

Library Navigator: A Novel Approach to Standard Library Presentation in Clinical Trials Using Define.xml

Catherine Laugel, PhD, Senior Data Standards Expert, DMMI, Merck KGaA

15May2025





2025

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Library Navigator: A Novel Approach to Standard Library Presentation in Clinical Trials Using Define.xml

Presented by Catherine Laugel, PhD, Senior Data Standards Expert,
DMMI, Merck KGaA



Meet the Speaker

Catherine Laugel

Title: Senior Data Standards Expert

Organization: Merck KGaA

- At Merck: Reference for data collection Standards, involved in study set-up and co-leading a trans functional Governance group for the review and approval of Merck KGaA Standard Library.
- 14+ years' experience in end-to-end data management of clinical trials, including database design, data collection and quality control, in both CRO and pharma companies.
- Education : PhD in Organic Chemistry in Fundamental Research from Strasbourg (France) and 2 years post-doctoral position in Berlin (Germany).
- Hobbies : If time permits between work and my 2 kids, spending remaining energy in training for semi-marathon !





Disclaimer and Disclosures

- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC or Merck KGaA.*
- *The author(s) have no real or apparent conflicts of interest to report.*



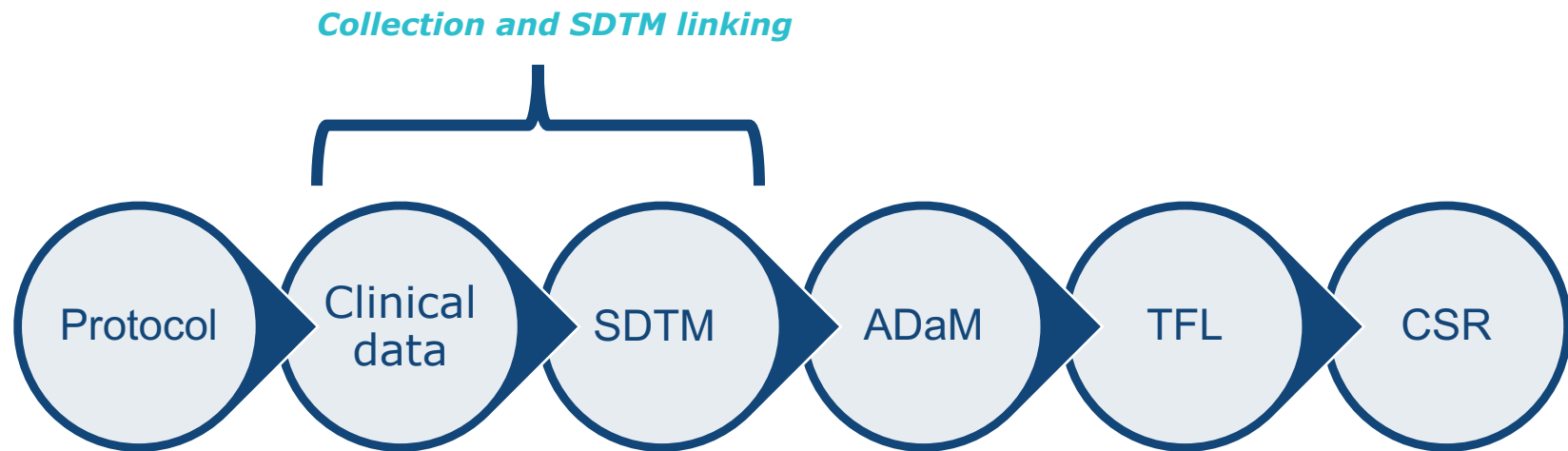
Agenda

1. Merck KGaA Standard Library Innovative Approach
2. Merck KGaA Standard Library Overview
3. Presentation of the Library Navigator
4. How to implement the Library Navigator?
5. Conclusion



