Abstract:

In pharmaceutical industry, submission of clinical trial data in CDISC standards is mandatory in US-FDA. Manual Standardization of clinical data is time consuming and repeated process. Automating the program creation process will reduce the time and human errors. This poster will focus on how SDTM program generation can be automated by SAS, using standard specification and standard metadata repository. It could be CDISC standards or Sponsor defined standards. Also, it emphasizes on the details of metadata repository and how that can be efficiently used for automation. The utility generated SAS programs will be in domain wise and can be used for further customization by the user.

Introduction:

CDISC SDTM is the set of specific standard requirements that should be followed in the preparation of submission datasets to regulatory authorities. As CDISC CDASH standards or standardized EDC are widely adopted in the database design in clinical trials, SAS macros can be developed for the automated conversion of the SDTM data structure from mapping specification. This work introduces a method, that has been developed to facilitate the automation of standardized RAW - SDTM conversion. In addition to that, creating a standard metadata library for SDTM IG standards and custom domains based on therapeutic area and sponsor. This also includes basic compliance checks in mapping specification against the SDTM IG standards at variable attributes.

Process flow:

1. Input Raw Datasets: All source datasets with CDISC standards or SDTM files standards
2. Generated Compare Report: Created by comparing SDTM Spec file and created spec data for compliance
3. Metadata with SDTM IG Standards: Metadata to create standard SDTM IG standard specific to the library
4. Developed SDTM Programs using %SDTM_ProgGen: Spec file is updated using SDTM programs developed for all the domains. User performs the study specific updates, also the programs are ready to be executed
5. Created SDTM SAS Programs: SDTM programs developed for all the domains. User performs the study specific updates, also the programs are ready to be executed
6. Sample Code Generated for the above Spec:

```sas
/* Macro calling for SDTM Program Generation*/
%SDTM_progGen('specified_code', /* Full path and filename of specification document*/
('domainname'), /*All or List of domains with space delimited*/
('SpecDoc') /*Program output location */)
```

References: