

VALSPEC Utility to Validate CDISC Specifications

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Agenda

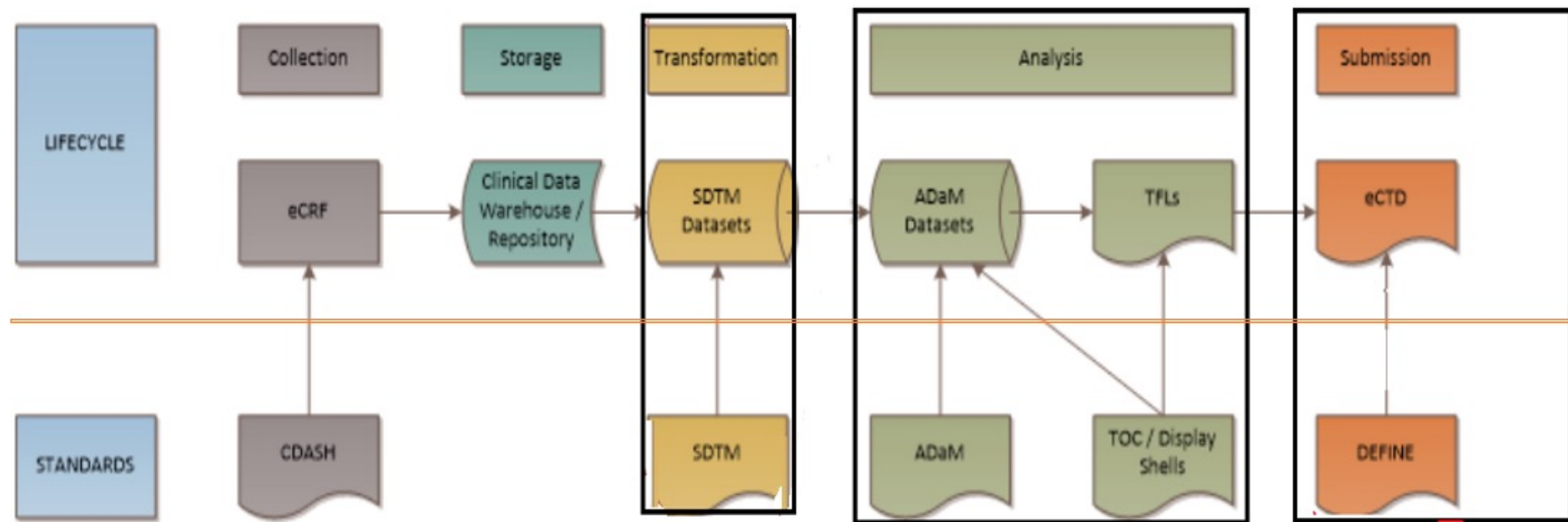
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- ❖ Examples
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Author's Bio

Hrideep Antony is a Principal Statistical Programmer with Syneos Health, and has over 15 years of extensive SAS experience. Hrideep enjoys developing and providing innovative/efficacious solutions to streamline the FDA submission process. He has been given opportunities to present at multiple SAS conferences in the past. Hrideep enjoys spirituality, music, travelling, volunteering at nursing homes/rehabilitation facilities, learning and sharing knowledge.

Aman Bahl is an Associate Director, Statistical Programming with Syneos Health, and has around 20 years of Technology and Data services experience including 17 years of Clinical industry experience in the areas of project management, team management, statistical programming and other statistical services. Aman enjoys outdoor sports, trekking, travelling and volunteering.

