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THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION

ADaM's Association with Associated Persons in SDTM

Monika Kawohl, Principal Statistical Programmer, mainanalytics GmbH

Speaker

Monika Kawohl
Principal Statistical Programmer
mainanalytics

Monika is a Principal Statistical Programmer at the CRO mainanalytics GmbH in Germany and has over 30 years of experience in the pharmaceutical industry.

She has been a member of the CDISC ADaM Team since 2009 and serves as a CDISC Authorized Instructor for ADaM, Define-XML and CDISC for Newcomers.

Agenda

1. Introduction
2. Associated Persons in SDTM in a Nutshell
3. ADaM Use Cases
4. Best Practices
5. Outlook: ADaM Knowledge Base Articles

Introduction

Persone Associate

- SDTM
  - CDISC SDTM Implementation Guide for Associated Persons - Version 1.0 (SDTMIG-AP v1.0)
  - Knowledge Base Article: Guideline on When to Use AP-QRS Domains vs. QRS Domains for QRS Instruments Related to Associated Persons
- ADaM
  - Example in TAUG for Kidney Transplant (TAUG-KT v1.0)
  - (Example in TAUG for HIV (TAUG-HIV v1.0))
  - Knowledge Base Article in Development: Handling Associated Persons Data in ADaM

The term "Associated Persons" is used to classify the non-subject participants in a clinical study. An associated person (AP) may be a family member or may have a non-familial relationship to a study subject for example the associated person might be a caregiver or an organ donor.

(SDTMIG-AP v1.0)

Associated Persons in SDTM in a Nutshell

Associated Persons in SDTM

Data on associated persons is stored in separate AP-- domains (e.g., APDM, APMH)

Structure, format and rules similar to respective SDTM domains for study subjects

dm.xpt

STUDYID	DOMAIN	USUBJID	SUBJID	…	AGE	AGEU	SEX	…
AP123	DM	AP123-001	001	…	21	YEARS	F	…

apdm.xpt

STUDYID	DOMAIN	APID	RSUBJID	SREL	SEX
AP123	APDM	AP123-001-R01	AP123-001	CHILD, BIOLOGICAL	M

Main Characteristics of SDTM AP-- Domains

APID (Associated Person Identifier) instead of USUBJID (Unique Subject Identifier)

Expected RSUBJID (Related Subject) includes the respective USUBJID value if there is a relationship to a study subject

Required SREL describes relationship of APID
to subject identified in RSUBJID or to device identified in RDEVID or to the study identified in STUDYID

Only variables that make sense in the associated person context are included in the AP-- domains

Core designations from respective domains described in the SDTMIG are not applicable

Supplemental qualifiers for AP-- domains are provided in SQAP– datasets
(e.g., SQAPDM includes the supplemental qualifiers for APDM)

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ADaM Use Cases

Use Case 1: ADSL for a Transplant Study (cf. TAUG-KT v1.0)

Use Case 1: SDTM AP-- and Resulting ADSL

apdm.xpt

Row	STUDYID	DOMAIN	APID	RSUBJID	SREL	AGE	AGEU	SEX	RACE
1	1	APDM	1-1001-D1	1-1001	DONOR, ORGAN	30	YEARS	M	ASIAN
2	1	APDM	1-2001-D1	1-2001	DONOR, ORGAN	51	YEARS	F	WHITE

apsc.xpt

Row	STUDYID	DOMAIN	APID	SCSEQ	RSUBJID	SREL	SCTESTCD	SCTEST	SCORRES
1	1	APSC	1-1001-D1	1	1-1001	DONOR, ORGAN	SURVSTAT	Survival Status	Deceased
2	1	APSC	1-2001-D1	1	1-2001	DONOR, ORGAN	SURVSTAT	Survival Status	Living

adsl.xpt, Class: SUBJECT LEVEL ANALYSIS DATASET

Row	STUDYID	SEX	AGE	AGEU	RACE	APSEX	APAGE	APAGEU	APRACE	APDSSTAT
1	1-1001	M	56	YEARS	ASIAN	M	30	YEARS	ASIAN	Deceased
2	1-2001	F	60	YEARS	WHITE	F	51	YEARS	WHITE	Living