Merck KGaA Standard Library Innovative Approach

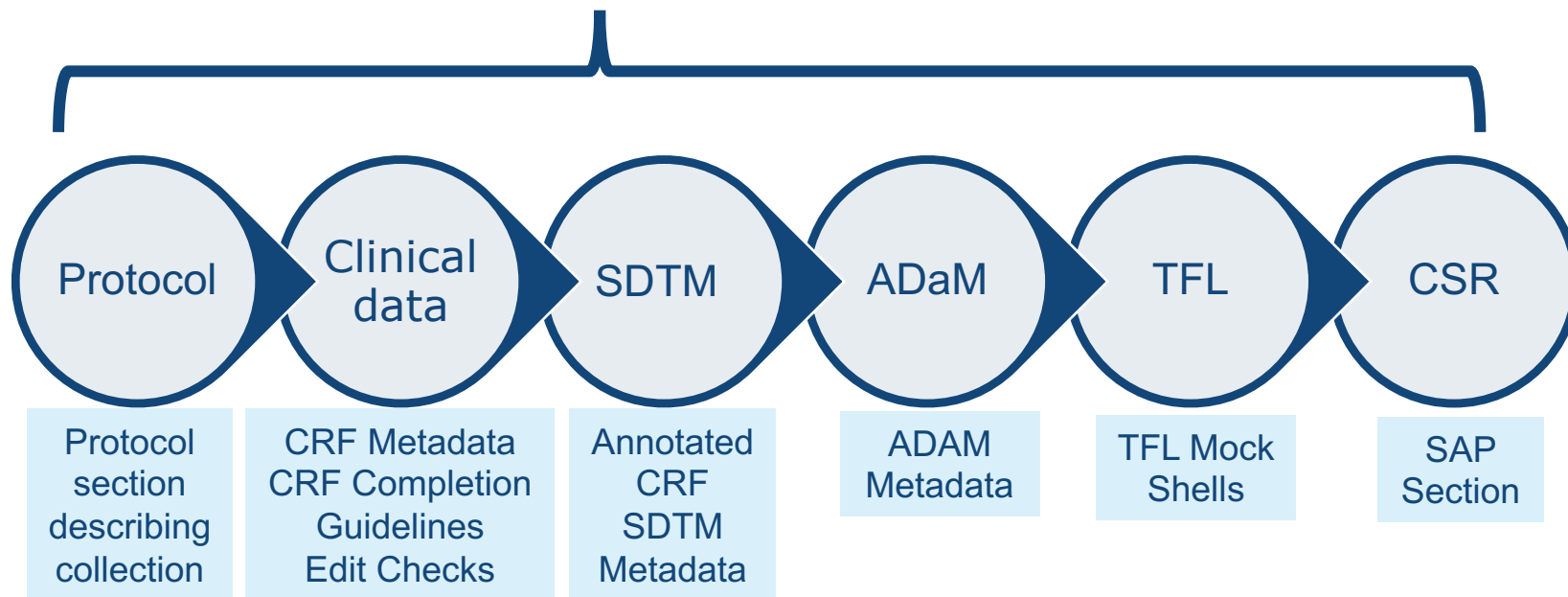
End-To-End Approach : Connect Elements together



- ✓ Smoother connectivity
- ✓ Less transformation effort
- ✓ Accelerate the setup and conduct activities of clinical trials, ensuring submission-ready data soon after database lock

Concept of Standard Element

A **Standard Element** provides a “**Topic**” in the clinical trial with all the information and “elements” needed for setup, conduct, and submission.

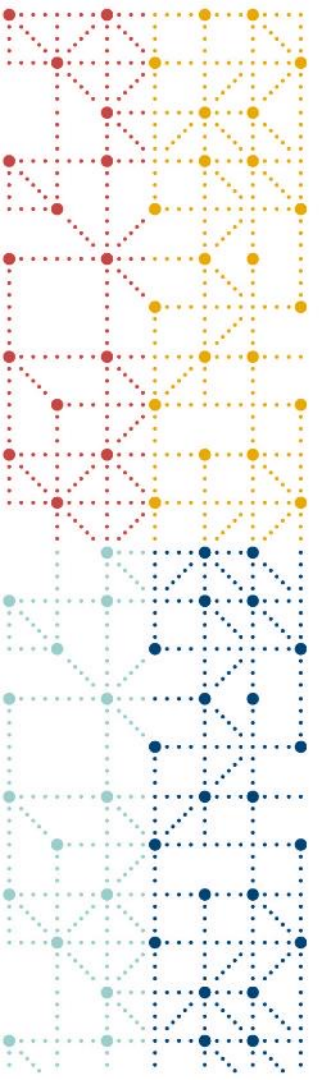


Development of the Standard Library

For each “Topic,” we defined a series of “objects” needed for the definition of setup, conduct, and submission of that topic : all accessible in one place with a single click !









The user will “**pick**” the standard elements needed for their trials from the standard library, which will provide them with the full eDC, SDTM, etc., for their study



Merck KGaA Standard Library Overview

Overview of Merck Standard Library

Flexible Access Options : we understand the need for flexibility, which is why we offer access to the library in **two formats**

- ▼  DMMI STANDARDS LIBRARY
 - ▼  DMMI_Standard_Library_V1.0_20240814
 - >  01.Standards_Individual_Elements
 - >  02.Combined_Library
 - >  03.Library_Navigator
 - >  04.Library_Documentation

Individual Standard Elements: Compiling multiple standard elements to support the eDC setup, SDTM, and submission readiness.

Standard Combined Library: This includes, for example, a combined CRF with all the standard CRF forms bookmarked, the full eDC metadata, the full SDTM metadata, etc.

