

Stay relaxed... An Utility to auto create specification!!

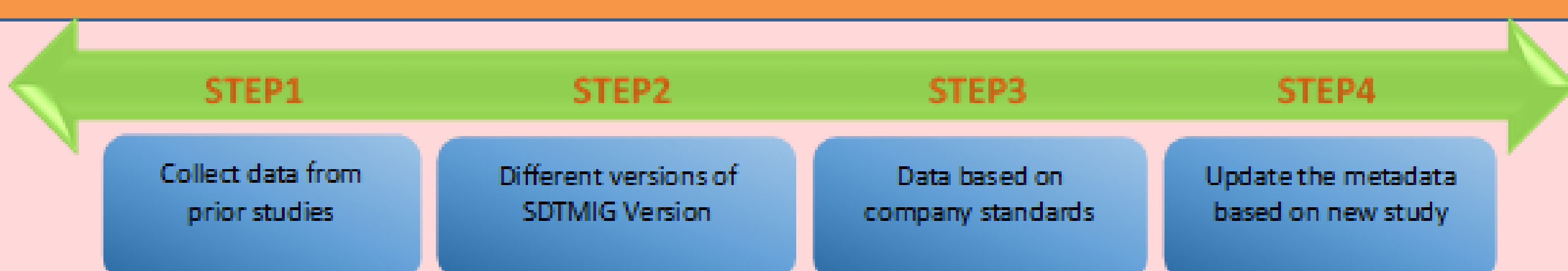
Abstract:

In the Pharmaceutical industry, specifications are core which mandates for all programming activities. Currently, SDTM and ADAM specifications are configured manually by mapping the raw data to the standard domains. This paper proposes an automatic and efficient approach to configure certain parts of SDTM specifications using SAS macros. This enables the auto-population of mapping rules into the specification, significantly reducing the manual work and make our deliverables on time with higher quality.

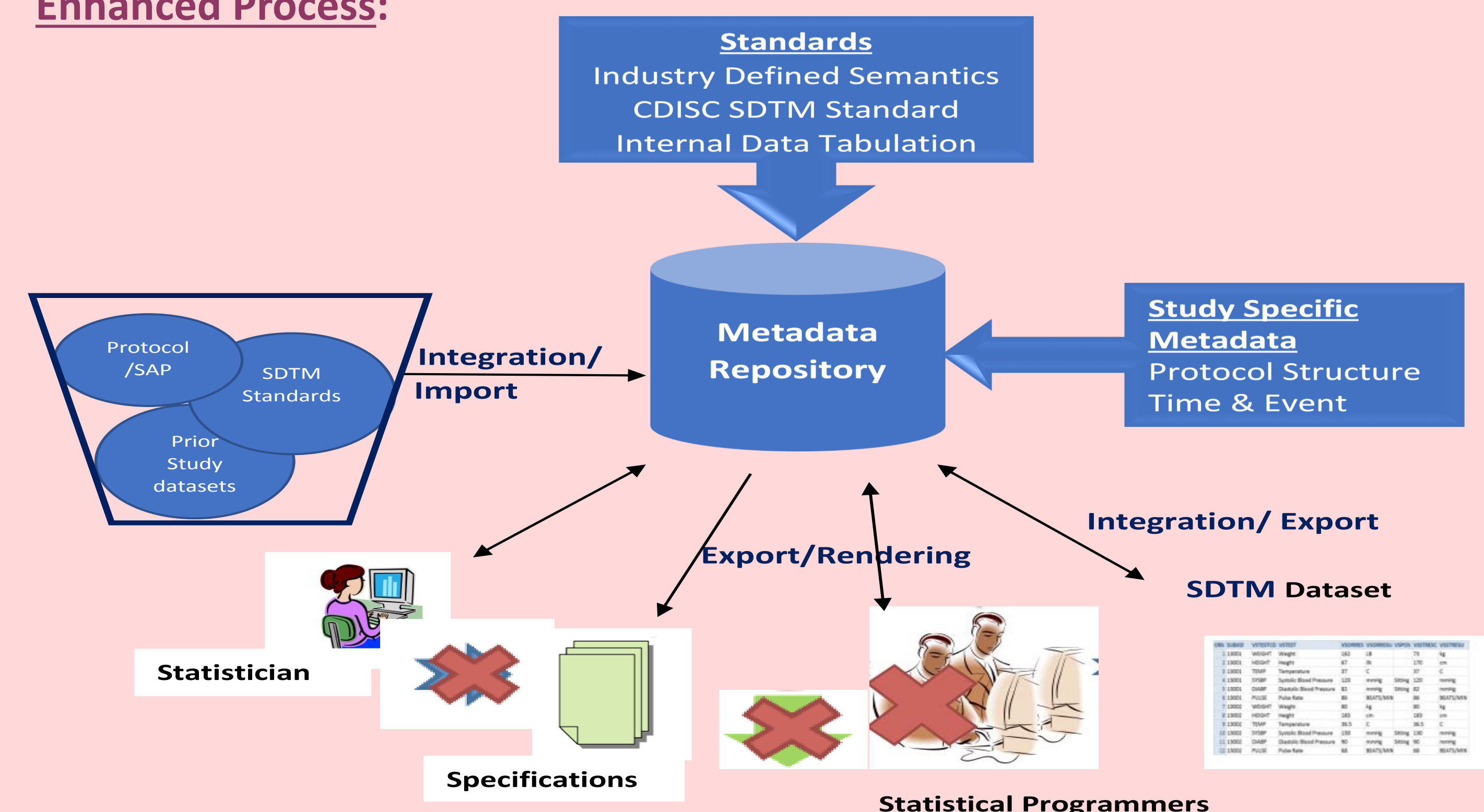
Introduction:

Specification generation process is to integrate/map data for different studies of a compound into a common integrated database. The source data can be any standard, also company standards with different therapeutic area. By using sas macro templates and metadata , we can generate the SDTM spec without doing repetitive work for spec writing process.

Metadata Creation :



Enhanced Process:



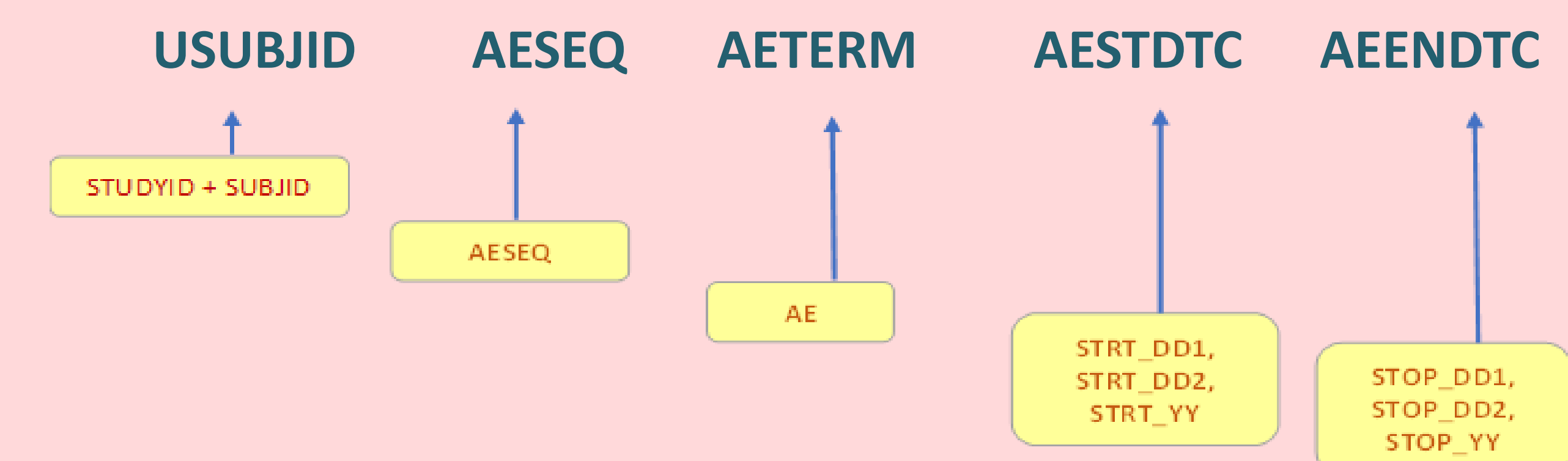
Source data :

DATASET	VARIABLE ID	VARIABLE	LABEL	DATA TYPE	FORMAT
AECDISC	15	AESEQ	AE Sequence	num	
AECDISC	16	AE_ANY	Did Subject Report Any Adverse Events?	num	NYF.
AECDISC	17	AE	Adverse Experience, Literal	char	
AECDISC	18	STRT_DD1	Onset Date Day (DD)	char	
AECDISC	19	STRT_DD2	Onset Date Month(MON)	char	
AECDISC	20	STRT_YY	Onset Date Year(YYYY)	char	
AECDISC	21	STRT_DT	Onset Date, Derived	num	DATE9.

