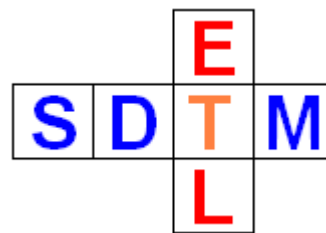


SDTM-ETL 4.1 User Manual and Tutorial

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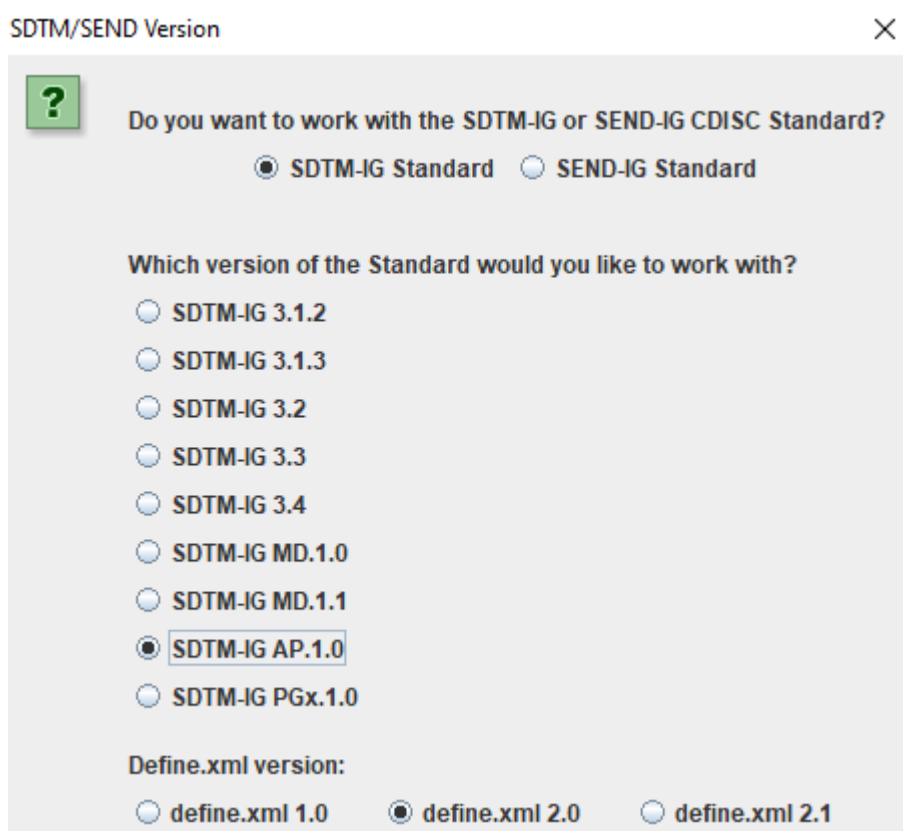
Last update: 2022-09-24



Working with the Associated Persons (AP) domain

In SDTM-ETL 4.1, there are a several ways of working with the SDTM "Associated Persons" domain.

The first way is to select "SDTM-IG AP.1.0" when starting creating definitions for SDTM domains, using the menu "File - Create define.xml" (CTRL-N), leading to:



This will then create templates for AP for a small number of selected AP domains:

Domains (ItemGroups)					
Domain	Variable	Variable	Variable	Variable	Vai
APDM	STUDYID	DOMAIN	AP.APID	AP.DM.RSUBJID	AP.DM.F
APRELSUB	STUDYID	AP.APID	AP.RSUBJID	AP.RDEVID	AP.SREI
APEX	STUDYID	DOMAIN	AP.APID	EX.EXSEQ	AP.RSU
APSU	STUDYID	DOMAIN	AP.APID	SU.SUSEQ	AP.RSU
APAE	STUDYID	DOMAIN	AP.APID	AE.AESEQ	AP.RSU
APMH	STUDYID	DOMAIN	AP.APID	MH.MHSEQ	AP.RSU
APLB	STUDYID	DOMAIN	AP.APID	LB.LBSEQ	AP.RSU
APQS	STUDYID	DOMAIN	AP.APID	QS.QSSEQ	AP.RSU
APRP	STUDYID	DOMAIN	AP.APID	RP.RPSEQ	AP.RSU
APSC	STUDYID	DOMAIN	AP.APID	SC.SCSEQ	AP.RSU

