When deriving ADaM from SDTM, the standardization provides more efficiency in terms of standardized programs and codes as the SAS programs are reusable. However, in practice, most of the time, program preparation starts when data collection is still ongoing. Thus, some raw datasets are empty or some variables have null values. When SDTM datasets are created, the corresponding all the data been collected. Therefore, the programmers need to check the new SDTM data every time when the database is retrieved so that the ADaM programs can be updated right after. That is time consuming. Sometimes, the worst is the programmers may forget to check the data and do not realize that additional SDTM data panels or values are generated. To avoid that, during the two particular domains that may not exist or only have partial data in the early program preparation stage. This paper will discuss the issues caused by partial SUPP-- or missing SUPP-- and CO and provide SUPP Dataset

### SUPP Dataset

**Case 1: Complete SUPP-- Dataset**

<table>
<thead>
<tr>
<th>USUBJID</th>
<th>IDVAR</th>
<th>IDVARVAL</th>
<th>QNAM</th>
<th>QLABEL</th>
<th>QVAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>99-123</td>
<td>ASEQ</td>
<td>6</td>
<td>AEOC1</td>
<td>Location of the Reaction 1</td>
<td>FACE</td>
</tr>
<tr>
<td>99-123</td>
<td>ASEQ</td>
<td>6</td>
<td>AEOC2</td>
<td>Location of the Reaction 2</td>
<td>BACK</td>
</tr>
<tr>
<td>99-123</td>
<td>ASEQ</td>
<td>6</td>
<td>AEOC3</td>
<td>Location of the Reaction 3</td>
<td>CHEST</td>
</tr>
<tr>
<td>99-123</td>
<td>ASEQ</td>
<td>6</td>
<td>AEOCOTH</td>
<td>Other Location of Reaction</td>
<td>RIGHT ARM</td>
</tr>
</tbody>
</table>

**Case 2: Incomplete SUPP-- Dataset**

<table>
<thead>
<tr>
<th>USUBJID</th>
<th>IDVAR</th>
<th>IDVARVAL</th>
<th>QNAM</th>
<th>QLABEL</th>
<th>QVAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>99-123</td>
<td>ASEQ</td>
<td>6</td>
<td>AEOC1</td>
<td>Location of the Reaction 1</td>
<td>FACE</td>
</tr>
<tr>
<td>99-123</td>
<td>ASEQ</td>
<td>6</td>
<td>AEOC2</td>
<td>Location of the Reaction 2</td>
<td>BACK</td>
</tr>
</tbody>
</table>

**Solution 1**

- Use data steps and macro instead of using PROC TRANSPOSE.
- SUPPDM may not exist when ADSL programming starts as on subjects have other race before DB lock.
- If programmer chooses to ignore SUPPDM, she/he need to check if SUPPDM exists during each run.
- The worst case is SUPPDM is generated at DB lock but the programmer forgets to include them in ADSL program, therefore, other race will be missing in ADSL.
- ADaM dataset programs need to handle SUPP data no matter if it exists or not to avoid future programming problems as long as those variables are collected in CRF.

**SAS Code**

```sas
data dm2;
set supp&rdomain;
where memname="SUPP&rdomain"
run;
run;
proc print;
run;
```

**Solution 2**

- Create an empty dataset ADAE using ATTRIB statement with all variables.
- Two variables AEOC3 and AEOCOTH specified in CRF may be missed in ADAE.
- Programs for TFLs cannot be prepared and tested smoothly because of missing variables in dataset.

**SAS Code**

```sas
%macro supp(rdomain=, var=, label=);
%let rdomain=%upcase(&rdomain);
%let var=%upcase(&var);
%let label=%upcase(&label);
proc sort data=&var;
by usubjid;
run;
proc print data=&var;
run;
```

**Solution 3**

- Create an empty dataset ADAE using ATTRIB statement with all variables.
- Concatenate the empty dataset ADAE and AE2 to get final ADAE dataset.
CONCLUSION

In the CDISC SDTM Implementation Guide, some empty datasets and permissible variables that contain null values will not be submitted. Thus, some SDTM domains or values in SUPP-- may not exist before all data are received. That will result in programming difficulty when we derive ADaM datasets. We discussed problems caused by relationship datasets SUPP-- and CO and provided out solution with SAS codes. There may be other problems when creating ADaM datasets from SDTM. We welcome further discussion.

CONTACT INFORMATION

Suwen Li
Everest Clinical Research Services, Inc.
675 Cochrane Drive
Suite 408, East Tower
Markham, Ontario, Canada L3R 0B8
Tel. 905.752.5253 Fax 905.752.5223
suwen.li@ecrscorp.com