Individual Standard Elements

- AEG01_Adverse_Events
- BEG01_Biospecimens
- CMG01_Prior_and_Concomitant_Medications
- CMG02_Concomitant_Medications
- CMG03_Prior_Treatment_Cancer_Systemic_Therapy
- CMG04_Post_Treatment_Cancer_Systemic_Therapy
- CMG05_Hydration
- CVG01_Cardiovascular_System_Findings
- DAG01_Product_Accountability
- DDG01_Death
- DMG01_Demographics
- DMG02_Study_Part
- DSG01_Disposition
- DSG02_Main_Consents
- DSG03_Additional_Consents
- DSG04_Withdrawal_Of_Main_Consent



From Standard Library Topics to Elements

- ✂ AEG01_Adverse_Events
- ✂ BEG01_Biospecimens
- ✂ CMG01_Prior_and_Concomitant_Medications
- ✂ CMG02_Concomitant_Medications
- ✂ CMG03_Prior_Treatment_Cancer_Systemic_Therapy
- ✂ CMG04_Post_Treatment_Cancer_Systemic_Therapy
- ✂ CMG05_Hydration
- ✂ CVG01_Cardiovascular_System_Findings
- ✂ DAG01_Product_Accountability
- ✂ DDG01_Death
- ✂ DMG01_Demographics
- ✂ DMG02_Study_Part
- ✂ DSG01_Disposition
- ✂ DSG02_Main_ConSENTs
- ✂ DSG03_Additional_ConSENTs
- ✂ DSG04_Withdrawal_Of_Main_ConSENT

“Topic”

1 Folder per Form

- ▼ ✂ CMG05_Hydration
 - > ✂ 01.Raw_Blank_CRF
 - > ✂ 02.Raw_CRF_Metadata_ALS
 - > ✂ 03.Raw_Data_Examples
 - > ✂ 04.SDTM_aCRF
 - > ✂ 05.SDTM_Metadata
 - > ✂ 06.SDTM_Data_Examples
 - > ✂ 07.eCRF_Completion_Guidelines

**Several sub-folders
per Form**









**“Standard
Library
Element”**

Browsing through folders and files individually can be cumbersome and not user-friendly. **We began exploring ways to enhance the user experience...**

Combined Standard Library

All these Standards Individual Elements are also present as **combined version**.



- ▼  DMMI_Standard_Library_V1.0_20240814
 -  01.Standards_Individual_Elements
 - ▼  02.Combined_Library
 -  01.Combined_Raw_Annotated_CRF
 -  02.Combined_CRF_Metadata_ALS
 -  03.Combined_SDTM_aCRF
 -  04.Combined_SDTM_Metadata
 -  05.Combined_eCRF_Completion_Guidelines

- **Holistic View:** Access a comprehensive, combined view of all objects, including CRF forms, full eDC metadata, and complete SDTM metadata.
- **Enhanced Browsing:** Easily navigate through the combined library to find all relevant information in one place, providing a seamless and efficient user experience.
- **Comprehensive Documentation:** Includes all related documentation, such as CRF completion guidelines and metadata, ensuring you have all the information you need at your fingertips.

Brainstorming...

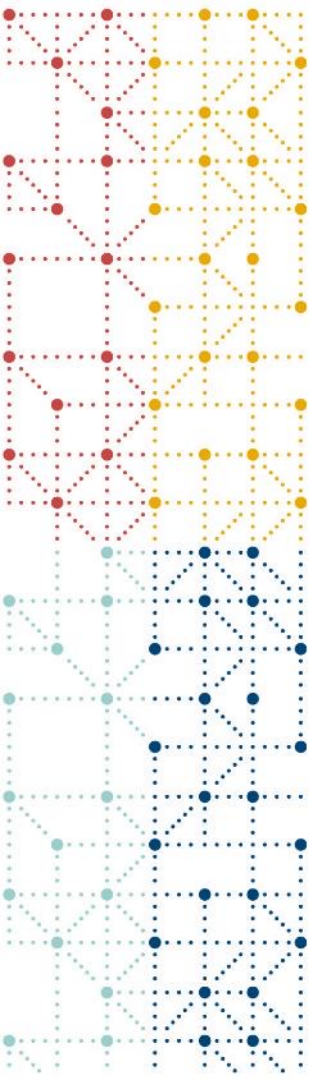
Despite having both combined and individual standard elements in our library, users still need to navigate through folders to access each different object.



How could we **enhance** the user experience ?

- ✓ Enable users to visualize the library and access its content effortlessly
- ✓ Allow users to retrieve both structured (excel files) and unstructured objects (PDF, word) with a single click.

=> Introduction of our **Library Navigator**



Presentation of the Library Navigator

Repurposing the Define.xml



Part of the Clinical Data Interchange Standards Consortium (CDISC) standards, the **define.xml** facilitates data sharing and submission to **regulatory authorities**.

The define.xml file is a **standardized document** used in clinical trials to represent at the study level both structured information like data and metadata for Study SDTM and ADaM and unstructured data like the aCRF, SAP.