Use Case 1: ADSL Metadata

Variable Name	Variable Label	Type	Codelist/ Controlled Terms	Source/Derivation/Comment
USUBJID	Unique Subject Identifier	text		DM.USUBJID
SEX	Sex	text	(SEX)	DM.SEX
AGE	Age	integer		DM.AGE
AGEU	Age Unit	text	(AGEU)	DM.AGEU
RACE	Race	text	(RACE)	DM.RACE
APSEX	Donor Sex	text	(SEX)	APDM.SEX where APDM.RSUBJID = ADSL.USUBJID
APAGE	Donor Age	integer		APDM.AGE where APDM.RSUBJID = ADSL.USUBJID
APAGEU	Donor Age Unit	text	(AGEU)	APDM.AGEU where APDM.RSUBJID = ADSL.USUBJID
APRACE	Donor Race	text	(RACE)	APDM.RACE where APDM.RSUBJID = ADSL.USUBJID
APDSSTAT	Donor Survival Status	text	Living, Deceased	APSC.SCORRES where APSC.SCTESTCD = "SURVSTAT" and APSC.RSUBJID = ADSL.USUBJID

ADaM Use Cases

Use Case 2: Pregnancy Outcome in a Pregnancy Registry

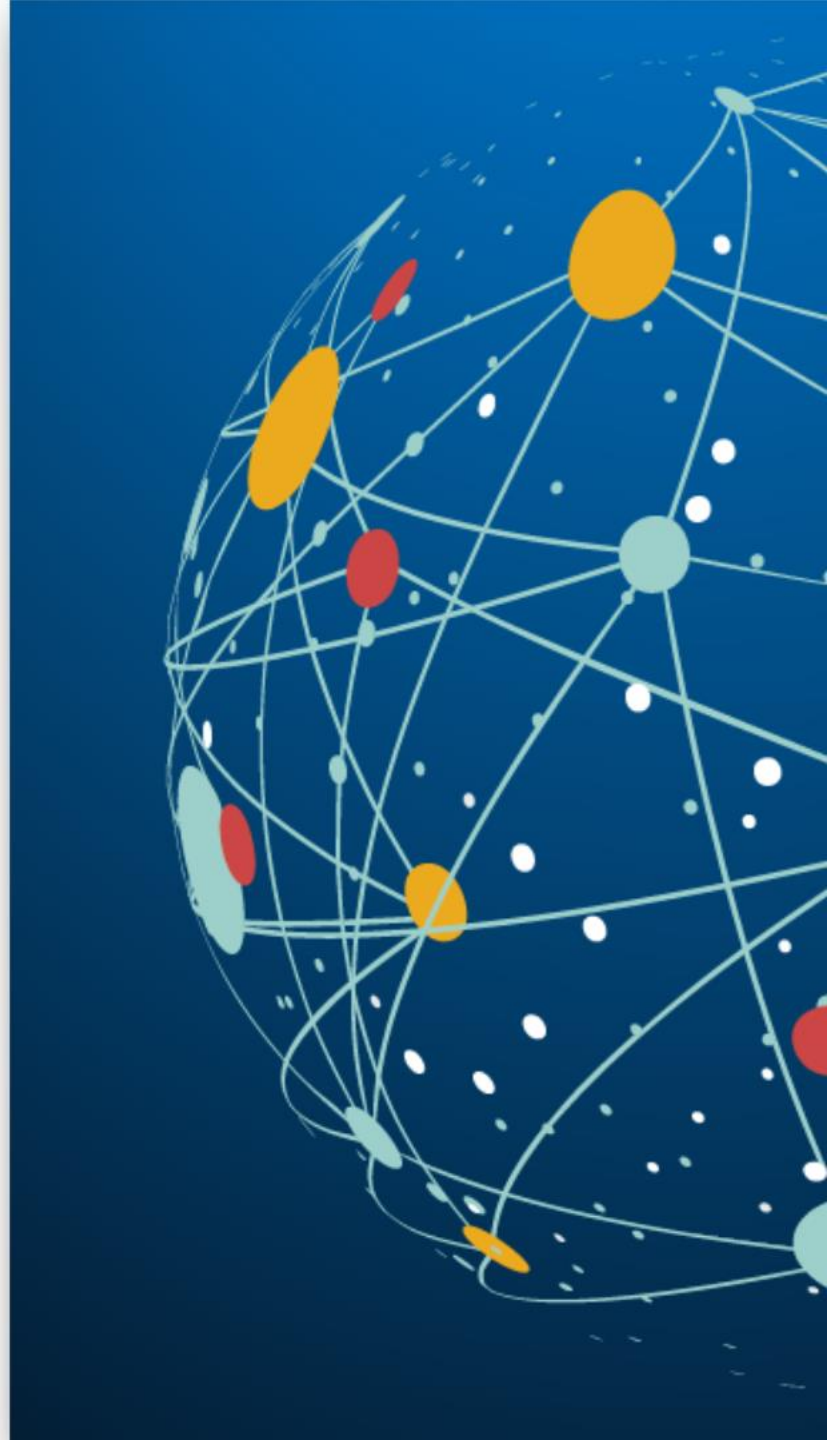
Use Case 2: Pregnancy Outcome Analysis

adprout.xpt, Class: BASIC DATA STRUCTURE

Row	USUBJID	PARCAT1	PARAMCD	PARAM	AVAL	AVALC	TRTA	SRCDOM	SRCVAR	SRCSEQ	APID
1	2-1001	Safety Outcomes - Mother	BRTLVIND	Live Birth Indicator		Y	Drug X	RP	RPSTRESC	25	
2	2-1001	Safety Outcomes - Mother	CABNIND	Congenital Abnormality Indicator		N	Drug X	RP	RPSTRESC	30	
3	2-1001	Safety Outcomes - Mother	EGESTAGE	Estimated Gestational Age (weeks)	36		Drug X	RP	RPSTRESN	24	
4	2-1001	Safety Outcomes - Infant	APWEIGHT	Weight (kg)	3.5		Drug X	APVS	VSSTRESN	2	2-1001-I1
5	2-1001	Safety Outcomes - Infant	APHEIGHT	Height (cm)	50		Drug X	APVS	VSSTRESN	1	2-1001-I1