Introduction



Updates to the SDTM specifications at the stage of DEFINE document creation may require SDTM, ADaM, and TFL updates



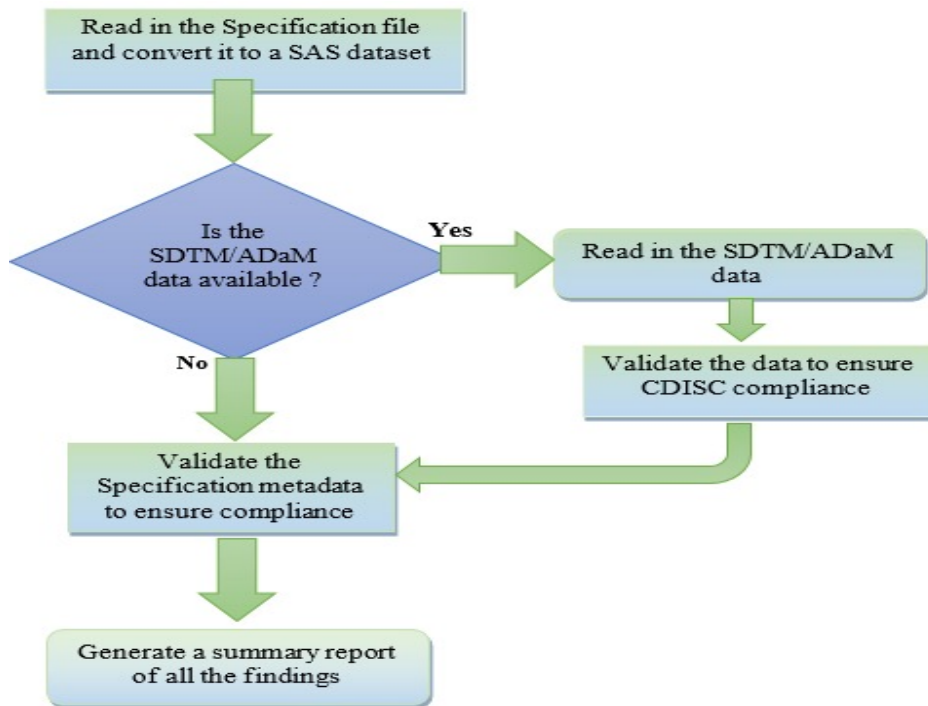
Define.xml creation challenge

- ❑ Define.xml is usually created at the end of the study database lock after the specifications are finalized and SDTMs are ready, as Pinnacle21 requires the SDTM datasets to validate the define.xml document
- ❑ Majority of the disputes in the specification documents are only identified after the Pinnacle 21 validation
- ❑ The validation of specification can be efficiently done at the initial stages before SDTM programming starts, to avoid rework.

VALSPEC Utility

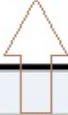
- The quality of the SDTM/ADaM specifications has a key role in determining the quality of the define.xml document, which is a key part of the CRT package submitted to the regulatory agencies for approval.
- VALSPEC is a utility to validate SDTM and ADaM specifications and streamline the creation of define.xml.
- VALSPEC alerts the author about the issues in the specification document at the very first stage of the creation of the SDTM/ADAM specifications by checking for compliance
- VALSPEC reads in the metadata and validates the references to the formats and terminologies that are used in the specification across the Select, Define, and Control terminologies

Process flow



Issue list for DM

Error represents that there are data values that are not consistent with the values in the Specification