Standard Metadata :

CLASS	DOMAIN	VARIABLENAME	VARIABLENAMEGENERAL	LABEL	TYPE	ROLE	CORE	MANDATORY
Events	AE	USUBJID	USUBJID	Unique Subject Identifier	Char	Identifier	Required	Yes
Events	AE	AESEQ	SEQ	Sequence Number	Num	Identifier	Required	Yes
Events	AE	AETERM	TERM	Reported Term for the Adverse Event	Char	Topic	Required	Yes
Events	AE	AESTDTC	STDT	Start Date/Time of Adverse Event	Char	Timing	Expected	No
Events	AE	AEENDTC	ENDTC	End Date/Time of Adverse Event	Char	Timing	Expected	No
Events	AE	AEDY	DY	Study Day of Visit/Collection/Exam	Num	Timing	Permissible	No
Events	AE	AESTDY	STDY	Study Day of Start of Adverse Event	Num	Timing	Permissible	No
Events	AE	AEENDY	ENDY	Study Day of End of Adverse Event	Num	Timing	Permissible	No

Metadata driven source to Target Transformations :



Look-Up Table :

Source_Dataset	Source_Variable	Source_Label	Data_Type	Length	Format	Target_Domain	Target_Variable	SDTM_Label	Mapping_Logics
AECDISC	AE	Adverse Experience, Literal	Char	70		AE	AETERM	Reported Term for the Adverse Event	If AETERM missing then delete from the dataset
AECDISC	STRT_DD1	Onset Date Day (DD)	Char	16	ISO 8601	AE	AESTDTC	Start Date/Time of Adverse Event	If not missing(STRT_DD1, STRT_DD2, STRT_YY) then concatenate and convert into ISO 8601 format.
AECDISC	STRT_DD2	Onset Date Month (MON)	Char	16	ISO 8601	AE	AESTDTC	Start Date/Time of Adverse Event	as above
AECDISC	STRT_YY	Onset Date Year(YYYY)	Char	16	ISO 8601	AE	AESTDTC	Start Date/Time of Adverse Event	as above
AECDISC	STRT_DT	Onset Date Derived							
AECDISC	STOP_DD1	End Date Day (DD)	Char	16	ISO 8601	AE	AEENDTC	End Date/Time of Adverse Event	If not missing(STOP_DD1, STOP_DD2, STOP_YY) then concatenate and convert into ISO 8601 format.
AECDISC	STOP_DD2	End Date Month (MON)	Char	16	ISO 8601	AE	AEENDTC	End Date/Time of Adverse Event	as above
AECDISC	STOP_YY	End Date Year(YYYY)	Char	16	ISO 8601	AE	AEENDTC	End Date/Time of Adverse Event	as above

Macro calling to create spec :

```
%m_specgen(ipdata = /** Source data library **/  
Metapath = /** Path for metadata file **/  
Whrcond = /** Metadata, where to get type of collection **/  
Lookupt = /** Target look up table location **/  
Outpath = /** Path, where to generate mapping spec **/  
Sdtmig = /** Specifies the SDTMIG version which need to use **/  
);
```

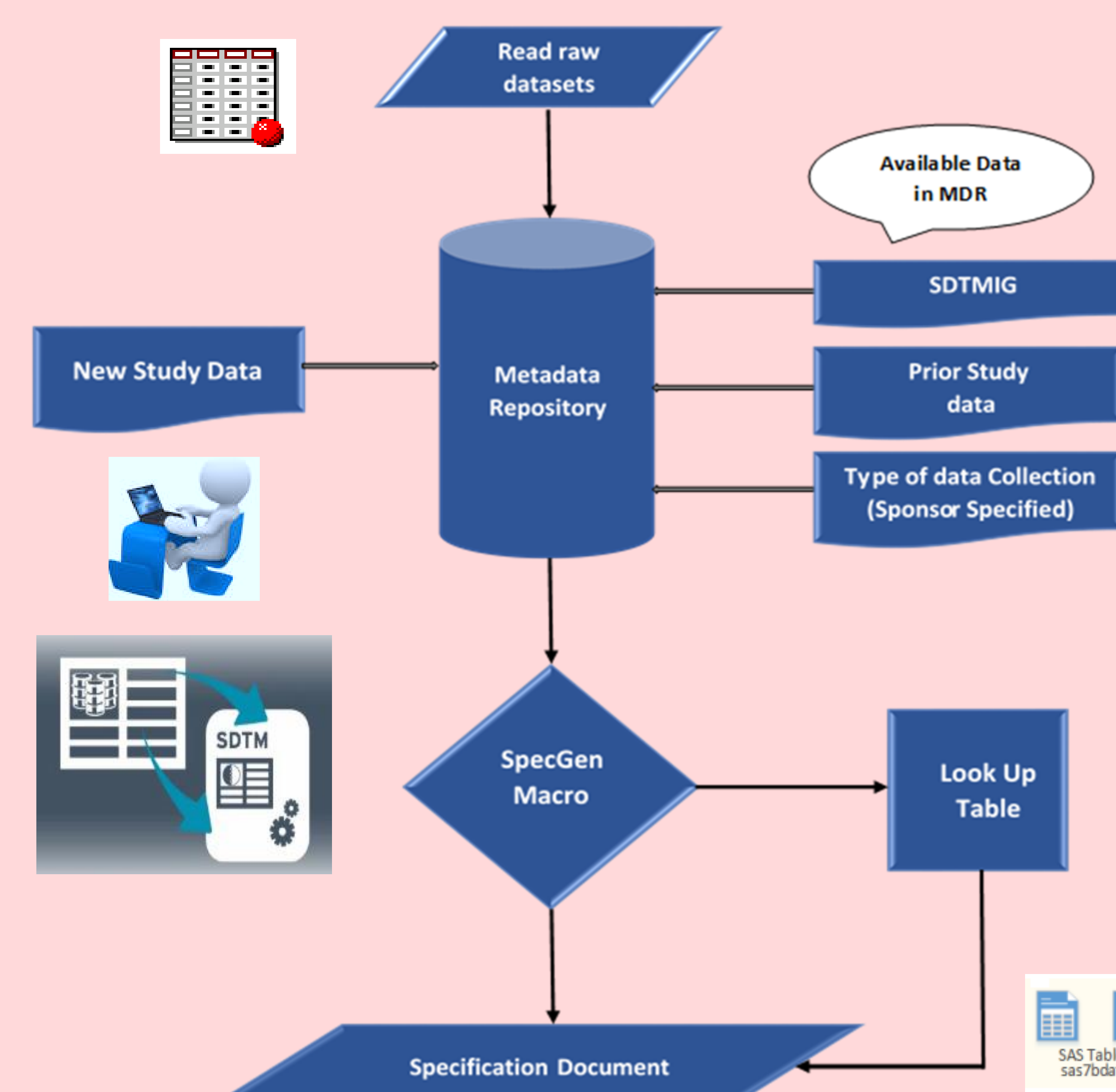
To compare source data with metadata :

