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:
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":

<table>
<thead>
<tr>
<th>Domain</th>
<th>Variable</th>
<th>Variable</th>
<th>Variable</th>
<th>Variable</th>
<th>Variable</th>
<th>Variable</th>
</tr>
</thead>
<tbody>
<tr>
<td>APDM</td>
<td>STUDYID</td>
<td>DOMAIN</td>
<td>AP_AIPIID</td>
<td>AP_DM_RSUBLID</td>
<td>AP_DM_F</td>
<td></td>
</tr>
<tr>
<td>APRELSUB</td>
<td>STUDYID</td>
<td>AP_AIPIID</td>
<td>AP_RSUBLID</td>
<td>AP_R0EQID</td>
<td>AP_SR5E</td>
<td></td>
</tr>
<tr>
<td>APEX</td>
<td>STUDYID</td>
<td>DOMAIN</td>
<td>AP_AIPIID</td>
<td>EX_EXSEQ</td>
<td>AP_RSU</td>
<td></td>
</tr>
<tr>
<td>APSU</td>
<td>STUDYID</td>
<td>DOMAIN</td>
<td>AP_AIPIID</td>
<td>SU_SUSEQ</td>
<td>AP_RSU</td>
<td></td>
</tr>
<tr>
<td>APAE</td>
<td>STUDYID</td>
<td>DOMAIN</td>
<td>AP_AIPIID</td>
<td>AE_AESEQ</td>
<td>AP_RSU</td>
<td></td>
</tr>
<tr>
<td>APMH</td>
<td>STUDYID</td>
<td>DOMAIN</td>
<td>AP_AIPIID</td>
<td>MH_MHSEQ</td>
<td>AP_RSU</td>
<td></td>
</tr>
<tr>
<td>APLB</td>
<td>STUDYID</td>
<td>DOMAIN</td>
<td>AP_AIPIID</td>
<td>LB_LBSEQ</td>
<td>AP_RSU</td>
<td></td>
</tr>
<tr>
<td>APOS</td>
<td>STUDYID</td>
<td>DOMAIN</td>
<td>AP_AIPIID</td>
<td>DS_DSSEQ</td>
<td>AP_RSU</td>
<td></td>
</tr>
<tr>
<td>APRP</td>
<td>STUDYID</td>
<td>AP_AIPIID</td>
<td>RP_RPSEQ</td>
<td>AP_RSU</td>
<td></td>
<td></td>
</tr>
<tr>
<td>APSC</td>
<td>STUDYID</td>
<td>DOMAIN</td>
<td>AP_AIPIID</td>
<td>SC_SCSEQ</td>
<td>AP_RSU</td>
<td></td>
</tr>
</tbody>
</table>
which is followed by a selection list:

```
Create Associated Persons Domain

Choose a base domain
- GF
- IE
- IS
- LB
- MB
- MI
- MK
- MS
- NV
- OE

AP is for the SUPPQUAL of the selected domain
Add RDEVID - Related Device - Variable

OK  Cancel
```

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:

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

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-XPT\(^1\) 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".

![Menu Screen](image)

When used, an information message appears:

![Message](image)

and the generated row than shows up as:

<table>
<thead>
<tr>
<th>STUDYID</th>
<th>USUBJID</th>
<th>POOLID</th>
<th>RSUBJID</th>
<th>SREL</th>
</tr>
</thead>
<tbody>
<tr>
<td>STUDYID</td>
<td>RDOMAIN</td>
<td>USUBJID</td>
<td>IDVAR</td>
<td>IDVAR/AL</td>
</tr>
<tr>
<td>APRELSUB</td>
<td>AP.APIID</td>
<td>AP.RSUBJID</td>
<td>AP.RDEVID</td>
<td>AP.SREL</td>
</tr>
</tbody>
</table>

"If everything you know is SAS Transport 5, everything is a table"
Also here, the SREL variable has the associated codelist:

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

#### 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.

#### 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.
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."