Design Considerations

- Mix of USUBJID and APID related parameters
- Standard Dataset Class: BDS
- AP--.RSUBJID used to populate USUBJID for AP-- related parameters
- Distinguishing features
  - Prefix “AP” for respective PARAMCDs
  - PARCATy
  - Traceability variables SRCDOM, SRCVAR, SRCSEQ
  - APID as additional traceability variable
  - APID as potential additional key variable



ADaM Use Cases

Use Case 3: Mother – Child Outcome Analysis
(cf. TAUG-HIV v1.0)

Mother-Child Outcome Analysis

adoutevt.xpt, Class: BASIC DATA STRACTURE

USUBJGR1	USUBJID	PARAM	PARAMCD	AVALC
FAMILY1	MOTHER1	Spontaneous Abortion	SPONAB	N
FAMILY1	MOTHER1	Fetal Death	FETALDTH	N
FAMILY1	INFANT1	Preterm Delivery	PTD	Y
FAMILY1	INFANT1	Small for Gestational Age	SGESTAGE	Y
FAMILY2	MOTHER2	Spontaneous Abortion	SPONAB	N
FAMILY2	MOTHER2	Fetal Death	FETALDTH	N
FAMILY2	INFANT2	Preterm Delivery	PTD	N
FAMILY2	INFANT2	Small for Gestational Age	SGESTAGE	N

Contributing events of either mother or children to final analysis parameter Adverse Pregnancy Outcome

adoutcom.xpt, Class: ADAM OTHER

USUBJGR1	PARAM	PARAMCD	AVALC
FAMILY1	Adverse Pregnancy Outcome	APOUTCOM	Y
FAMILY2	Adverse Pregnancy Outcome	APOUTCOM	N

Structure: BDS-like but no USUBJID
→ Class: ADAM OTHER.
Dataset structure chosen based on the analysis need.

Not based on SDTM AP--domains, as mother and children were considered study subjects in this example.

