

PhUse 2012
SDE Belgium

How a metadata repository
maximizes efficiencies across the clinical domain

Janssen Research & Development

Stijn Rogiers

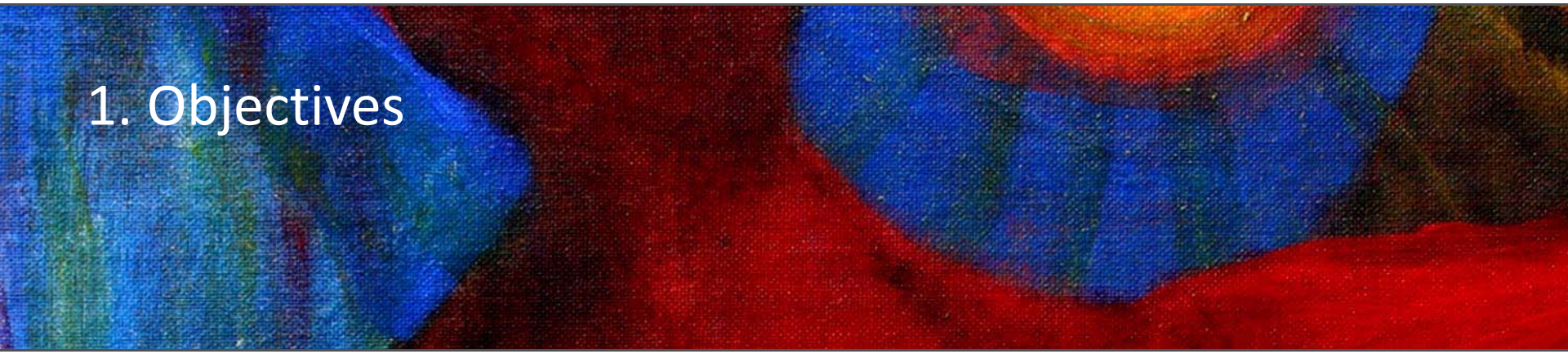
Domain Lead Infrastructure Team

Integrated Data Services (IDS)



Agenda:

1. Objectives
2. Process Overview
3. Data Standards Library
4. Study MetaData Repository
5. Generating Study MetaData Specifications & Reports
6. Verifying Study Data & MetaData
7. Conclusion

An abstract, textured background featuring a mix of vibrant blue, deep red, and warm orange hues. The colors are blended in a way that suggests a sunset or a close-up of a celestial body, with a grainy, painterly texture.

1. Objectives

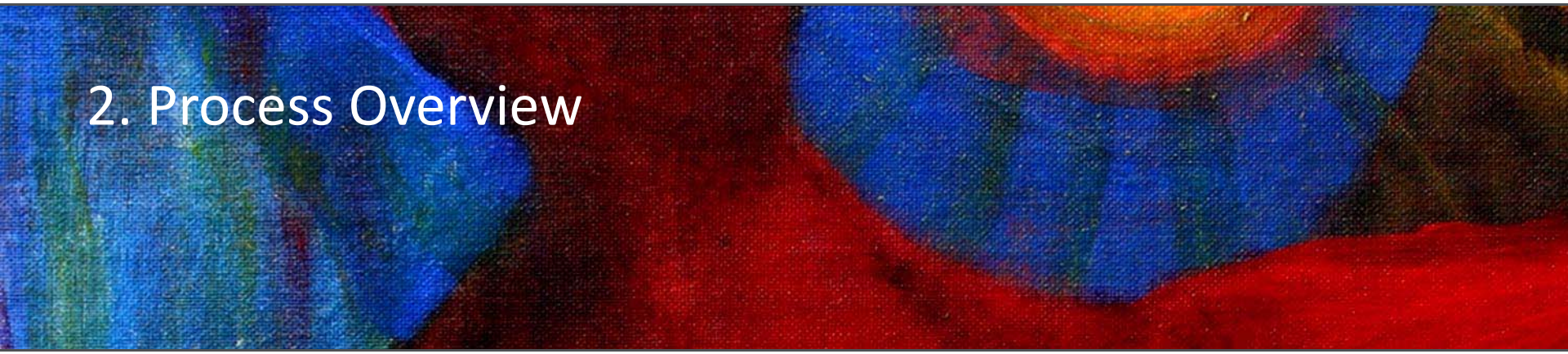
1. Objectives

New standards project focusing on the following objectives :

- ✓ *Maximize re-usability and increase efficiency of our data management processes*
- ✓ *Disconnect standard definitions from technical implementation through a common metadata layer*
- ✓ *Achieve customization towards Therapeutic Area requirements*
- ✓ *Build a foundation facilitating future efficiencies
(i.e. e-Protocol, EDC Setup via ODM + vendor extensions, ...)*

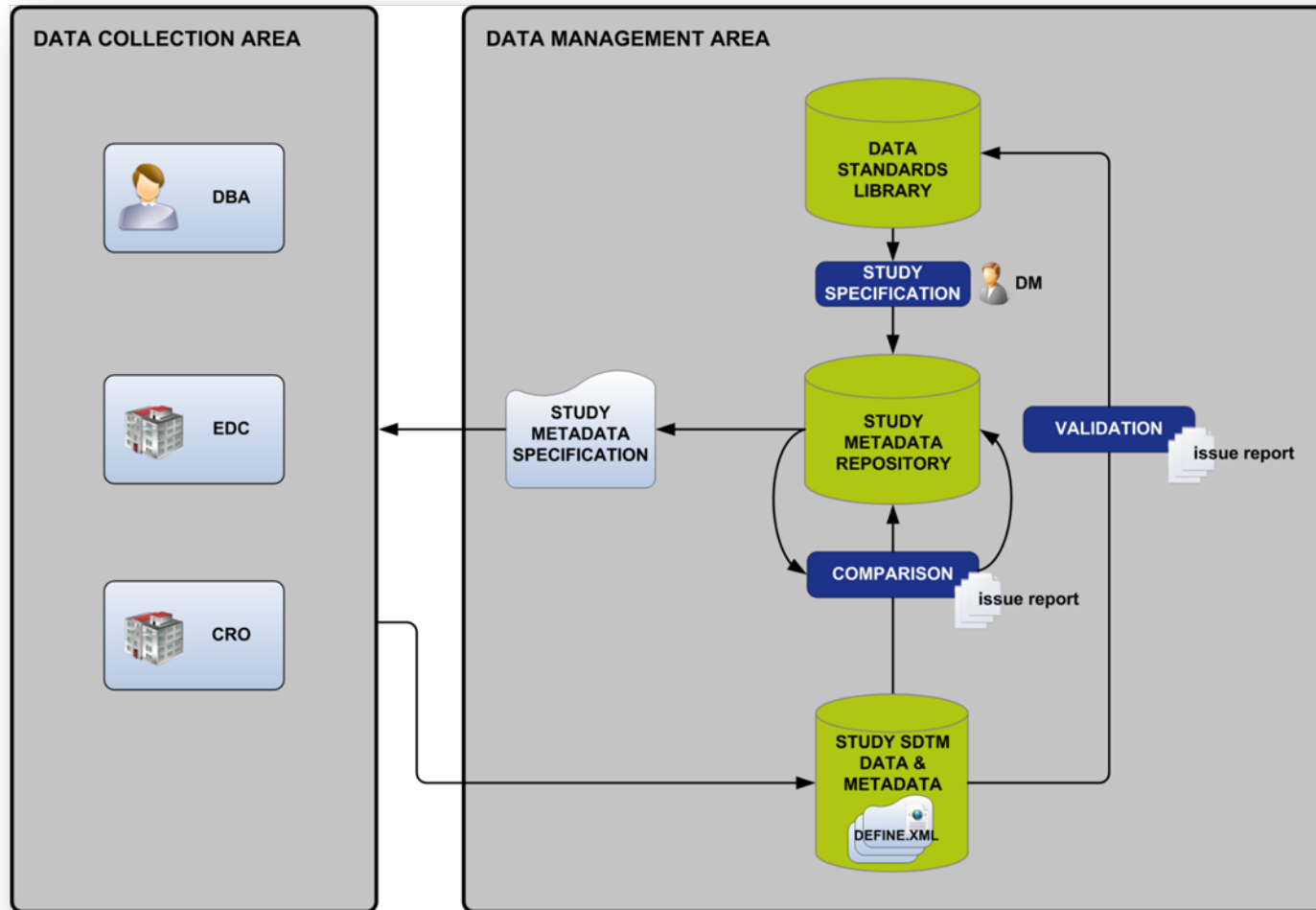
Partnering for Innovation :



An abstract, textured background featuring a mix of vibrant blue, deep red, and warm orange hues, resembling a close-up of a colorful fabric or a digital art piece.