However, the Define.xml was not originally designed to represent CRF (raw) data.

=> Repurposing the Define.xml to effectively represent CRF data

Navigating through the Library with Define.html - CRF

Merck Standard Library

Supplemental Documents

Release Notes <#>

Merck Standard Rave Library CRF <#>

Merck eCRF Completion Guidelines <#>

CDASHIG v2.3 <#>

CDASH Model v1.3 <#>

Standards

Form

AEG01 (AEG01_Adverse_Events)

BEG01 (BEG01_Biospecimens)

CMG01 (CMG01_Prior_and_Concomitant_Medications)

CMG02 (CMG02_Concomitant_Medications)

CMG03 (CMG03_Prior_Treatment_Changes)

CMG04 (CMG04_Post_Treatment_Changes)

CMG05 (CMG05_Hydration)

CVG01 (CVG01_Cardiovascular_System)

DAG01 (DAG01_Product_Accountability)

DDG01 (DDG01_Death)

DMG01 (DMG01_Demographics)

DMG02 (DMG02_Study_Part)

DSG01 (DSG01_Disposition)

DSG02 (DSG02_Main_Consents)

DSG03 (DSG03_Additional_Consent)

DSG04 (DSG04_Withdrawal_of_Medication)

DSG05 (DSG05_Randomization)

DSG06 (DSG06_Treatment_Unblind)

ECG01 (ECG01_Study_Drug_Administration)

ECG02 (ECG02_Study_Drug_Administration)

EGG01 (EGG01_ECG_Evaluation_Local_Laboratory)

EGG02 (EGG02_ECG_Evaluation_Local_Laboratory)

EGG03 (EGG03_ECG_Evaluation_Central_Laboratory)

HOG01 (HOG01_Hospitalization)

IEG01 (IEG01_Inclusion_Exclusion_Criteria)

LBG01 (LBG01_Local_Laboratory)

LBG02 (LBG02_Local_Laboratory)

LBG03 (LBG03_Local_Laboratory)

Study Name

Merck Standard Library

Study Description

Merck standard library CRF metadata

Protocol Name

This define document outlines the Merck Standards Library in its raw form based on CDASH Model v1.3 and CDASHIG v2.3

Metadata Name

Study Merck Standard Library Data Definitions

Date/Time of Define-XML document generation: 2024-09-03T10:33:16+01:00

Define-XML version: 2.1.0

Define-XML Context: Submission

Stylesheet version: 2019-02-11

Standards for Study Merck Standard Library

Standard	Type	Status	Documentation
CDISC/NCI SDTM 2024-03-29	CT	FINAL	
SDTMIG 3.4	IG	FINAL	
eCRF Completion Guidelines	GUIDE	FINAL	Merck eCRF Completion Guidelines Merck eCRF Completion Guidelines #
CDASHIG v2.3	CDASHIG	FINAL	CDASHIG v2.3 CDASHIG v2.3 #
CDASH Model v1.3	CDASH MODEL	FINAL	CDASH Model v1.3 CDASH Model v1.3 #

Datasets

Form	Form Name	System	Structure	Purpose	Keys	Documentation	Raw Data
AEG01 []	AEG01_Adverse_Events	RAVE	Log-Portrait			See page in, Merck eCRF Completion Guidelines [5] #	aeg01.xpt #
BEG01 []	BEG01_Biospecimens	RAVE	Log-Landscape			See page in, Merck eCRF Completion Guidelines [16] #	beg01.xpt #
CMG01 []	CMG01_Prior_and_Concomitant_Medications	RAVE	Log-Portrait			See page in, Merck eCRF Completion Guidelines [16] #	cmg01.xpt #
CMG02 []	CMG02_Concomitant_Medications	RAVE	Log-Portrait			See page in, Merck eCRF Completion Guidelines [20] #	cmg02.xpt #

References to Standards used to create the library.

The user can browse all the forms and documentation available in the library and click on them for more details.

Navigating through the Library with Define.html - CRF

Merck Standard Library

Supplemental Documents

Release Notes <#>

Merck Standard Rave Library CRF <#>

Merck eCRF Completion Guidelines <#>

CDASHIG v2.3 <#>

CDASH Model v1.3 <#>

Standards

Form

AEG01 (AEG01_Adverse_Events)

BEG01 (BEG01_Biospecimens)

CMG01 (CMG01_Prior_and_Concomitant_Medications)

CMG02 (CMG02_Concomitant_Medications)

CMG03 (CMG03_Prior_Treatment_Laboratory_Results)

CMG04 (CMG04_Post_Treatment_Laboratory_Results)

CMG05 (CMG05_Hydration)

CVG01 (CVG01_Cardiovascular_System)

DAG01 (DAG01_Product_Accountability)

DDG01 (DDG01_Death)

DMG01 (DMG01_Demographics)

DMG02 (DMG02_Study_Part)