Still, useful for modelling of further use cases.

ADaM Use Cases

Use Case 4: Infant Outcome in a Pregnancy Registry

Use Case 4: Infant Outcome Analysis

adapiout.xpt, Class: ADAM OTHER

Row	APID	RSUBJID	SREL	PARAMCD	PARAM	AVAL	TRTA	VSSEQ
1	2-1001-I1	2-1001	CHILD, BIOLOGICAL	WEIGHT	Weight (kg)	3.5	Drug X	2
2	2-1001-I1	2-1001	CHILD, BIOLOGICAL	HEIGHT	Height (cm)	50	Drug X	1

Design considerations

- AP-- related data only
  - Dataset name prefix “ADAP”
- BDS-like but no USUBJID (APID and RSUBJID instead)
  - Class: ADAM OTHER
- Analysis-ready for analysis by actual treatment (TRTA)
  - Obtained via relationship between APVS.RSUBJID and ADSL.USUBJID
- Data derived from only 1 source dataset APVS
  - VSSEQ sufficient for traceability

ADaM Use Cases

Use Case 5: Infant Abnormal Conditions Analysis

Use Case 5: Infant Abnormal Conditions Analysis

adapce.xpt, Class: ADAM OTHER

Row	APID	RSUBJID	SREL	CETERM	CEPRESP	CEOCCUR	TRTA	CESEQ
1	2-1001-I1	2-1001	CHILD, BIOLOGICAL	Respiratory Distress	Y	N	Drug X	1
2	2-1001-I1	2-1001	CHILD, BIOLOGICAL	Feeding Problems	Y	Y	Drug X	2
3	2-1001-I1	2-1001	CHILD, BIOLOGICAL	Sepsis	Y	N	Drug X	3
4	2-1001-I1	2-1001	CHILD, BIOLOGICAL	Seizure or serious neurologic dysfunction	Y	N	Drug X	4