2. Process Overview

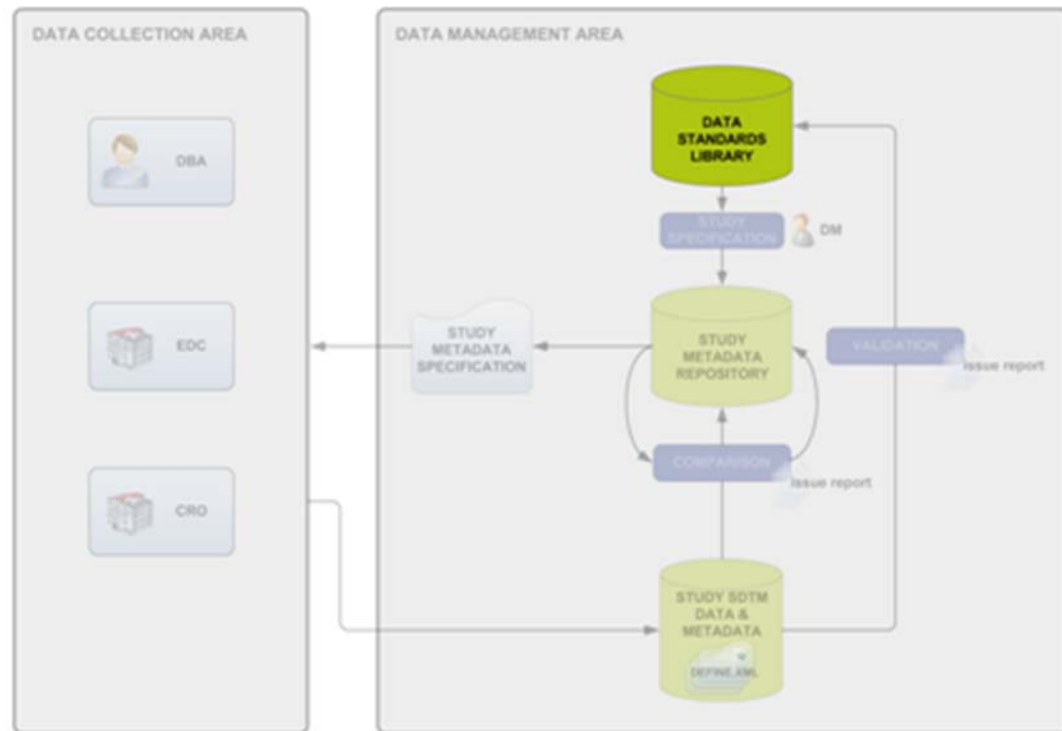
2. Process Overview



2. Process Overview

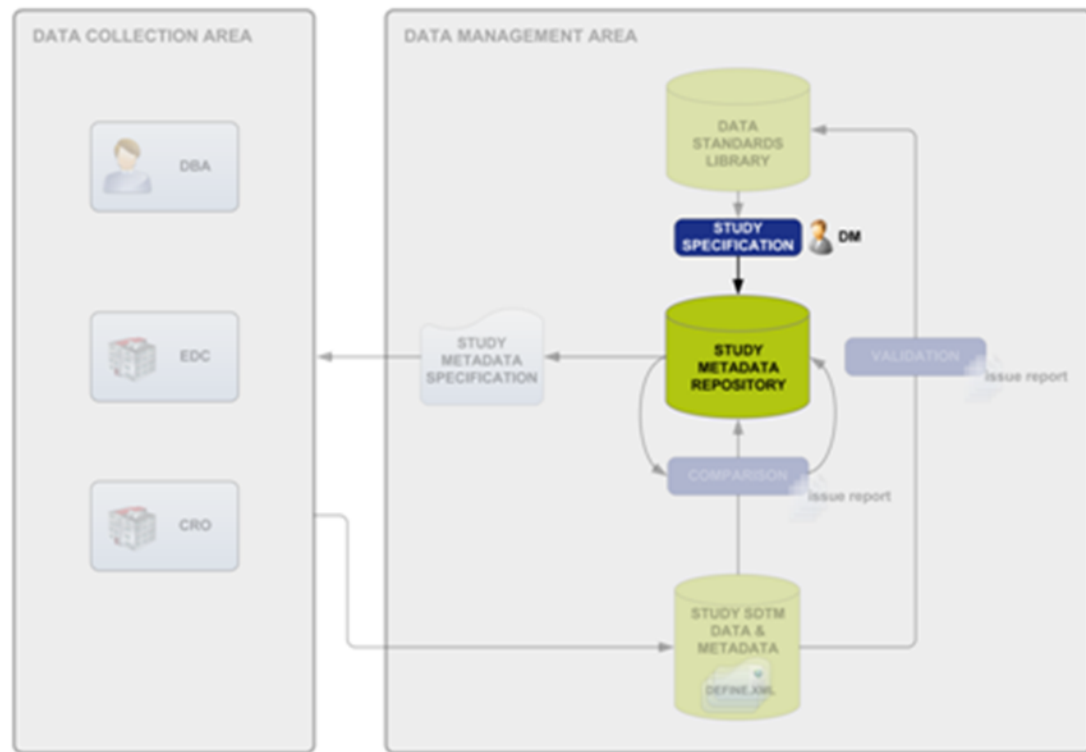
- The Data Standards Library contains :
 - Standard CRF templates (CDASH)
 - Metadata definitions (SDTM, Therapeutic area)

→ *used to
create study
metadata*



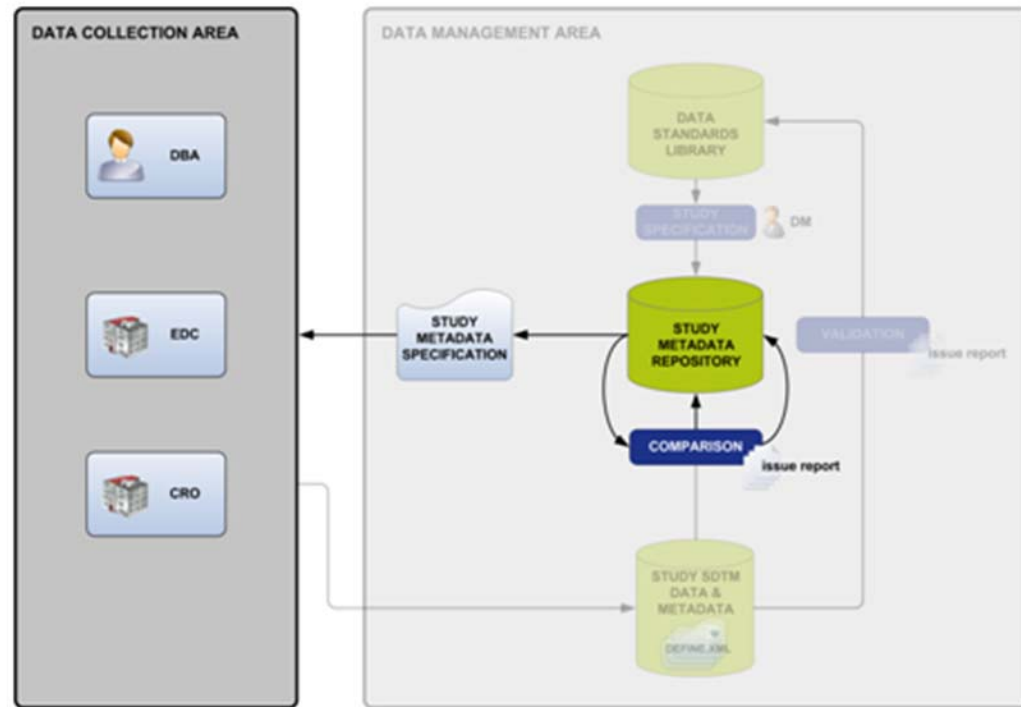
2. Process Overview

- Generating study metadata by selecting CRF templates from the Data Standards Library