DSG01 (DSG01_Disposition)

DSG02 (DSG02_Main_Consents)

DSG03 (DSG03_Additional_Consent)

DSG04 (DSG04_Withdrawal_of_Participant)

DSG05 (DSG05_Randomization)

DSG06 (DSG06_Treatment_Unblind)

ECG01 (ECG01_Study_Drug_Administration)

ECG02 (ECG02_Study_Drug_Administration)

EGG01 (EGG01_ECG_Evaluation)

EGG02 (EGG02_ECG_Evaluation_Laboratory_Results)

EGG03 (EGG03_ECG_Evaluation_Laboratory_Results)

HOG01 (HOG01_Hospitalization)

IEG01 (IEG01_Inclusion_Exclusion_Criteria)

LBG01 (LBG01_Local_Laboratory_Results)

LBG02 (LBG02_Local_Laboratory_Results)

LBG03 (LBG03_Local_Laboratory_Results)

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CDISC/NCI SDTM 2024-03-29	CT	FINAL	
SDTMIG 3.4	IG	FINAL	
eCRF Completion Guidelines	GUIDE	FINAL	Merck eCRF Completion Guidelines Merck eCRF Completion Guidelines #
CDASHIG v2.3	CDASHIG	FINAL	CDASHIG v2.3 CDASHIG v2.3 #
CDASH Model v1.3	CDASH MODEL	FINAL	CDASH Model v1.3 CDASH Model v1.3 #

Datasets

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AEG01 []	AEG01_Adverse_Events	RAVE	Log-Portrait			See page in, Merck eCRF Completion Guidelines [5 #]	aeg01.xpt #
BEG01 []	BEG01_Biospecimens	RAVE	Log-Landscape			See page in, Merck eCRF Completion Guidelines [16 #]	beg01.xpt #
CMG01 []	CMG01_Prior_and_Concomitant_Medications	RAVE	Log-Portrait			See page in, Merck eCRF Completion Guidelines [16 #]	cmg01.xpt #
CMG02 []	CMG02_Concomitant_Medications	RAVE	Log-Portrait			See page in, Merck eCRF Completion Guidelines [20 #]	cmg02.xpt #

Date/Time of Define-XML document generation: 2024-09-03T10:33:16+01:00

Define-XML version: 2.1.0

Define-XML Context: Submission

Stylesheet version: 2019-02-11

Library Navigator
presentation for CRF
forms, with
hyperlinks to:

CRF completion
guideline PDF files

Raw data example
in XPT files

When the Form is
selected...

Navigating through the Library with Define.html - CRF

When the Form is selected... it will display the list of variables, with type, format and more details :

AEG01 (AEG01_Adverse_Events) - [] Location: aeg01.xot

Variable	Label / Description	Type	Length or Display Format	Controlled Terms or ISO Format	Origin / Source / Method / Comment
AETERM	Adverse Event	text	200		Collected (Source: Investigator) See page in, Merck Standard Rave Library CRF [6 7 8 9 10 11 12 13 14]
AESTDAT	Start Date	date9			Collected (Source: Investigator) See page in, Merck Standard Rave Library CRF [6 7 8 9 10 11 12 13 14]
AEENDAT	End Date	date9			Collected (Source: Investigator) See page in, Merck Standard Rave Library CRF [6 7 8 9 10 11 12 13 14]
AEONGO	Is the adverse event ongoing?	text	1	CL_C66742_JY • "Y" = "Yes" • "N" = "No"	Collected (Source: Investigator) See page in, Merck Standard Rave Library CRF [6 7 8 9 10 11 12 13 14]
AEOUT	Outcome	text	50	CL_C66768_OUT [6 Terms]	Collected (Source: Investigator) See page in, Merck Standard Rave Library CRF [6 7 8 9 10 11 12 13 14]

Opening of the Rave Raw PDF

CL_C66768_OUT [C66768] [CDISC/NCI SDTM 2024-03-29]

Permitted Value (Code)	Display Value (Decode)
RECOVERED/RESOLVED [C49498]	Recovered or Resolved
RECOVERED/RESOLVED WITH SEQUELAE [C49495]	Recovered or Resolved with Sequelae
RECOVERING/RESOLVING [C49496]	Recovering or Resolving
NOT RECOVERED/NOT RESOLVED [C49494]	Not Recovered or Not Resolved
UNKNOWN [C17998]	Unknown
FATAL [C48275]	Fatal

Display of the codelist details

Combined_Raw_Annotated_CRF - X

Merck Standards, Version 1.0 : Raw Annotated CRF: Unique
Project Name: MERCK_STANDARDS
Form: AEG01_Adverse_Events
Generated On: 07 Aug 2024 12:48:38