O	DATASET	SUBMISSION_VALUE	CTLIST Name	Message
1	DM	DRGA		Error: Format value DRGA-Not found
2	DM	Placebo		Error: Format value Placebo -Not found
3	DM	TRTA	ARM	Warning: Format ARM-TRTA-Not used in the data
4	DM	TRTB	ARM	Warning: Format ARM-TRTB-Not used in the data
5	DM	1	ARMCD	Warning: Format ARMCD-1-Not used in the data
6	DM	2	ARMCD	Warning: Format ARMCD-2-Not used in the data
7	DM	8		Error: Format value 8-Not found
8	DM	9		Error: Format value 9-Not found
9	DM	BEL	COUNTRY	Warning: Format COUNTRY-BEL-Not used in the data
10	DM	CZE	COUNTRY	Warning: Format COUNTRY-CZE-Not used in the data
11	DM	DEU	COUNTRY	Warning: Format COUNTRY-DEU-Not used in the data
12	DM	ESP	COUNTRY	Warning: Format COUNTRY-ESP-Not used in the data
13	DM	FRA	COUNTRY	Warning: Format COUNTRY-FRA-Not used in the data
14	DM	GBR	COUNTRY	Warning: Format COUNTRY-GBR-Not used in the data
15	DM	IND	COUNTRY	Warning: Format COUNTRY-IND-Not used in the data
16	DM	ITA	COUNTRY	Warning: Format COUNTRY-ITA-Not used in the data
17	DM	MEX	COUNTRY	Warning: Format COUNTRY-MEX-Not used in the data
18	DM	NLD	COUNTRY	Warning: Format COUNTRY-NLD-Not used in the data
19	DM	PRI	COUNTRY	Warning: Format COUNTRY-PRI-Not used in the data
20	DM	ROU	COUNTRY	Warning: Format COUNTRY-ROU-Not used in the data
21	DM	RUS	COUNTRY	Warning: Format COUNTRY-RUS-Not used in the data
22	DM	AMERICAN INDIAN OR ALASKA NATIVE	RACE_ALL	Warning: Format RACE_ALL-AMERICAN INDIAN OR ALASKA NATIVE-Not used in the data
23	DM	NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	RACE_ALL	Warning: Format RACE_ALL-NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER-Not used in the data

Warnings are issued for redundant information in the specification file that is not used in the data

DM Define terminology and Select Terminology examples

Inconsistent values in the submission value and SDTM data

DATASET	VARIABLE	CONDITIONAL DATASET1	CONDITIONAL VARIABLE1	CONDITIONAL_VALUE1	CONDITIONAL_DA TASET2	CONDITIONAL VARIABLE2	CONDITIONAL_VALUE2	SUBMISSION_VALUE	DECODE
DM	ARM	TRTASGN	TRTDESC		EX1001_YPRIM			TRTA	
DM	ARM	TRTASGN	TRTDESC		EX1001_YPRIM			TRTB	
DM	ARMCD	TRTASGN	TRTCD		EX1001_YPRIM				1 TRTA
DM	ARMCD	TRTASGN	TRTCD		EX1001_YPRIM				2 TRTB

These country codes need to be removed from the terminology list as they are not being used in the study

DATASET	VARIABLE	CONDITIONAL DATASET2	CONDITIONAL VARIABLE2	CONDITIONAL VALUE	CTLIST	XMLTYPE	CTLIST_CODE	SUBMISSION_VALUE	DECODE
DM	COUNTRY				COUNTRY	text		BEL	Belgium
DM	COUNTRY				COUNTRY	text		CAN	Canada
DM	COUNTRY				COUNTRY	text		CZE	Czech Republic
DM	COUNTRY				COUNTRY	text		DEU	Germany
DM	COUNTRY				COUNTRY	text		ESP	Spain
DM	COUNTRY				COUNTRY	text		FRA	France
DM	COUNTRY				COUNTRY	text		GBR	United Kingdom
DM	COUNTRY				COUNTRY	text		IND	India
DM	COUNTRY				COUNTRY	text		ITA	Italy
DM	COUNTRY				COUNTRY	text		JPN	Japan
DM	COUNTRY				COUNTRY	text		MEX	Mexico
DM	COUNTRY				COUNTRY	text		NLD	Netherlands
DM	COUNTRY				COUNTRY	text		PRI	Puerto Rico
DM	COUNTRY				COUNTRY	text		ROU	Romania
DM	COUNTRY				COUNTRY	text		RUS	Russian Federation
DM	COUNTRY				COUNTRY	text		USA	United States

Conclusion

- **The quality of the SDTM/ADaM specifications has a key role in determining the quality of the define.xml document, which is a key part of the CRT package submitted to the regulatory agencies for approval.**
- **Specification updates based on the compliance findings while creating the final CRT package may result in post-lock updates to the SDTM/ADaM and TFLs. These Post-lock updates can cause significant submission delays.**
- **VALSPEC utility is designed to alert such non-compliance aspects at an earlier stage thereby streamlining submission process and minimizing any rework risks.**

Acknowledgements

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