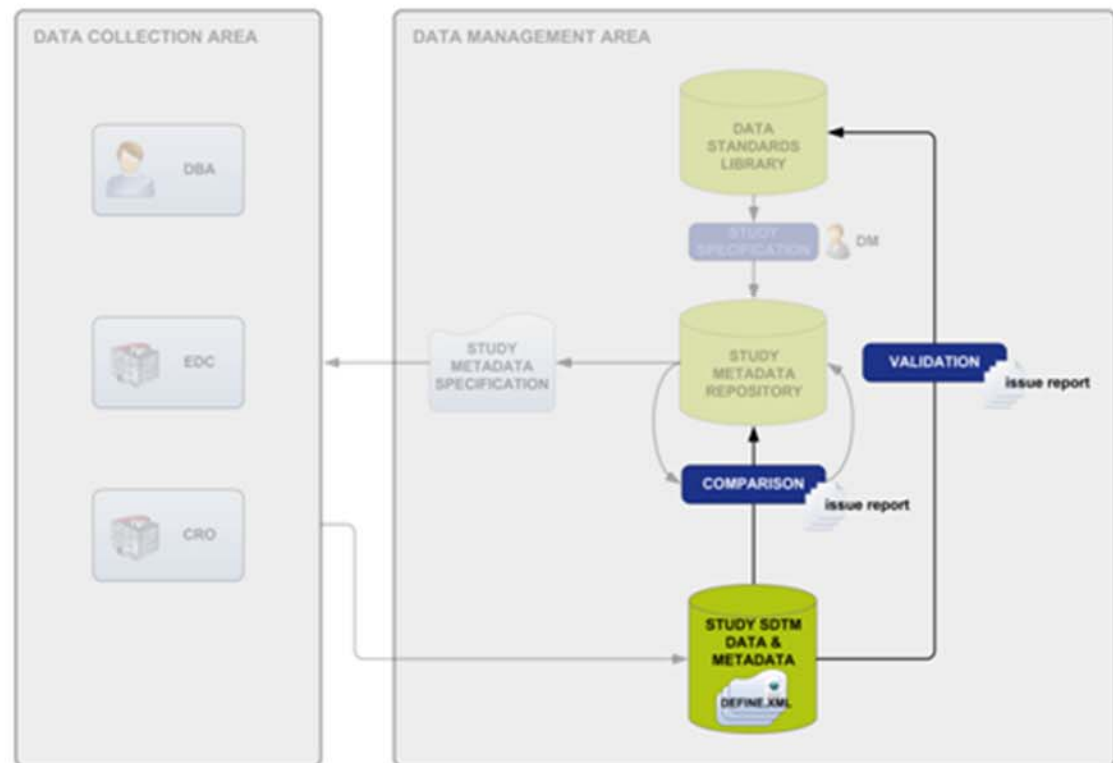
2. Process Overview

- Study Metadata Repository is used to measure the consistency of metadata
- Study metadata is sent to external or internal partners for database build



2. Process Overview

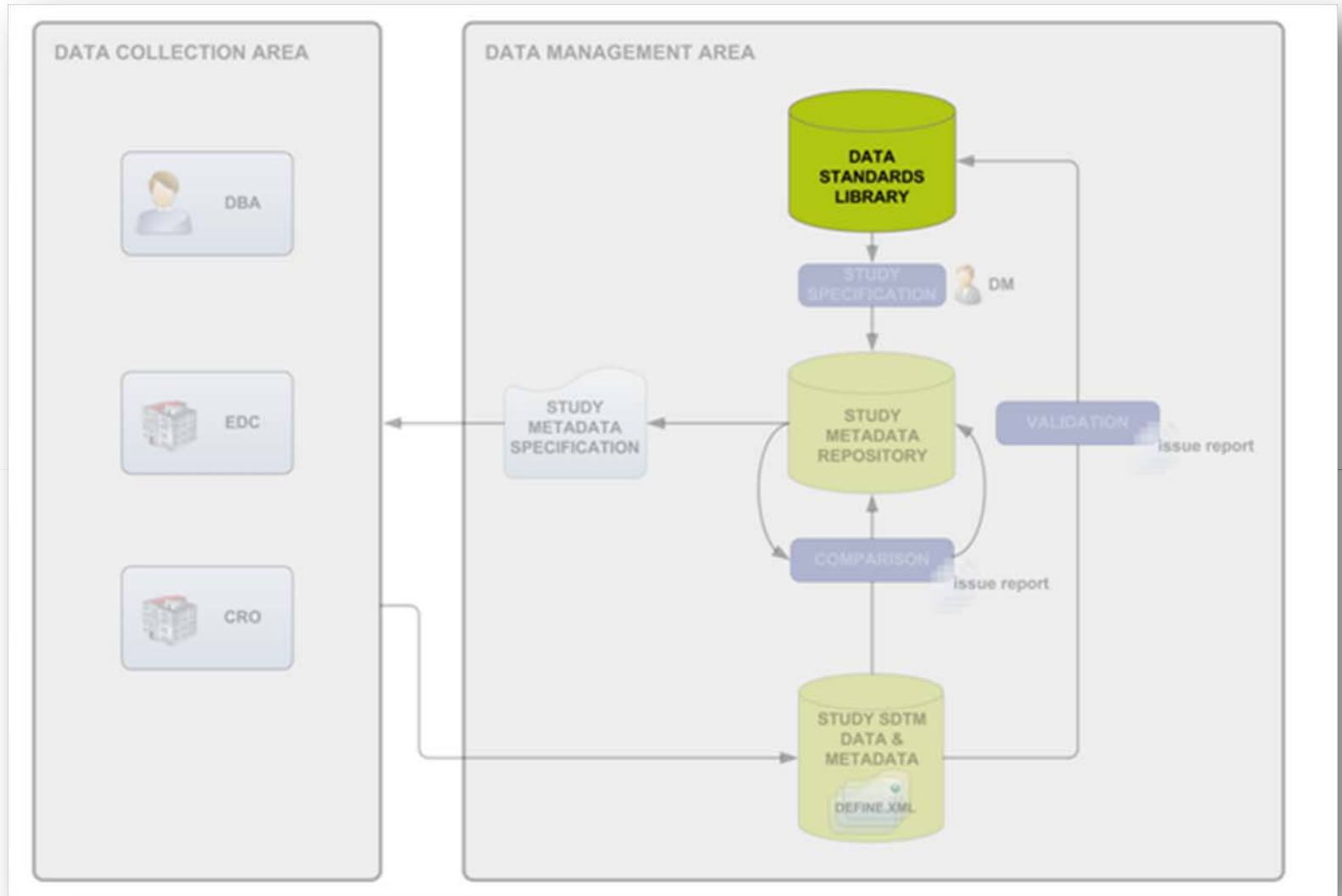
- After study build, data and metadata will be:
 - compared against the Study Metadata Repository
 - validated against the Data Standards Library
- Verification**