Adverse Event _____ ①
Start Date _____ ②
End Date _____ ③

Navigating through the Library with Define.html - SDTM

← ↻ 🏠 [🌐](#) | ① File | C:/Users/M333655/OneDrive%20-%20MerckGroup/Documents/Pinnacle%2021%20Community/defines/define-2024-09-10T17-59-32-73... ☆ 🔄 | 📖 ☆ 📎 🌐 🔄

Merck Standard Library

- + Annotated Case Report Form 📄
- + Supplemental Documents
- + Complex Algorithms 📄
- + Reviewers Guide 📄
- + SDTM Merck Implementation
- + SDTM IG v 3.4 📄
- + Study Data Tabulation Model
- + Controlled Terminology 2024
- + FDA Technical Guidelines 📄
- + Release Notes 📄
- Standards
- Datasets
 - TA (Trial Arms)
 - TE (Trial Elements)
 - TI (Trial Inclusion/Exclusion C
 - TM (Trial Disease Milestones)
 - TS (Trial Summary)
 - TV (Trial Visits)
 - CO (Comments)
 - DC (Demographic as Collecte
 - DM (Demographics)
 - SE (Subject Elements)
 - SM (Subject Disease Mileston
 - SV (Subject Visits)
 - CM (Concomitant/Prior Medic
 - EC (Exposure as Collected)
 - EX (Exposure)
 - ML (Meal Data)
 - PR (Procedures)
 - SU (Substance Use)
 - AE (Adverse Events)

Date/Time of Define-XML document generation: 2024-06-28T20:34:21+05:30
Define-XML version: 2.1.0
Define-XML Context: Submission
Stylesheet version: 2019-02-11

Study Name Merck Standard Library

Study Description Merck Standard Library SDTM Metadata

Protocol Name This define document outlines the Merck Standard Library for its SDTM

Metadata Name Study Merck Standard Library SDTM Data Definitions

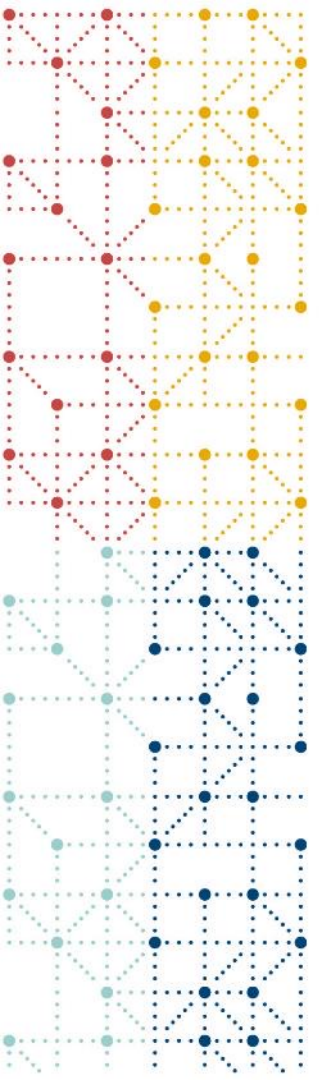
Standards for Study Merck Standard Library

Standard	Type	Status	Documentation
CDISC/NCI SDTM 2024-03-29	CT	FINAL	Controlled Terminology Controlled Terminology 2024-03-29 📄
SDTMIG 3.4	IG	FINAL	SDTM IG 3.4 SDTM IG v 3.4 📄
FDA Technical Guidelines	GUIDE	FINAL	FDA Technical Guidelines FDA Technical Guidelines 📄
Merck SDTM Guidelines	GUIDE	DRAFT	SDTM Merck Implementation Guide SDTM Merck Implementation Guide 📄
Study Data Tabulation Model 2.0	GUIDE	FINAL	Study Data Tabulation Model v 2.0 Study Data Tabulation Model v 2.0 📄

Datasets

Dataset	Description	Class	Structure	Purpose	Keys	Documentation	Location
TA [SDTMIG 3.4]	Trial Arms	TRIAL DESIGN	One record per planned Element per Arm	Tabulation	STUDYID, ARMCD, TAETORD	Trial Arms SDTM Merck Implementation Guide [82] 📄	ta.xpt 📄

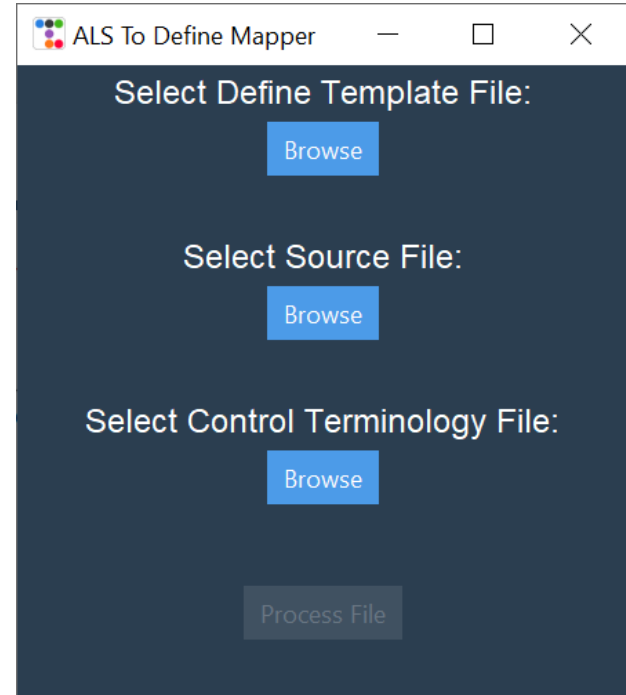
Same principle
for SDTM data




How to implement the Library Navigator?

Technical implementation – CRF Library Navigator

- Taking the Merck Library Combined ALS Metadata this file is transformed into the define.xml format using an in-house Python developed tool which will convert almost entirely the ALS structure, including Rave centric length, format types into the required format.
- Using the ALS, and CDISC CT to fill in any gaps with NCI codes for Codelists.



Technical implementation - CRF Library Navigator




FormOID	FieldOID	Ordinal	DraftFieldNumber	DraftFieldName	DraftFieldActive	VariableOID	DataFormat	DataDictionaryName
AEG01	AETERM	1		AETERM	TRUE	AETERM	\$200	
AEG01	AESTDAT	2		AESTDAT	TRUE	AESTDAT	dd- MMM yyyy	
AEG01	AEENDAT	3		AEENDAT	TRUE	AEENDAT	dd- MMM yyyy	
AEG01	AEONGO	4		AEONGO	TRUE	AEONGO	\$1	CL_C66742_NY
AEG01	AEOUT	5		AEOUT	TRUE	AEOUT	\$50	CL_C66768_OUT
AEG01	AETOXGR	6		AETOXGR	TRUE	AETOXGR	\$16	CL_SP_AETOXGR
AEG01	AESEV	7		AESEV	TRUE	AESEV	\$16	CL_C66769_AESEV

Order	Dataset	Variable	Label	Data Type	Length	Significant Digits	Forma	Mandator	Assigned Value	Codelist
1	AEG01	AETERM	Adverse Event	text	200		\$200	No		
2	AEG01	AESTDAT	Start Date	date9				No		
3	AEG01	AEENDAT	End Date	date9				No		
4	AEG01	AEONGO	Is the adverse event ongoing?	text	1		\$1	No		CL_C66742_NY
5	AEG01	AEOUT	Outcome	text	50		\$50	No		CL_C66768_OUT
6	AEG01	AETOXGR	Toxicity Grade	text	16		\$16	No		CL_SP_AETOXGR
7	AEG01	AESEV	Severity	text	16		\$16	No		CL_C66769_AESEV

As shown here you can see that the tool converts the ALS columns into columns that are suitable to convert to define.xml, including the adjustment of lengths, format and significant digits.

Technical implementation - CRF Library Navigator



DataDictionaryName	CodedData	Ordinal	UserDataString	Specify	Standard Team Instructions
CL_C66768_OUT	RECOVERED/RESOLVED		1 Recovered or Resolved	FALSE	
CL_C66768_OUT	RECOVERED/RESOLVED WITH SEQUELAE		2 Recovered or Resolved with Sequelae	FALSE	
CL_C66768_OUT	RECOVERING/RESOLVING		3 Recovering or Resolving	FALSE	
CL_C66768_OUT	NOT RECOVERED/NOT RESOLVED		4 Not Recovered or Not Resolved	FALSE	
CL_C66768_OUT	UNKNOWN		5 Unknown	FALSE	
CL_C66768_OUT	FATAL		6 Fatal	FALSE	

ID	Name	NCI Codelist Code	Data Type	Terminology	Comme	Orde	Term	NCI Term Code	Decoded Value
CL_C66768_OUT	CL_C66768_OUT	C66768	text	SDTM 2024-09-27			1 RECOVERED/RESOLVED	C49498	Recovered or Resolved
CL_C66768_OUT	CL_C66768_OUT	C66768	text	SDTM 2024-09-27			2 RECOVERED/RESOLVED WITH SEQUELAE	C49495	Recovered or Resolved with Sequelae
CL_C66768_OUT	CL_C66768_OUT	C66768	text	SDTM 2024-09-27			3 RECOVERING/RESOLVING	C49496	Recovering or Resolving
CL_C66768_OUT	CL_C66768_OUT	C66768	text	SDTM 2024-09-27			4 NOT RECOVERED/NOT RESOLVED	C49494	Not Recovered or Not Resolved
CL_C66768_OUT	CL_C66768_OUT	C66768	text	SDTM 2024-09-27			5 UNKNOWN	C17998	Unknown
CL_C66768_OUT	CL_C66768_OUT	C66768	text	SDTM 2024-09-27			6 FATAL	C48275	Fatal

As shown here you can see how the Rave DataDictionaryEntries is converted to a usable Codelists sheet with all NCI Codelist Code and NCI Term Codes populated automatically. NCI Term Code is not part of Rave but our process brings this in.