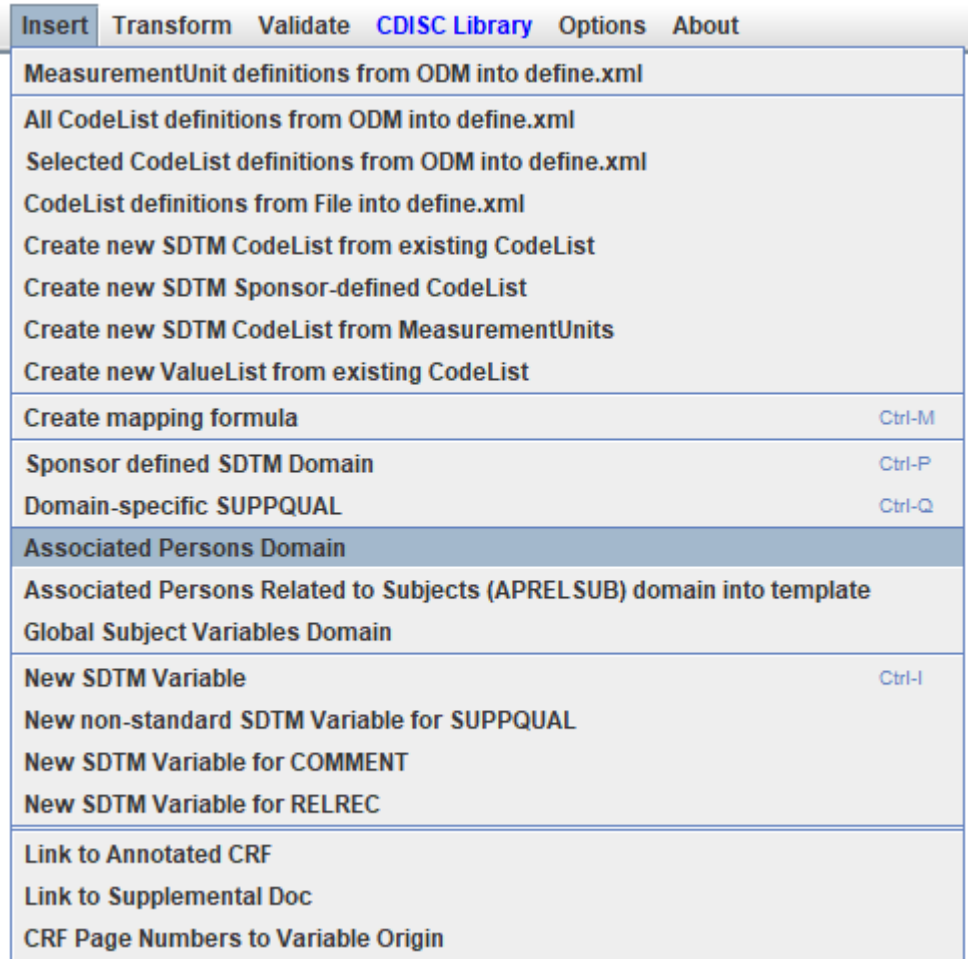
The advantage is that one can concentrate on "associated persons" aspects of the study, but can still merge the generated mappings with those of the subjects themselves.

The generated templates also include APRELSUB (Associated Persons Related to Subjects) which should be used when there is a 1:N relationship between the associated person and the subject (see further).