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3. Data Standards Library

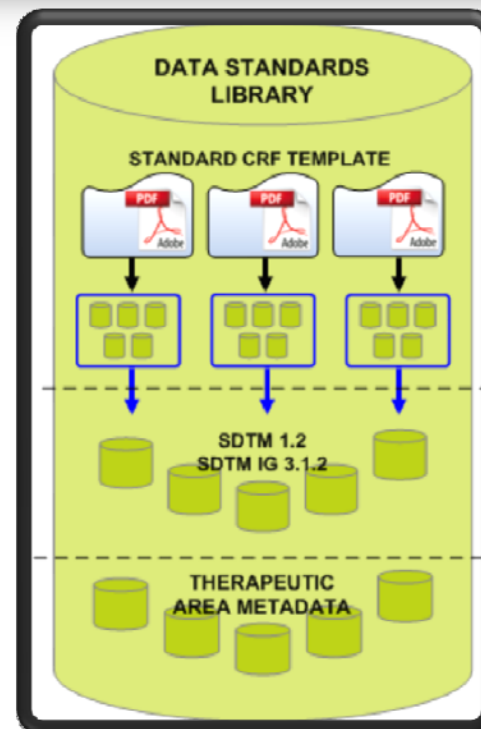
3. Data Standards Library



3. Data Standards Library

Data Collection Modules (CRF Templates) with:

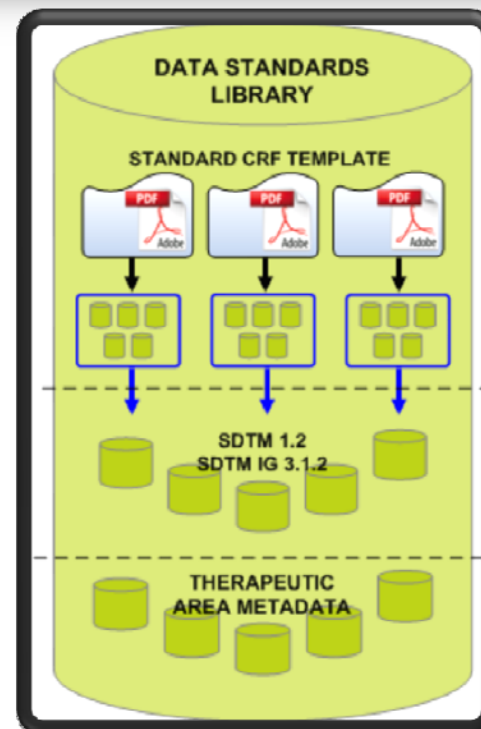
CDASH annotations; SDTM annotations; CDASH metadata; SDTM metadata; “Front-end” DVR (Data Validation Rule) edit check definitions; QC “Back-end” DVR (Data Validation Rule) edit check definitions; Controlled Terminology; Implementation Guide; Completion Guidelines



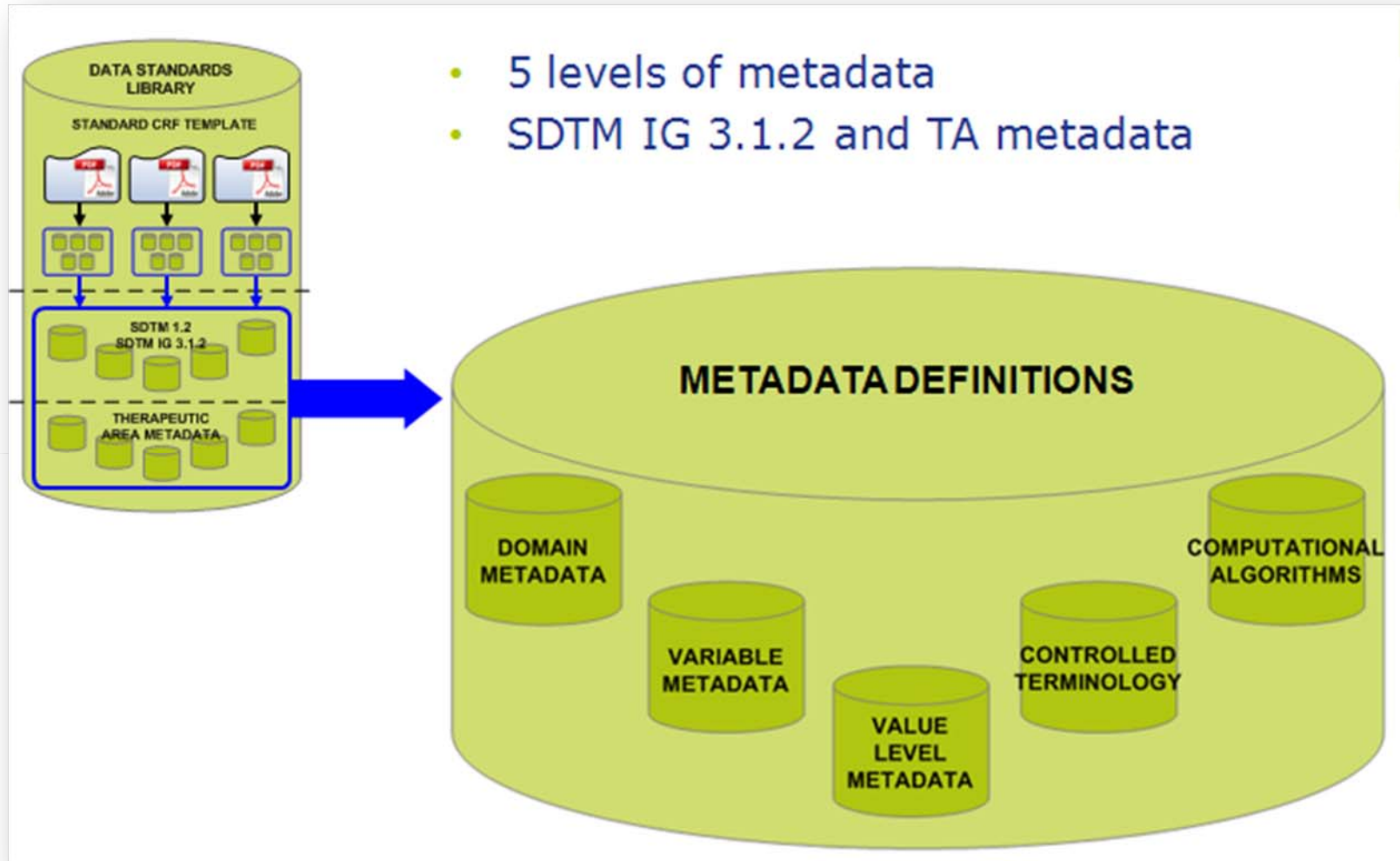
3. Data Standards Library

Data Collection Modules (CRF Templates) with:

CDASH annotations; SDTM annotations; CDASH metadata; SDTM metadata; “Front-end” DVR (Data Validation Rule) edit check definitions; QC “Back-end” DVR (Data Validation Rule) edit check definitions; Controlled Terminology; Implementation Guide; Completion Guidelines