Technical implementation - CRF Library Navigator

Datasets							
Form	Form Name	System	Structure	Purpose	Keys	Documentation	Raw Data
AEG01 []	AEG01_Adverse_Events	RAVE	Log-Portrait			See page in, Merck eCRF Completion Guidelines [5] []	aeg01.xpt []
BEG01 []	BEG01_Biospecimens	RAVE	Log-Landscape			See page in, Merck eCRF Completion Guidelines [16] []	beg01.xpt []

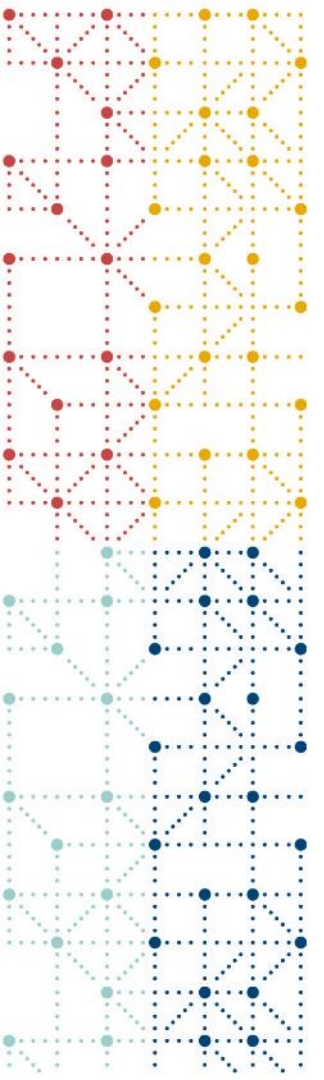
Library Navigator for CRF

For the Merck EDC Navigator we have created a custom stylesheet which provides **different colouring** to our SDTM Navigator.

Datasets							
Dataset	Description	Class	Structure	Purpose	Keys	Documentation	Location
TA [SDTMIG 3.4]	Trial Arms	TRIAL DESIGN	One record per planned Element per Arm	Tabulation	STUDYID, ARMCD, TAETORD	Trial Arms SDTM Merck Implementation Guide [97] []	ta.xpt []
TE [SDTMIG 3.4]	Trial Elements	TRIAL DESIGN	One record per planned Element	Tabulation	STUDYID, ETCD	Trial Elements SDTM Merck Implementation Guide [86] []	te.xpt []

Library Navigator for SDTM

It also **adjusts column names** as seen here to suit the EDC, with columns such as, Form, Form Name, System & Raw data.



Conclusion

Take Home Message



- **Holistic Access:** The repurposed Define.xml provides easy access to a wealth of interconnected data, offering a truly holistic view of every standard library object.

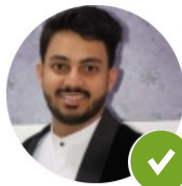
- **Individual Elements:** Users can explore individual elements that encapsulate all relevant information for specific topics, such as adverse events, ensuring you have everything you need in one place.
- **User-Friendly Navigation:** With a single click, you can visualize, browse, and retrieve all essential trial components, dramatically improving efficiency and reducing the time spent navigating through folders and files.



The Library Navigator not only enhances users experience but also represents a significant advancement in how we manage and access standard library elements.



Thank You!



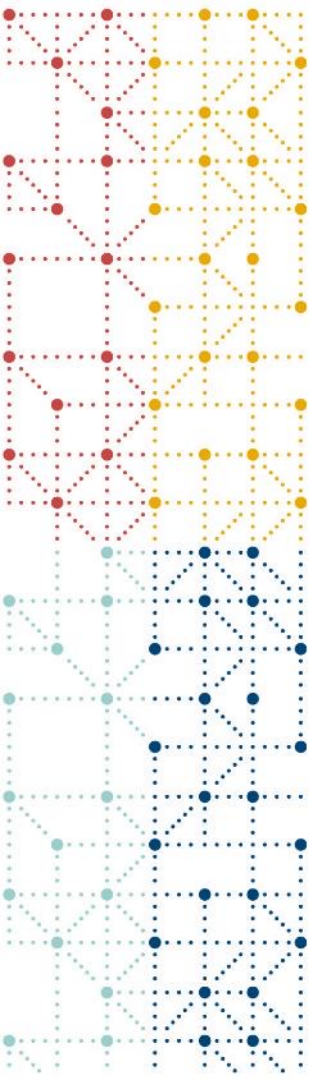
Krishna Shyam
Narayan Gupta



Wafaa
Jebert



Colm
Smyth



Back-up Slides

Concept of Standard Element - Example

“Topic” = **Adverse Event**