- ❖ Compare the variables in Source Dataset and Metadata using SAS Macro.
- ❖ Where statement in macro filters the type of data collection which is based on each therapeutic area under company standards.
- ❖ Create target domain table with matched variables and its transformation.
- ❖ Check and update the generated specification manually for the variables which is not available in the Metadata.

Advantages :

- 👉 Allow the specification to adopt a uniform structure over all the studies.
- 👉 It will also facilitate Use and Re-Use of existing/previous Study based on rules in metadata.
- 👉 Reduce a considerable amount of time and manpower involved which in turn reduces the manual errors.

Process overflow :



Final automated specification :

Variable Name	Variable Label	Type	Length	Controlled Terms or Format	Origin	Role	Core	From Dataset	Variable Name or Fixed Value	Mapping Logic	General Comments / Questions
USUBJID	Unique Subject Identifier	Char	24		Sponsor Defined	Identifier	Req	AECDISC	ID	Create Subject ID in a combination of Studyid and subjectid	
AESEQ	Sequence Number	Num	8		Derived	Identifier	Req			Unique identification of records per subject. Sort by USUBJID, AESTDTC, AEBODSYS, and AETERM	
AETERM	Reported Term for the Adverse Event	Char	70			Topic	Req	AECDISC	AE	If AETERM missing then delete from the dataset	
AESTDTC	Start Date/Time of Adverse Event	Char	16	ISO 8601		Timing	Exp	AECDISC	STRT_DD1, STRT_DD2, STRT_YY		
AEENDTC	End Date/Time of Adverse Event	Char	16	ISO 8601		Timing	Exp	AECDISC	STOP_DD1, STOP_DD2, STOP_YY		
AESTDY	Study Day of Start of Adverse Event	Num	8		Derived	Timing	Perm	SDTM.DM, SDTM.AE	DM.RFSTDT, AE.AESTDTC	For RFSTDT and AESTDTC not missing: If <RFSTDT then AESTDTC-RFSTDT; If AESTDTC=RFSTDT then AESTDTC-RFSTDT+1	
AEENDY	Study Day of End of Adverse Event	Num	8		Derived	Timing	Perm	SDTM.DM, SDTM.AE	DM.RFSTDT, AE.AEENDTC	For AEENDTC and RFSTDT not missing: If AEENDTC-RFSTDT then AEENDTC-RFSTDT; If AEENDTC=RFSTDT then AEENDTC-RFSTDT+1	

Future amendment :

To generate mapping specification for ADAM datasets with the use of standard metadata repository to get all the common variables for all the datasets.

Conclusion :

Creating SDTM specifications using SAS macros can eliminate most of the manual and repetitive work from the spec writing process. This Overall automation process produces more efficient, higher quality, and less error prone specifications.

References :

- SAS Institute Inc. (2008). *SAS Component Language 9.2: Reference*. Cary, NC: SAS Institute Inc.
- Judith Goud, Priya Shetty. (2016), "How a Metadata Repository enables dynamism and automation in SDTM-like dataset generation" <https://www.lexjansen.com/phuse/2016/dh/DH05.pdf>