3. Data Standards Library – MetaData Definitions



3. Data Standards Library – MetaData Definitions

Table Metadata

Dataset Name
Dataset Label
Class
Structure
Purpose
Keys

Variable Metadata

Variable Name
Variable Label
Type
Controlled Terminology
Origin
Role
Comment

Value Level Metadata

Source Variable
Value
Label
Type
Controlled Terminology
Origin
Comment

Controlled Terminology

Code Value
Code Text

Computational Algorithms

Reference Name
Computation Method

3. Data Standards Library – MetaData Definitions

Table Metadata

Dataset Name

Dataset Label

Class

Structure

Purpose

Keys

Dataset	Description	Class	Structure	Purpose	Keys	Location
CM	Concomitant Medications	Interventions	One record per recorded medication occurrence or constant-dosing interval per subject	Tabulation	STUDYID, USUBJID, CMTRT, CMSTDTC	..\Tabulations\cm.xpt
EX	Exposure	Interventions	One record per constant dosing interval per subject	Tabulation	STUDYID, USUBJID, EXSTDTC, EXENDTC, EXDOSE, EXTRT	..\Tabulations\ex.xpt
AE	Adverse Events	Events	One record per adverse event per subject	Tabulation	STUDYID, USUBJID, AEDECOD, AETERM, AESTDTC	..\Tabulations\ae.xpt

3. Data Standards Library – MetaData Definitions

Variable Metadata

Variable Name
Variable Label
Type
Controlled Terminology
Origin
Role
Comment

Variable	Label	Type	Controlled Terminology	Origin	Role	Comment
STUDYID	Study Identifier	text		Protocol, CRF	IDENTIFIER	The STUDYID variable has a fixed format: 'XXXX-YYYY', where 'XXXX' indicates the 4-digit compound code and the 'YYYY' the 4-digit study code
DOMAIN	Domain Abbreviation	text	DOMAIN	Assigned	IDENTIFIER	
USUBJID	Unique Subject Identifier	text		Protocol	IDENTIFIER	The USUBJID variable has a fixed format: 'XXXX-YYYY-ZZZZZ', where 'XXXX' indicates the 4-digit compound code, 'YYYY' the 4-digit study code and 'ZZZZZ' the 6-digit patient code

3. Data Standards Library – MetaData Definitions

Value Level Metadata

Source Variable
Value
Label
Type
Controlled Terminology
Origin
Comment

Value Level Metadata (ValueList.VS.VSTESTCD)						
Source Variable	Value	Label	Type	Controlled Terminology	Origin	Comment
VSTESTCD	BMI	BODY MASS INDEX	integer		Derived	See Computational Method: VS.BMI
VSTESTCD	DIABP	DIASTOLIC BLOOD PRESSURE	integer		CRF	
VSTESTCD	HEIGHT	HEIGHT	integer		CRF	
VSTESTCD	PULSE	PULSE RATE	integer		CRF	
VSTESTCD	SYSBP	SYSTOLIC BLOOD PRESSURE	integer		CRF	
VSTESTCD	WEIGHT	WEIGHT	integer		CRF	

3. Data Standards Library – MetaData Definitions

POSITION, Reference Name (Codelist.POSITION)	
Code Value	Code Text
STANDING	STANDING
SUPINE	SUPINE

SEX, Reference Name (Codelist.SEX)	
Code Value	Code Text
F	Female
M	Male
U	Unknown

Controlled Terminology

Code Value
Code Text

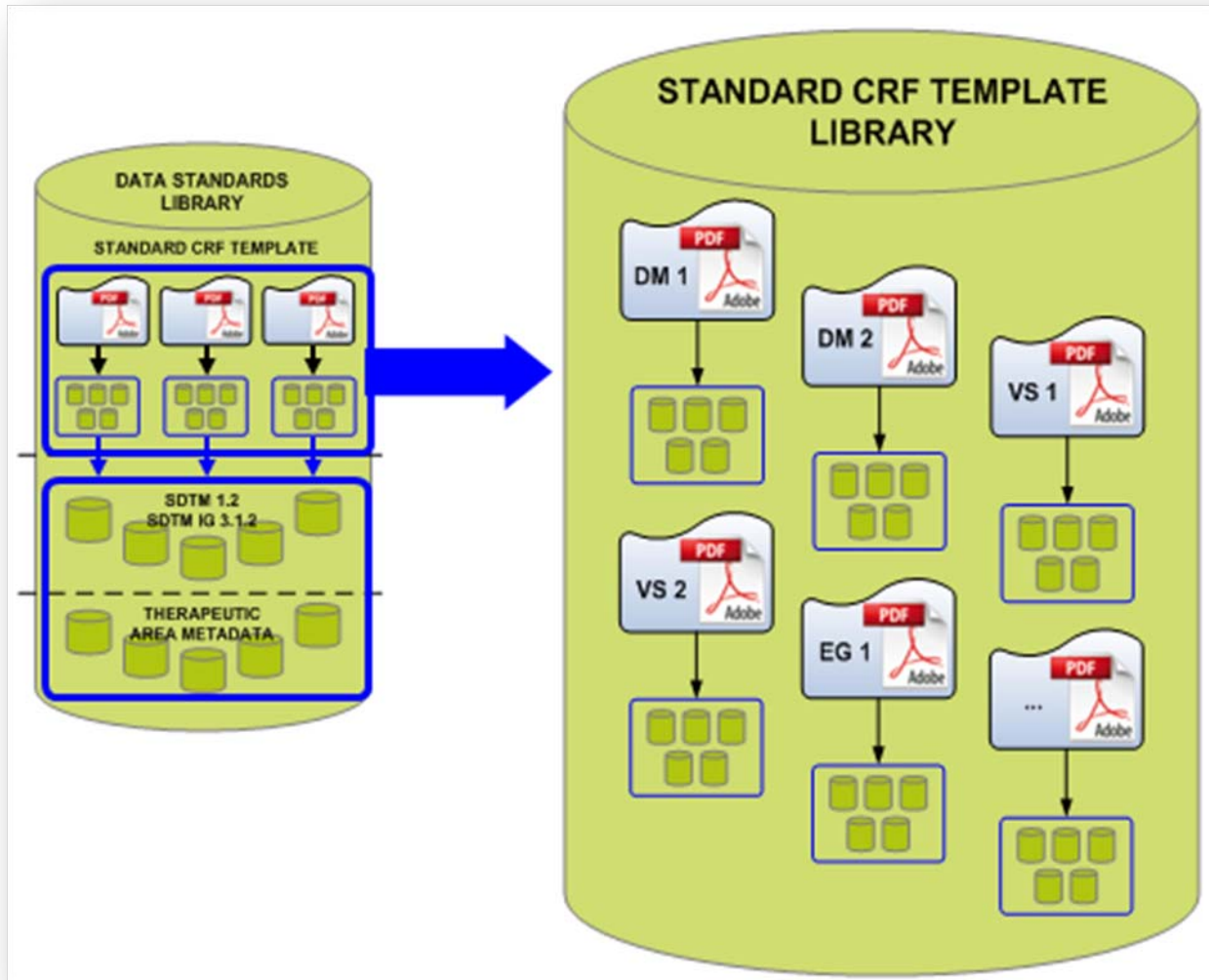
3. Data Standards Library – MetaData Definitions

Computational Algorithms (VS.BMI)	
Reference Name	Computation Method
VS.BMI	Equals to WEIGHT DIVIDED BY HEIGHT SQUARED
Computational Algorithms (VS.VSDY)	
Reference Name	Computation Method
VS.VSDY	Equals to (VS.VSDTC - DM.RFSTDTC) + 1 IF VSDTC is on or after RFSTDTC Equals to (VS.VSDTC - DM.RFSTDTC) IF VSDTC precedes RFSTDTC

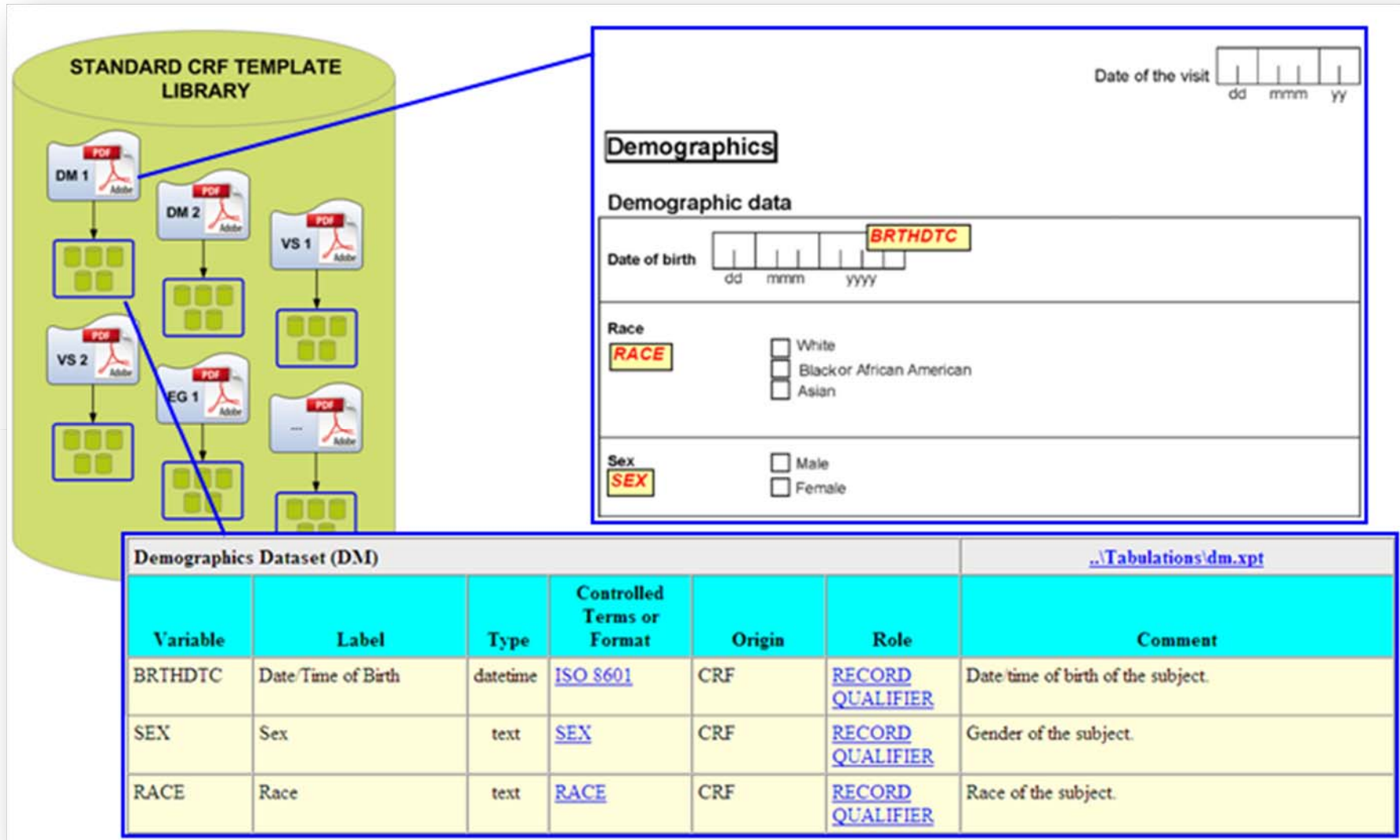
Computational
Algorithms

Reference Name
Computation Method

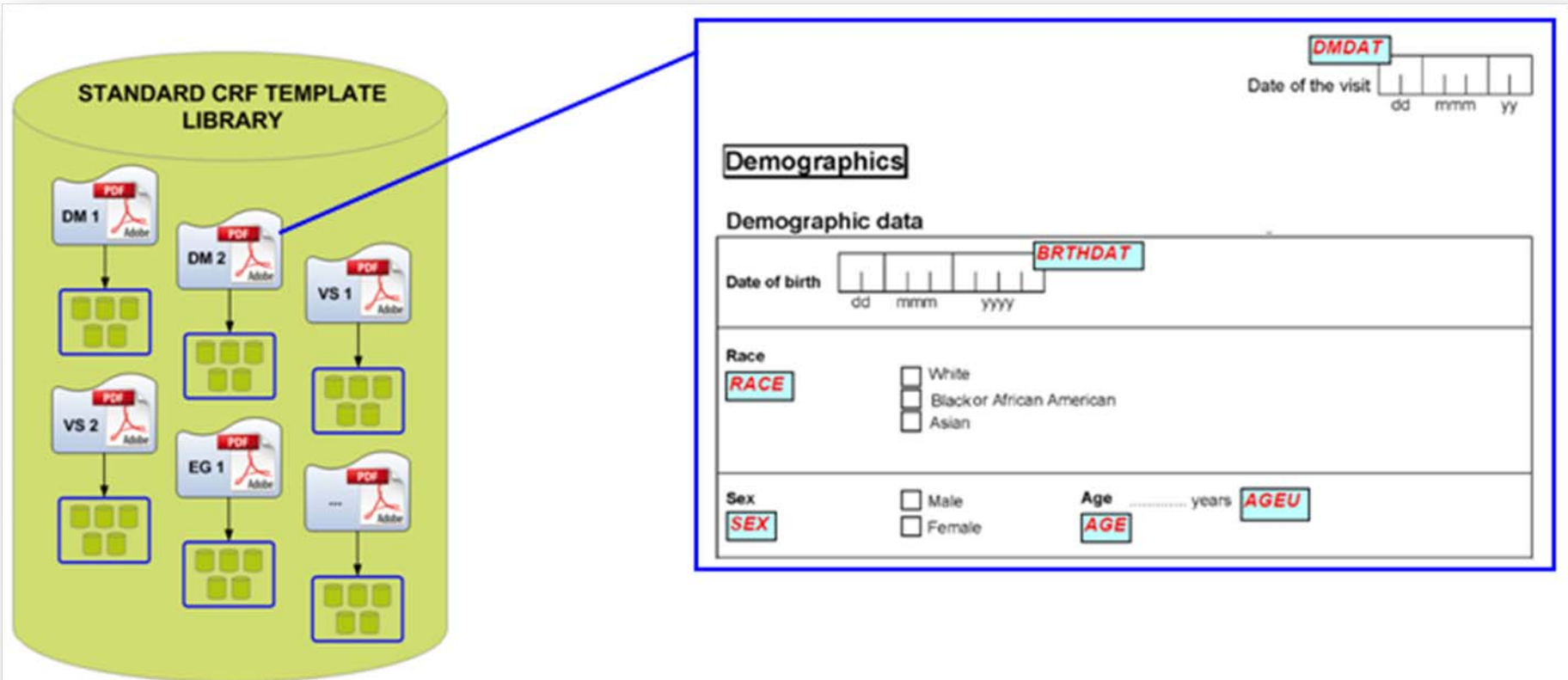
3. Data Standards Library – Standard CRF Templates (Data Collection Modules)