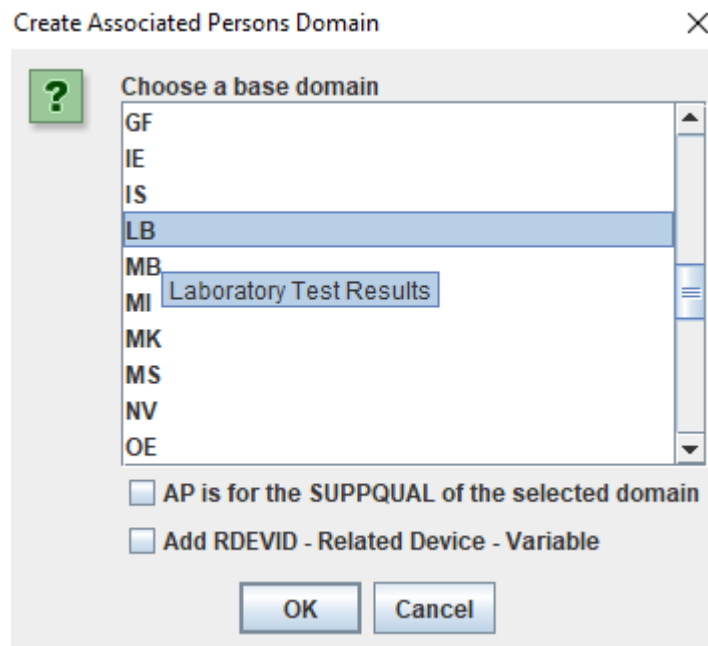
The disadvantage is that it has the templates for the most popular AP domains only, and that it is based on a rather old version of the SDTMIG (SDTMIG-3.2, 2013), not including any of the variables and features of the later SDTMIG versions such as 3.3 and 3.4.

Each of the templates can then be instantiated to a "study-specific" dataset definition by drag-and-drop to the bottom of the table. Working with them then works in exactly the same way as with any other dataset definitions.

The second way is to use any of the "normal" SDTMIG versions (e.g. 3.3, 3.4) as usual, and then use the menu "Insert - Associated Persons Domain":



which is followed by a selection list:



listing all the currently loaded domains.

The checkbox "AP is for the SUPPQUAL of the selected domain" will, when checked a so-called SQAP-dataset definition will be created, applying to a SUPPxx dataset. So, for example, that you have a SUPPLB dataset definition, the checking the checkbox will mean that the AP will be related

to SUPPLB (instead of LB), and the AP dataset name will then be SQAPLB.

The checkbox "Add RDEVID - Related Device - Variable", will, when checked, add a RDEVID variable to the dataset definition. It is used when there is a related device, and describes the relation of the associated person(s) identified in APID to the device identified in RDEVID.

Suppose that we want to create an "associated persons" dataset definition for LB (laboratory) as some lab tests have been done on family members of the subject.

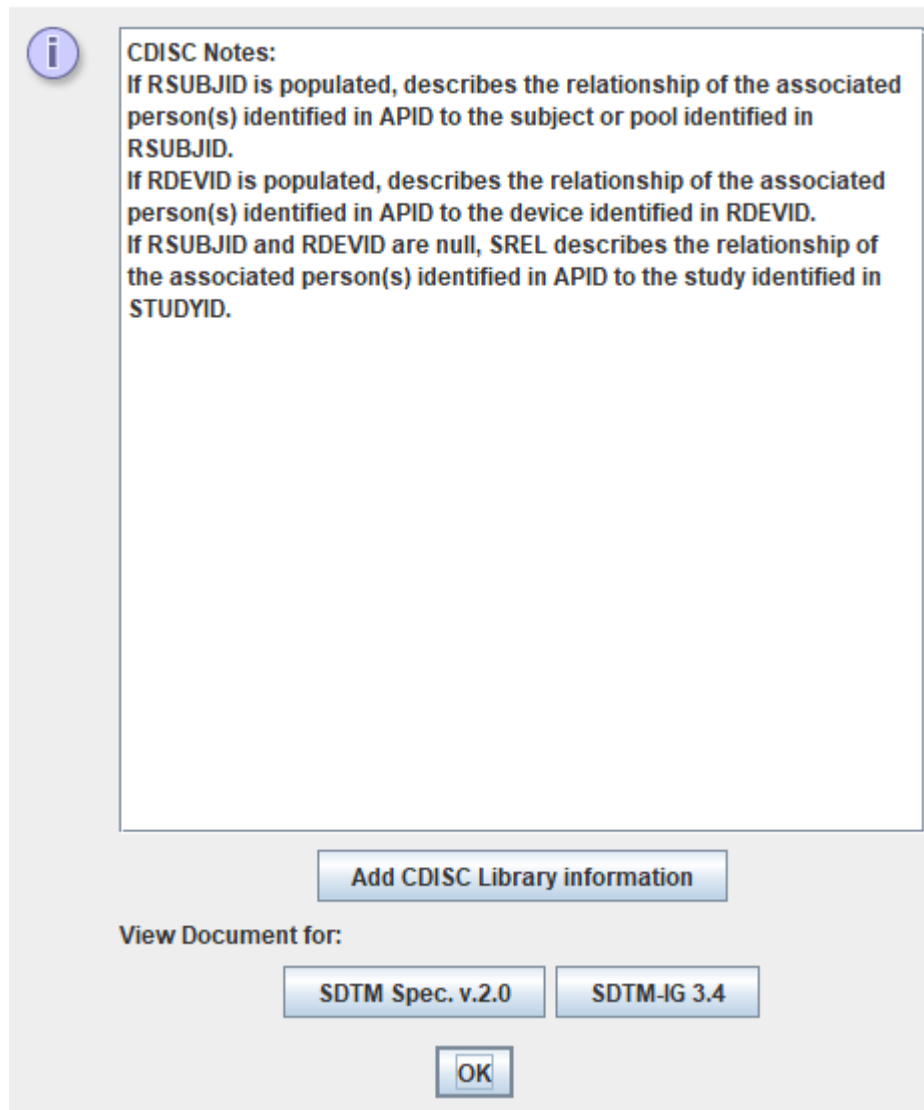
The resulting row created then shows as:

TS	STUDYID	DOMAIN	TS.TSSEQ	TS.TSGRPID	TS.TSPARMCD	TS.TSPARM	TS.TSVAL	TS.TSVALNF	TS.TSVALCD	TS.TSVCDFREF	TS.TSVCDFVER
TV	STUDYID	DOMAIN	TV.VISITNUM	TV.VISIT	TV.VISITDY	TV.ARMCD	TV.ARM	TV.TVSTRL	TV.TVENRL		
OI	STUDYID	DOMAIN	OI.OISEQ	OI.OIARMCD	OI.OIARM	OI.OIVAL					
RELREC	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID				
RELSPEC	STUDYID	USUBJID	REFID	SPEC	PARENT	LEVEL					
RELSUB	STUDYID	USUBJID	POOLID	RSUBJID	SREL						
SUPPOUAL	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG	QEVAL	
CES:APLB	STUDYID	DOMAIN	AP.APID	LB.LBSEQ	AP.RSUBJID	AP.SREL	LB.LBGRPID	LB.LBREFID	LB.LBSPID	LB.LBTESTCD	LB.LBTEST

One sees that mappings for STUDYID, DOMAIN and USUBJID have already been added automatically, but one can of course still change these.

One also sees that all "normal" LB variables have been added, based on the corresponding domain in the template.

Let us have a look at the "CDISC Notes" of the SREL variable, by selecting the cell and then use the menu "View - SDTM CDISC Notes" or using the keyboard combination CTRL-H. This leads to:



CDISC Notes:
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.

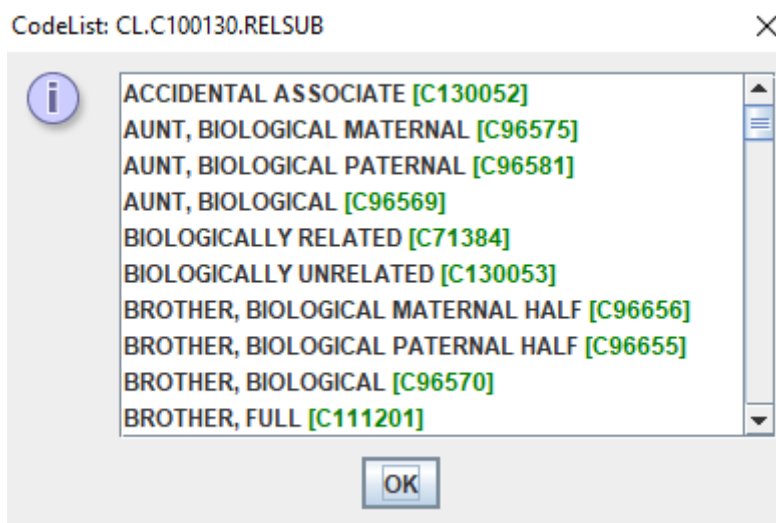
Add CDISC Library information

View Document for:

