

Study subjects’ information/data are mapped in Study Data Tabulation Model (SDTM) datasets. In some clinical studies, information about persons other than the study participant may also be collected and these needs to be included in SDTM models. These persons are classified as “Associated Persons”. CDISC has specific guidelines that deals with Associated Persons (AP) data => Study Data Tabulation Model Implementation Guide: Associated Persons (SDTMIG-AP).

WHO ARE ASSOCIATED PERSONS ?

AP are defined as non-study subject participants in a clinical study. It can include, but is not limited to a family member, an organ donor, a caregiver, environmental exposure, accidental study treatment exposure, etc.
An AP may or may not have a relationship with study subject. They can be associated with the study, or a device used in the study.

AP SDTM DATASETS

- Separate from study subject data
- AP domains based on traditional SDTM domains
- Only created if information about APs is collected
- AP dataset name prefixed with ‘AP--’
- AP dataset label begin with ‘Associated Persons’
- Supplemental qualifiers started with ‘SQAP’ instead of ‘SUPP’

SOME EXAMPLES OF AP DATA

- Parent’s data in pediatric study
- Family history data
- Data of original owners of donated organs, blood, tissues
- Smoking habits of a person who lives in the same household as a study subject
- Non enrolled subjects accidently exposed to a study treatment
- Partner pregnancy status

AP DATASET STRUCTURE

Structure is the same as those for study subject domains, apart from variables only applicable to study subjects (USUBJID).

APID can represent a single person, a group of people or a pool of people

- RSUBJID represent the USUBJID of the related study subject. Will be null for AP related to the study and not to study subjects
- RSUBJID = “MULTIPLE” when an AP has relationships to multiple subjects.

- SREL describes the relationship of the AP to the related study subject, to the pool of subjects (identified in RSUBJID) or to the device (identified in RDEVID).
- SREL = “MULTIPLE” when an AP has relationships to multiple subjects or devices or when an AP has multiple relationships to a single subject or device.

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char		Identifier	Four-character abbreviation for the domain, AP--.	Req
APID	Associated Persons Identifier	Char		Identifier	Identifier for a single associated person, a group of associated persons, or a pool of associated persons. If APID identifies a pool, POOLDEF records must exist for each associated person.	Req
--SEQ	Sequence Number	Num		Identifier	Sequence number to ensure uniqueness of records within a domain for associated persons. Unique within APID within the domain.	Req
RSUBJID	Related Subject	Char		Record Qualifier	Identifier for a related study subject or pool of study subjects. The subject(s) may be human or animal. RSUBJID will be populated with the USUBJID of the related subject or the POOLID of the related pool.	Exp
					RSUBJID will be null for data about associated persons who are related to the study but not to any of the study subjects.	
RDEVID	Related Device	Char		Record Qualifier	Identifier for a related device. RDEVID will be populated with the SPDEVID of the related device	Perm
SREL	Subject, Device, or Study Relationship	Char	(RELSUB)	Record Qualifier	If RSUBJID is populated, describes the relationship of the associated person(s) identified in APID to the subject or pool identified in RSUBJID. If RDEVID is populated, describes the relationship of the associated person(s) identified in APID to the device identified in RDEVID. If RSUBJID and RDEVID are null, SREL describes the relationship of the associated person(s) identified in APID to the study identified in STUDYID.	Req

Other variables named as in traditional SDTM datasets

APRELSUB dataset is required when SREL values of MULTIPLE appears in AP dataset but can be helpful even when not required, as a single dataset with all relationships of AP to study subjects. APRELSUB contains each of the individual relationships.

aprelsub.xpt, Associated Persons Related to Subjects, Version 0.5. One record per relationship

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
APID	Associated Persons Identifier	Char		Identifier	Identifier for a single associated person, a group of associated persons, or a pool of associated persons. If APID identifies a pool, POOLDEF records must exist for each associated person.	Req
RSUBJID	Related Subject or Pool Identifier	Char		Identifier	Identifier for a related subject or pool of subjects. RSUBJID may be populated with the USUBJID of the related subject or the POOLID of the related pool. RSUBJID will be null for data about associated persons who are related to the study but not to any study subjects.	Exp
RDEVID	Related Device Identifier	Char		Record Qualifier	Identifier for a related device. RDEVID will be populated with the SPDEVID of the related device.	Perm
SREL	Subject, Device, or Study Relationship	Char	(RELSUB)	Record Qualifier	If RSUBJID is populated, describes the relationship of the associated person(s) identified in APID to the subject or pool identified in RSUBJID. If RDEVID is populated, describes the relationship of the associated person(s) identified in APID to the device identified in RDEVID. If RSUBJID and RDEVID are null, SREL describes the relationship of the associated person(s) identified in APID to the study identified in STUDYID.	Req

* Indicates variable may be subject to controlled terminology, (Parenthesis indicates CDISC/NCI codelist code value).

- Only relationship of AP to study subjects are represented
- Relationship of a study subject to AP are not included
- Relationship between AP are not included

POOLDEF DATASET

POOLDEF dataset required if APID identifies a pool. A pool is composed of individually identified persons.

Below is the POOLDEF table that defines POOL1 and POOL2.
Rows 1-5: The individual associated persons that make up POOL1.
Rows 6-10: The individual associated persons that make up POOL2.

pooldef.xpt

Row	STUDYID	POOLID	APID
1	ABC	POOL1	AP001
2	ABC	POOL1	AP002
3	ABC	POOL1	AP003
4	ABC	POOL1	AP004
5	ABC	POOL1	AP005
6	ABC	POOL2	AP006
7	ABC	POOL2	AP007
8	ABC	POOL2	AP008
9	ABC	POOL2	AP009
10	ABC	POOL2	AP010

CAUTION

- Study subject variables would not be used (RFSTDCTC,RFXSTDTC, RFXENDTC, RFCIDTC, RFPENDTC, ARMCD, ARM, ACTARMCD, ACTARM)
- Timing variables (study day, visit, EPOCH...) may be ambiguous and should be used with caution – one AP can be related to multiple study subjects
- AP domains not recognized in Pinnacle 21 check

Issue Summary				
Source	Pinnacle 21 ID	Message	Severity	Found
APEG	SD9999	Dataset APEG class not recognized.		1

- SOME THOUGHTS -

- Which subjects are included in the protocol?
- Which subjects are enrolled in the study?
- Which data are collected in CRF for non-study subject?
-> AP domains to annotate in aCRF
- Create AP domains for non-study subject data when collected even if data collection are not planned as per study design
- What is the relationship of the non-study subject with the study or with study subject?

WHAT’S NEXT STEP ?

- Manual compliance checks :
 - ✓ Check dataset name and dataset label
 - ✓ SQAPxx used instead of SUPPxx
 - ✓ Ensure all AP required variables are populated
 - ✓ Same APID always identify the same associated person
 - ✓ Ensure RELSUB codelist is apply for SREL
 - ✓ Ensure that a record is present in APRELSUB when APxx.SREL = “MULTIPLE”
 - ✓ Ensure POOLDEF dataset generated if pool is used
 - ✓ Rules apply for traditional SDTM datasets also apply to AP datasets
- Clearly document SDTM AP mapping in Study Data Reviewer’s Guide
- ADaM datasets mapping :
 - ✓ Based on analysis needs, separate ADaM for AP data (ADAPxx) can be generated or traditional SDTM and SDTM AP can be combined in the same ADaM dataset
 - ✓ Clearly document ADaM AP mapping in ADaM Reviewer’s Guide