3. Data Standards Library – Standard CRF Templates (Data Collection Modules / SDTM)

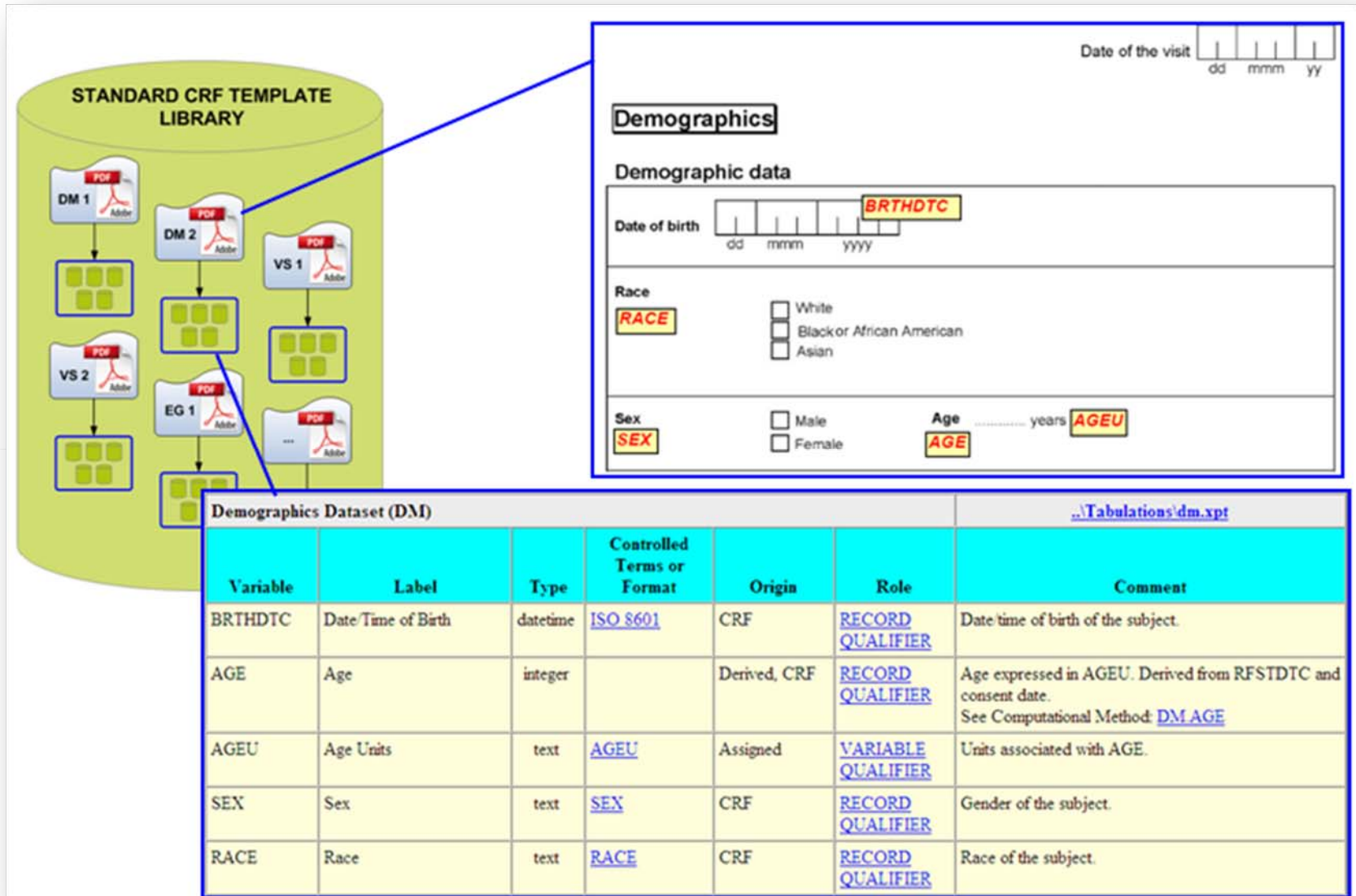


3. Data Standards Library – Standard CRF Templates (Data Collection Modules / CDASH)

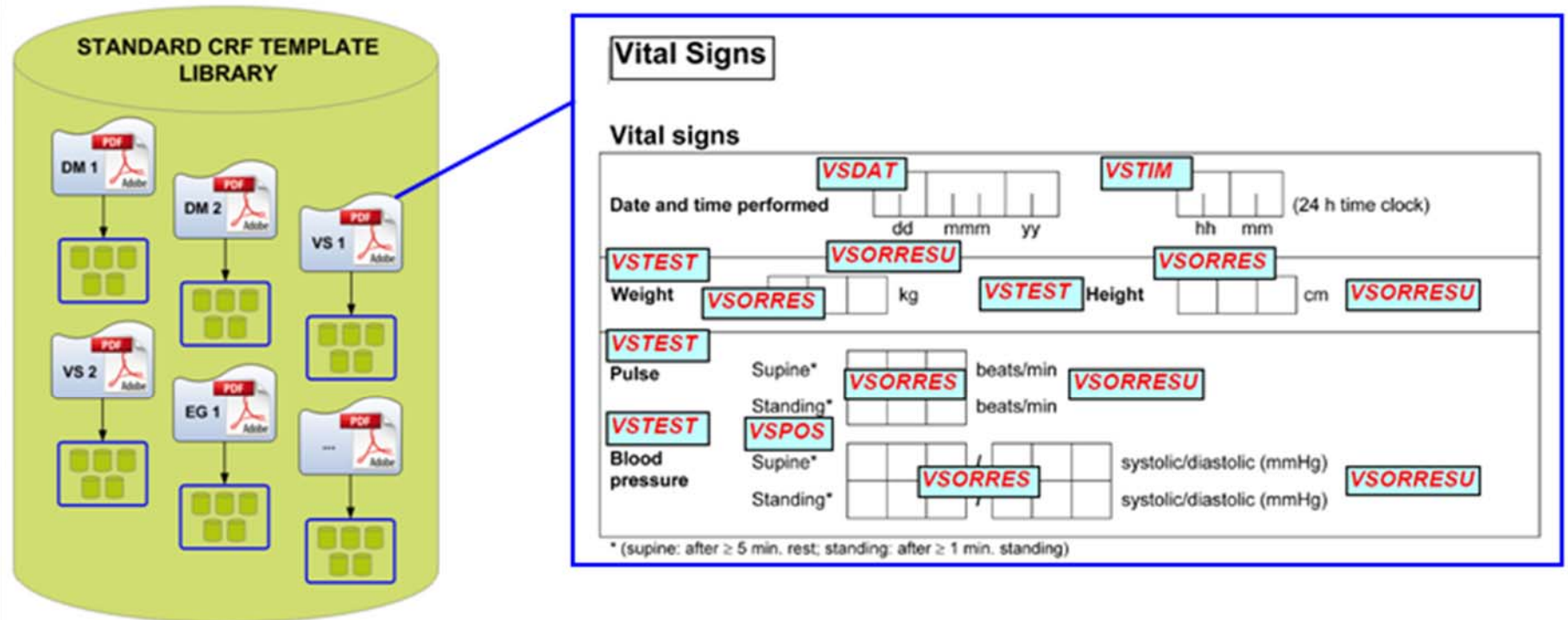


- CRF template using CDASH annotations

3. Data Standards Library – Standard CRF Templates (Data Collection Modules / SDTM)

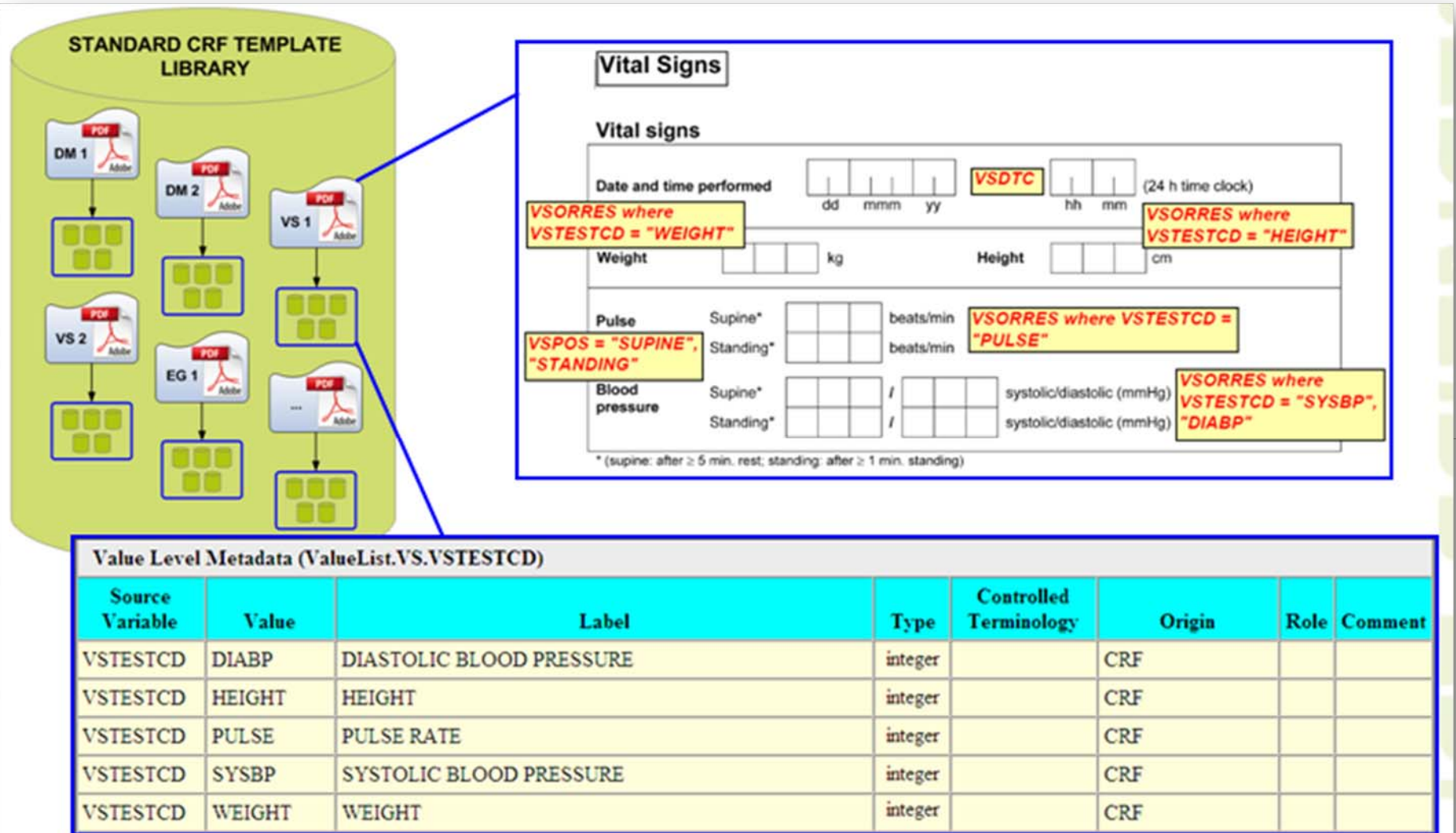


3. Data Standards Library – Standard CRF Templates (Data Collection Modules / CDASH)