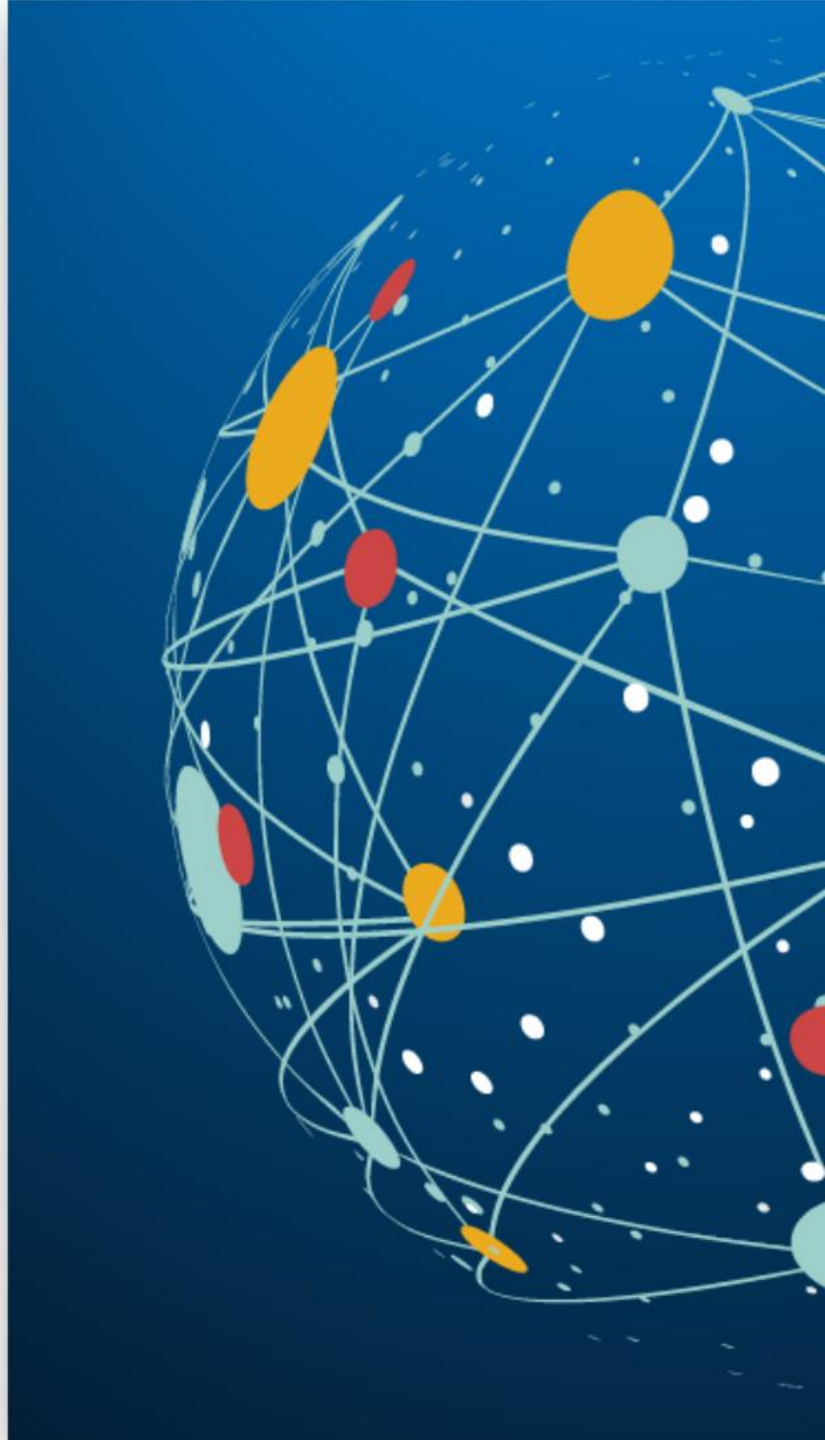
Design considerations

- AP-- related data only → dataset name prefix “ADAP”
- OCCDS-like but no USUBJID (APID and RSUBJID instead)
  - Class: ADAM OTHER
- Majority of variables copied from APCE incl. traceability variable CESEQ
- Analysis-ready for analysis by actual treatment (TRTA) of study subject