SDTM Spec. v.2.0 SDTM-IG 3.4

OK

SREL has an associated codelist, as one can see when using the menu "View - SDTM Associated CodeList":



CodeList: CL.C100130.RELSUB

ACCIDENTAL ASSOCIATE [C130052]
AUNT, BIOLOGICAL MATERNAL [C96575]
AUNT, BIOLOGICAL PATERNAL [C96581]
AUNT, BIOLOGICAL [C96569]
BIOLOGICALLY RELATED [C71384]
BIOLOGICALLY UNRELATED [C130053]
BROTHER, BIOLOGICAL MATERNAL HALF [C96656]
BROTHER, BIOLOGICAL PATERNAL HALF [C96655]
BROTHER, BIOLOGICAL [C96570]
BROTHER, FULL [C111201]

OK

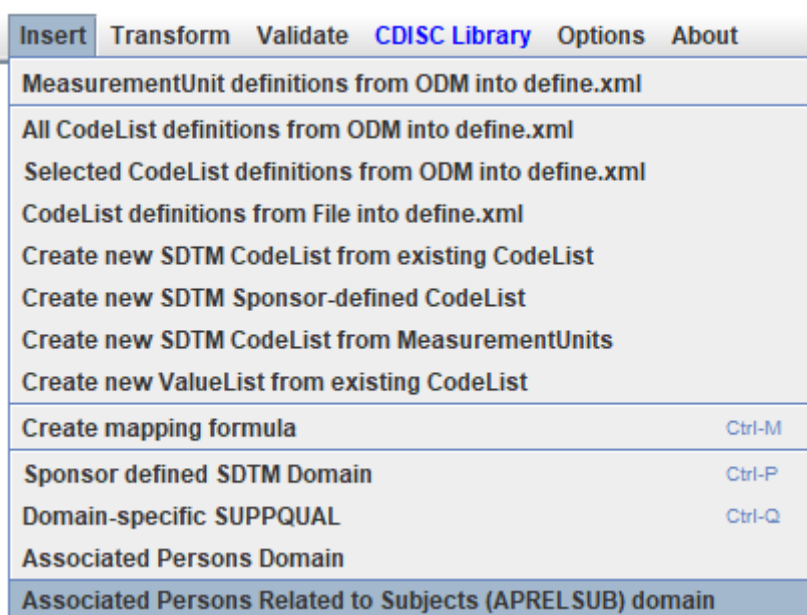
Once loaded, one can then start creating the mappings in the normal way.

We showed the codelist for SREL for a special reason, as SREL only allows to set one relationship type, e.g. "BROTHER, BIOLOGICAL".

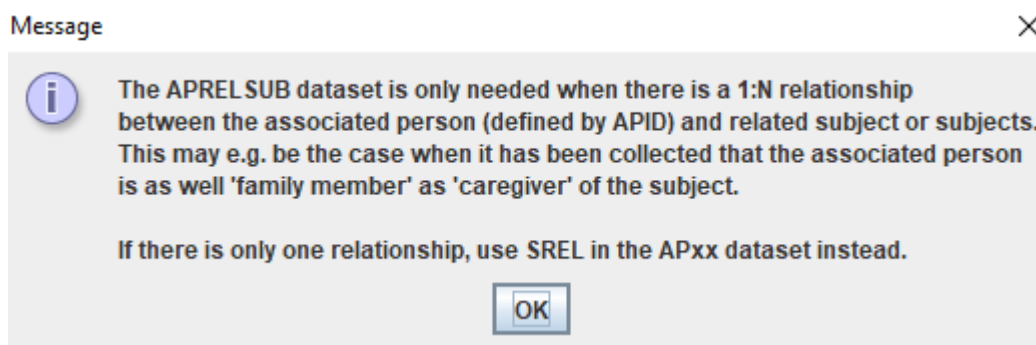
There are however cases, that there are multiple relationships between subject and associated person, e.g. that the associated person is as well "caregiver" as "domestic partner". As SDTM is "tabular", and a variable is supposed to have only one value, another solution is necessary. If the regulatory authorities would switch from SAS-XPT¹ to a modern format like [Dataset-JSON](#) or [Dataset-XML](#), there would be no problem at all.

