study 1
 - 18-40, >40-65, >65
 - AGEGR2 used in study 2
 - <65 vs >=65
- RACEGRy/RACEGRyN added
white vs non-white
- No CT defined – should there be?

3) ADSL Population Indicator(s) Variables

- No changes
- Discussions with SDS to remove from SUPPDM

4) ADSL Treatment Variables

- ACTARM added
- TSEQPGy/TSEQPGyN/TSEQAGy/TSEQAGyN added
- DOSExxP/DOSExxA/DOSExxU added
 - Defined as numeric
 - Do we need a character counterpart to capture combinations?

5) ADSL Trial Dates and Times Variables

- Moved APxx variables to next section

NEW - Subject-Level Period, Subperiod, and Phase Timing Variables

- APxx variables moved here
- PxxSw variables added – subject level sub-period
- PHw variables added – subject level phase variables

NEW ADSL Subject-Level Trial Experience Variables

- First totally new section
- Captures important subject level variables
- Both entry and exit concepts defined as well as some on-study summary values
- Added methodology to capture “multiple” dates such as multiple IC dates
- Defined variables to capture dates and reasons for discontinuation from treatment and study
- Treatment compliance and duration variables added
- Cause of Death variables added

6) Identifier Variables for BDS Datasets

- ASEQ added
- Provides traceability to a record in a ADaM dataset if used to build a subsequent ADaM dataset
- Introduced in ADTTE appendix
- SRCxxx variables left as-is (even though SRCDOM implies a tie to a domain instead of an analysis dataset)

7) Record-Level Treatment Variables for BDS Datasets

- TRTP changed from Req to Cond
 - If TRTxxP is sufficient/appropriate for analysis then TRTP is not needed
 - Parallel design where treatment does not vary
 - Scenarios where subject level values are used for analysis instead of record level (e.g. open label extension where analysis is broken out by randomization group values)
- Added variables to describe the dosing associated with a record

8) Timing Variables for BDS Datasets

- Put sub-period start/end dates in next section
- Moved * variables to separate section

NEW - List of Record-Level Period, Subperiod, and Phase Timing Variables

- Subperiod variables start/end added based on subject level variables added in ADSL
- Added phase start/end dates

NEW - Suffixes to Use for Timing Variables for BDS Datasets

- A set of suffixes that can only have those meanings when present in an ADaM variable
- Any variable ending with <suffix> will be ...
 - Ending with DT will be a numeric date variable
- Still to be worked out – what happens when there is a conflict with SDTM
 - --ELTM is not a numeric time variable in SDTM – it is a character variable that captures elapsed time in IS8601 format
 - Can the metadata capture whether it is an SDTM source variable or an ADaM created variable?
 - Wrinkle – ARELTM defined in ADaMIG 1.0 – it is defined as numeric however it is not a time variable ☹️

9) Analysis Parameter Variables for BDS Datasets

- Only addition – MCRITy
- CRITy/CRITyFL are tied to a binary definition (Y/N)
- MCRITy/MCRITyML are tied to multiple possible levels
 - Change from baseline was an increase of 2 or 3 or 4

10) Analysis Descriptor Variables for BDS Datasets

- No changes

11) Analysis Visit Windowing Variables for BDS Datasets

- No changes

12) Time-to-Event Variables for BDS Datasets

- No changes

13) Lab-Related Variables for BDS Datasets

- Changed attribute for ANRLO/ANRHI/AyLO/AyHI
 - SDTM has –ORNR– version and –STNR-- version
 - Originally defined as character to match –ORNR– attributes
 - Numeric version primary in ADaM to allow calculations for ANRIND determination
- Added ANRLOC/ANRHIC/AyLOC/AyHIC – character version

14) Flag Variables for BDS Datasets

- MCRITyML/MCRITyMLN added

14) BDS Population Indicator(s) Variables

- No changes

15) Datapoint Traceability Variables

- added language about ASEQ

NEW - Required Fragments for Use in Naming ADaM Variables

- Date suffixes as well as some important other suffixes
 - --Gry
 - Gy also discussed in CDISC notes but decision was made not to make all grouping variables Gy for backwards compatibility
 - --ML

NEW - Additional Fragments That May Be Used in Naming ADaM Variables

- Suggested fragments for usage
- Not reserved as required if they appear in a variable
- Reserved fragments are all suffixes so restricting usage is clear
- Fragments defined in this section may appear anywhere in a variable and may not be related to fragment definition
 - Section added to describe how to put together the pieces of the puzzle when building variables
 - For dates, then, the structure of the variable name is FF(xx)*, where * represents the date fragment (e.g., DT, SDT, EDTM, etc.) (up to 4 characters) and FF represents the timing fragment. This is consistent with ADSL timepoint variables such as RANDDT, TR01SDT, etc.
 - No mandatory but suggested

Appendix B: Revision History - highlights

- Added discussion of analysis datasets and ADaM datasets.
- Added wording to be clear that not everything from ADSL needs to be copied to BDS
- Added definition of w
- Allow y to go from 1-99
- Clarified when not important for indexed variables to be used sequentially.
- Clarified regarding variable pairs – one-to-one mapping, when both variables are required
- Clarified conditions for requirement (COND variables)
- Announced retirement of PARAMTYP

Then came the comments ...

- Typos/cosmetics
- We want more examples
- Please clarify
- Variable needs a tweak
- Can you add variable xyz

And we said ...

- We will fix typos
- We will add some examples
- Your question does not make sense
- You do not understand the standard (gently of course)
- You are correct – we will update
- We will consider adding in ADaMIG 2.0

Thank You!!

- TO:
 - the ADaM team for your valuable input, time and camaraderie
 - CDISC for driving the standards
 - FDA for requesting the standards
 - PhUSE for providing the table for everyone to sit around
 - YOU – for your interest in learning, using, and improving the standards

Contact information

- nfreimark@thegriessergroup.com