We implemented the STREAM concept in a pilot study. Designed SAP and ADaM specifications with a close link to each other. Designed most of the ADaMs as BDS. This reduces programming efforts and validation efforts. Put the exact values in the ADaM that needs to be reported. Parameter response in AVALC. Use numeric sorting variables to control the display order. Title in PARCAT1. Automatically extract reporting metadata from ADaM.

**Implementation of Concept**

### 1. Consistency through Metadata

**ADaM – Metadata linked from SAP**
- Define the parameters concisely in SAP (along with the intended order of reporting)
- Use BDS data structure to design the ADaM
- Create variables with values directly coming from SAP (e.g. PARCAT1, PARAM)
- Use numeric sorting variables to control the display order (e.g. PARCAT1, PARAM)

**Reporting – Metadata linked from ADaM**
- Put the exact values in the ADaM that needs to be reported
  - Title in PARCAT1
  - Parameter description in PARAM
  - Parameter sorting in PARAM
  - Parameter response in AVAL
  - Response sorting / Numeric response in AVAL

**External formats for treatment and population label**

### 2. ADaM – Metadata linked from SAP

**Plan**
- Define the ADaM Specification (ADS) as per the SAP definitions and create a SAS dataset to store the metadata from ADS.
- Derive only PARAMCD, AVAL & AVALC in temporary ADaM and link reporting metadata created in STEP 1 with this data to get the final ADaM.

**Standardized Mockups**
- can be created to cater various layouts.
- Below example shows an example of BDS data’s layout for a summary table with both numeric and character parameters.

**Standardized programs**
- can be created based on the standard layouts to generate the summary tables.
- Next figure shows how looping through various PARCAT1 values in a BDS ADaM will create summary table of similar layout.

Number of values in PARCAT1 controls the number of tables and any number of parameters can be added within PARCAT1. All parameters within a same PARCAT1 will be reported in the same table. If new tables are needed then we add new values in PARCAT1 in ADaM and if new parameters are needed in an existing PARCAT1 then we only have to update our ADaM program and this change will flow directly to the table output.

### Conclusion

- Reduces programming efforts
- Ensures consistency
- No need for Table specifications
- Produces > 90% of summary tables
- Very few standard macros are needed
- Reduces validation effort

**Pilot Implementation Results**

- We implemented the STREAM concept in a pilot study.
- Designed SAP and ADaM specification with close link to each other.
- Designed most of the ADaMs as BDS.
- Created standardized reporting mockups & standardized reporting macros.
- We were able to generate 99% of all the summary tables using this approach.
- Below figure show the different ADaMs that we are able to use directly from this approach.