When the relationship is multiple, the value for SREL must be "MULTIPLE", and the relationships listed in an additional APRELSUB () dataset.

A row for the latter can be added using the menu "Insert - Associated Persons Related to Subjects (APRELSUB) domain".



When used, an information message appears:



and the generated row than shows up as:

RELSUB	STUDYID	USUBJID	POOLID	RSUBJID	SREL
SUPPQUAL	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL
CES:APRELSUB	STUDYID	AP.APID	AP.RSUBJID	AP.RDEVID	AP.SREL

"If everything you know is SAS Transport 5, everything is a table"

Also here, the SREL variable has the associated codelist:

TV.VISITD	define.xml information:
OI.OIPARI	AP.SREL
IDVARVAL	Mandatory: No
PARENT	OrderNumber: 5
SREL	ItemDef/SDTM Name: SREL
IDVARVAL	Data type: text
AP.SREL	Length: 20
	Description: Subject, Device, or Study Relationship
	CodeList: CL.C100130.RELSUB

Some typical examples for the APRELSUB dataset are also provided by the "[Associated Persons Implementation Guide](#)":

4.1.3 APRELSUB Dataset Examples

Example 1

In this example, two study subjects received donated organs from the same AP, who was also biologically related to one of them.

- Row 1: The first subject to whom the AP is related.
 Rows 2-3: The second subject to whom the AP is related.

apreلسub.xpt

Row	STUDYID	APID	RSUBJID	SREL
1	NVM_0896	NS51	NVM10051	DONOR, ORGAN
2	NVM_0896	NS51	NVM10082	DONOR, ORGAN
3	NVM_0896	NS51	NVM10082	RELATIVE, BIOLOGICAL

Example 2

In this example, the sponsor has chosen to include all of the APs in the APRELSUB dataset, even though only one of them has multiple relationships to the subject.

apreلسub.xpt

Row	STUDYID	APID	RSUBJID	SREL
1	ZY_098	A0101	ZY_098_01	HOUSEHOLD MEMBER
2	ZY_098	A0101	ZY_098_01	SIBLING, FULL
3	ZY_098	A0102	ZY_098_01	HOUSEHOLD MEMBER
4	ZY_098	A0103	ZY_098_01	HOUSEHOLD MEMBER
5	ZY_098	A0104	ZY_098_01	HOUSEHOLD MEMBER

Example 3

In this example, data were collected about the caregivers and family members of study subjects. The sponsor has chosen to include only those APs with multiple relationships in the APRELSUB dataset.

- Rows 1-2: An AP with two relationships to a subject.
 Rows 3-4: An AP with relationships to two subjects.
 Rows 5-7: An AP with three relationships to a subject.
 Rows 8-9: An AP whose relationship to the subject requires more than one value from controlled terminology.

apreلسub.xpt

Row	STUDYID	APID	RSUBJID	SREL
1	VII	AP005	VII_02	CAREGIVER
2	VII	AP005	VII_02	AUNT, BIOLOGICAL PATERNAL
3	VII	AP006	VII_02	MOTHER
4	VII	AP006	VII_03	COUSIN, BIOLOGICAL PATERNAL
5	VII	AP027	VII_07	CAREGIVER
6	VII	AP027	VII_07	AUNT, BIOLOGICAL MATERNAL
7	VII	AP027	VII_07	MOTHER, STEP
8	VII	AP030	VII_07	TWIN, DIZYGOTIC
9	VII	AP030	VII_07	BROTHER, FULL

Conclusions:

The SDTM-ETL software has very good features for working with the "Associated Persons" (AP) domain and creating the datasets for them.

In most case, one will want to generate the dataset specification for one or more AP datasets starting from the menu "Insert - Associated Persons Domain".

If the relationship between associated person and subject is multiple, one will set SREL in the AP dataset definition itself to "MULTIPLE", and then have several rows in the "APRELSUB" dataset, for which the dataset definition is loaded using the menu Insert - Associated Persons Related to Subjects (APRELSUB) domain".