Best Practices

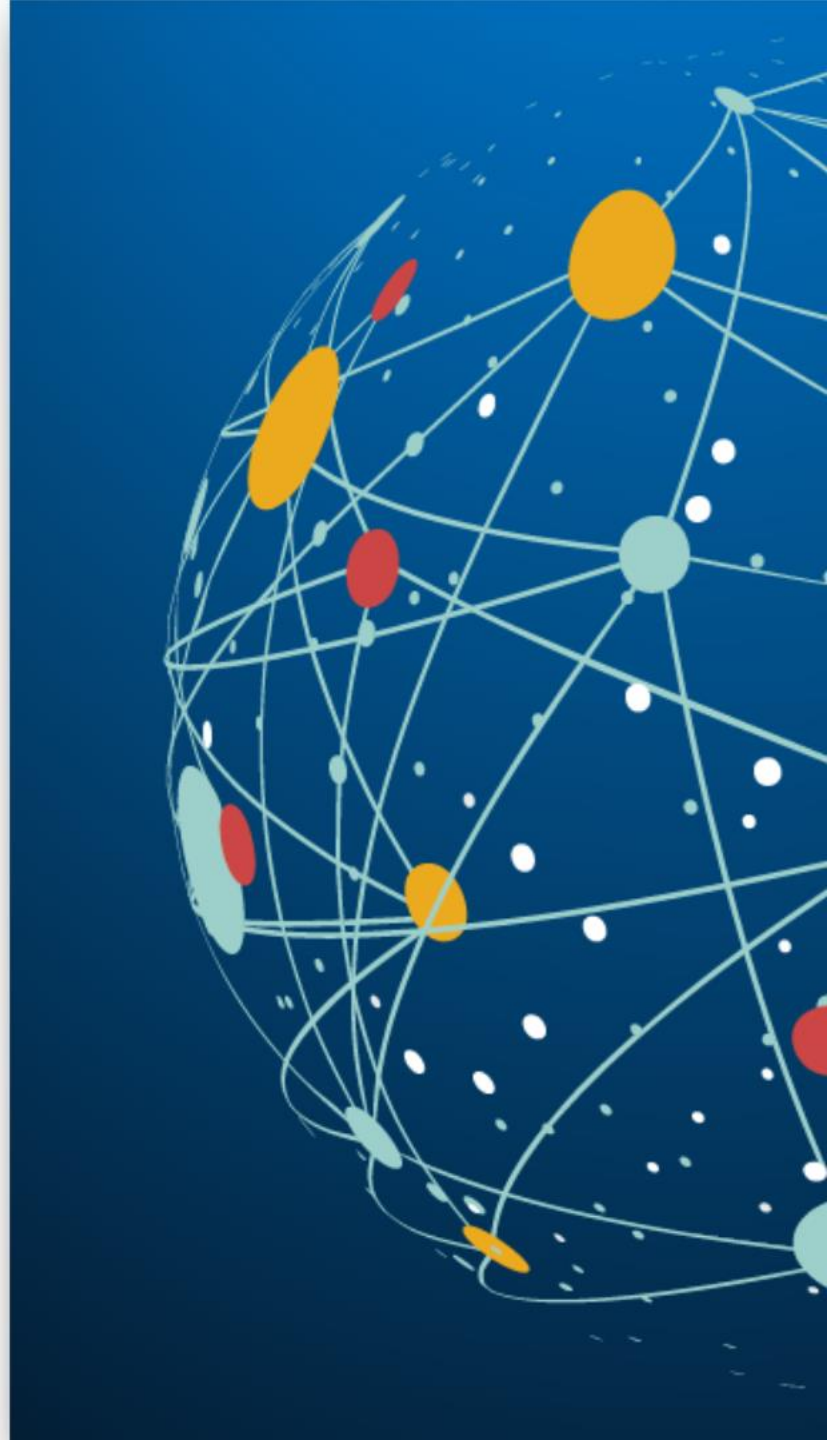
Best Practices

- Design your ADaM datasets with AP-- content based on the analysis need
  - Choice of Data Structure
    - ADAM OTHER may be a valid option
  - No requirement to create an ADaM dataset when AP-- data is only needed for listings
  - Join study subject and AP-- content: <SDTM/ADaM dataset>.USUBJID = <AP-- domain>.RSUBJID



Naming Conventions

- When mixing USUBJID and APID content, distinguish between sources via
  - Prefix “AP” for variable names
  - Prefix “AP” for PARAMCD values
  - Specific PARCATy values
  - Traceability Variables
    - SRCDOM, SRCVAR, SRCSEQ
    - APID as additional traceability variable
    - --SEQ only in combination with APID
- Prefix “ADAP” for datasets with APID related content only



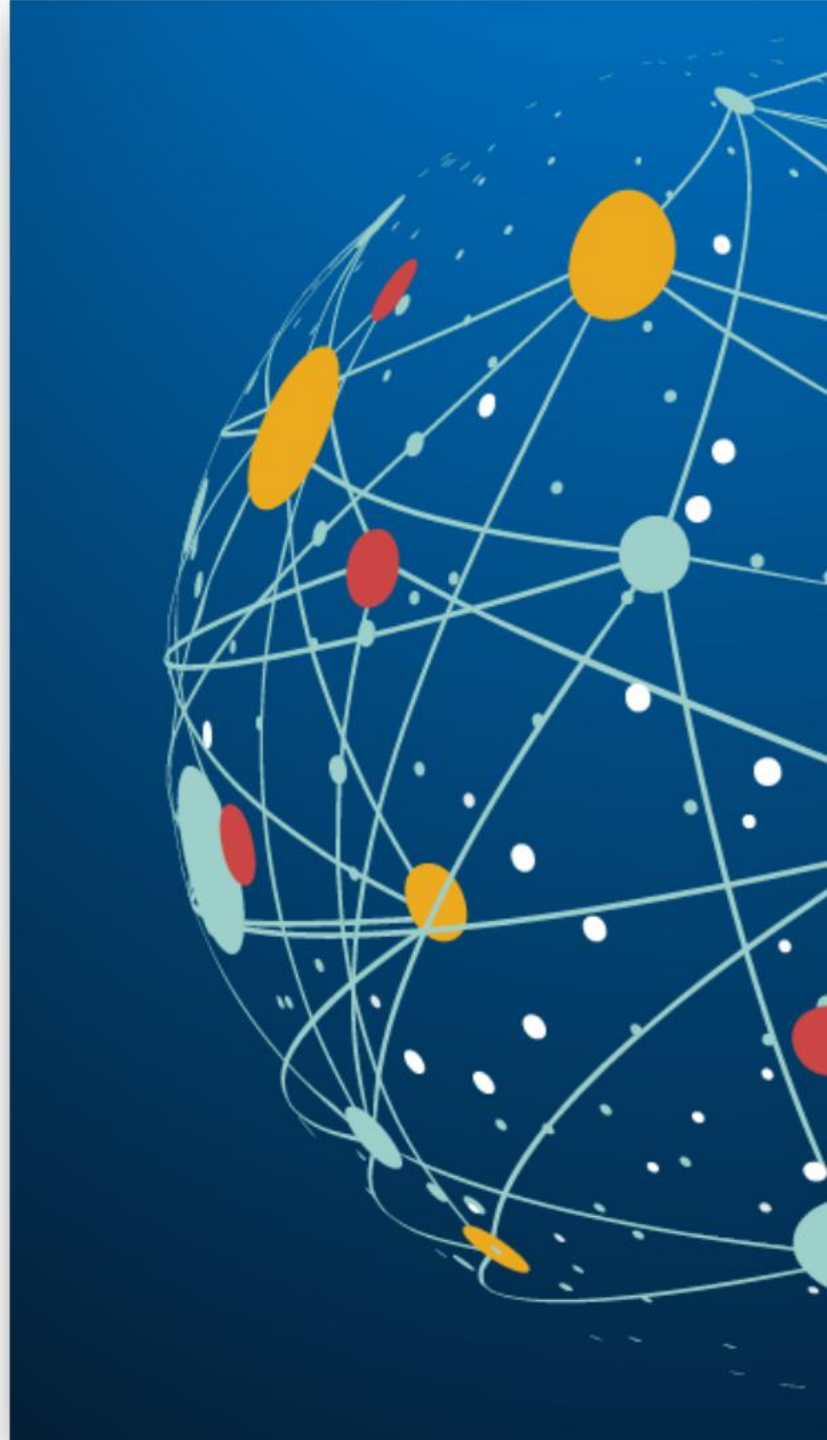
Need for ADAPL?

Associated Person Level Analysis Data

- *Structure: 1 record per associated person*
- *ADSL-like with basic information about associated persons incl. relevant core variables from RSUBJID*
- *Use cases:*
  - *Basic characteristics of APs*
  - *Denominators in for AP event summaries*

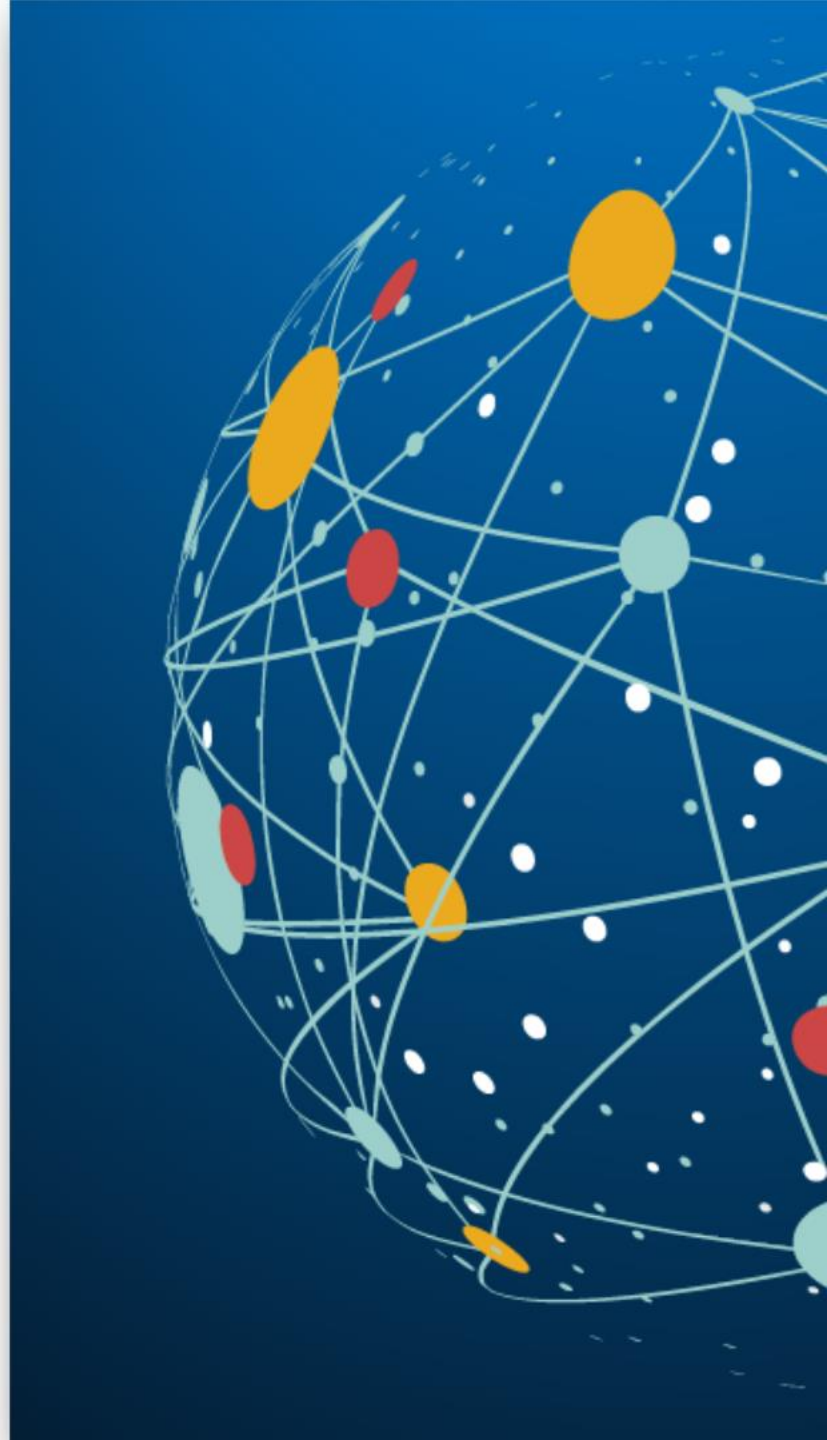
Potentially, if

- no 1-1 relationship between APID and USUBJID
- Analysis need of unsolicited APMH, APCE, etc.



Documentation Best Practices

- Clearly describe
  - Sources
  - Derivations
  - Dataset design considerations
- in
  - Metadata (define.xml)
  - Analysis Data Reviewer’s Guide (ADRG)



Outlook: ADaM Knowledge Base Articles

ADaM's Contribution to the Knowledge Base

Review of existing content with a relation to ADaM

Inventory of examples in non-normative ADaM documents

- e.g., TAUGs

New Knowledge Base Articles

- Clarification and examples for specific ADaM concepts
- Rather short
- Common template
  - Introduction
  - Advice/Instructions/Guidance
  - Examples
  - References
  - Additional Information

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Knowledge Base Articles in Development

- Multiple Participations
- Handling Associated Persons Data in ADaM
- Deciding When to Use Phase, Period, and Subperiod
- Deciding how and when to use Toxicity Variables
- Applying Bidirectional Toxicity Variables
- AyIND, ByIND, vs CRIT vs MCRIT vs AVALCATy
- Flag Variables for BDS Datasets - how to create ANL variables and when ANLzzFL should be used
- Traceability using SRCDOM, SRCVAR, SRCSEQ when multiple input sources are used
- Exploring the Use of Analysis Windowing Variables
- Origin Type and Source in ADaM define.xml
- etc.

Curious?

Explore the CDISC Knowledge Base.

Thank You!

Grazie Mille!

Questions?