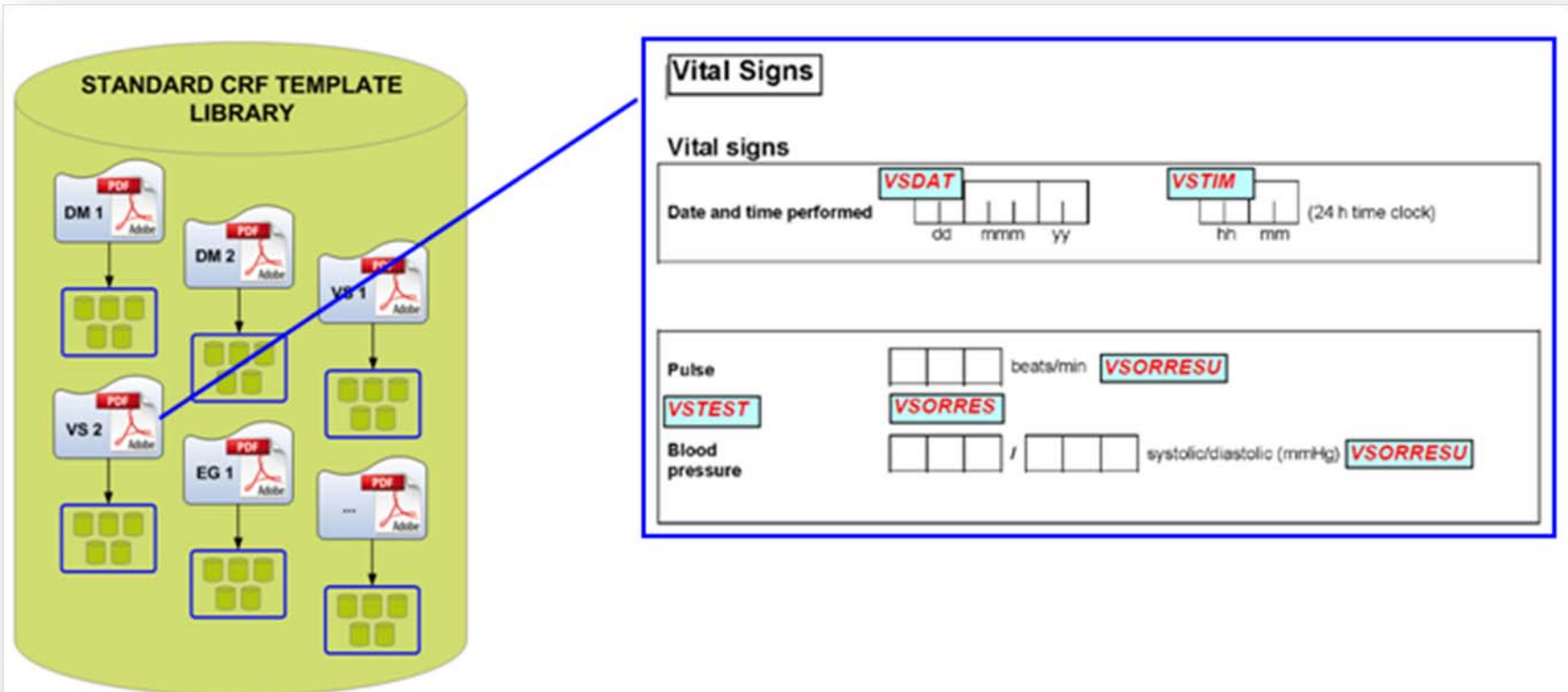


- CRF template using CDASH annotations

3. Data Standards Library – Standard CRF Templates (Data Collection Modules / SDTM)

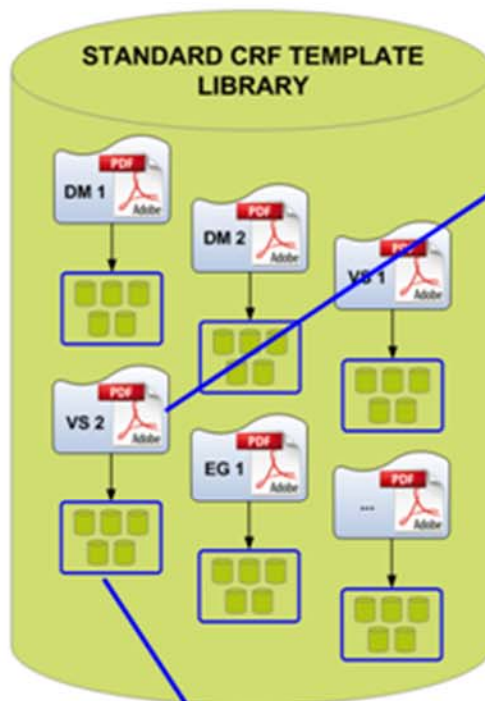


3. Data Standards Library – Standard CRF Templates (Data Collection Modules / CDASH)



- CRF template using CDASH annotations

3. Data Standards Library – Standard CRF Templates (Data Collection Modules / SDTM)



Vital Signs

Vital signs

Date and time performed **VSDTC** (24 h time clock)
dd mmm yy hh mm

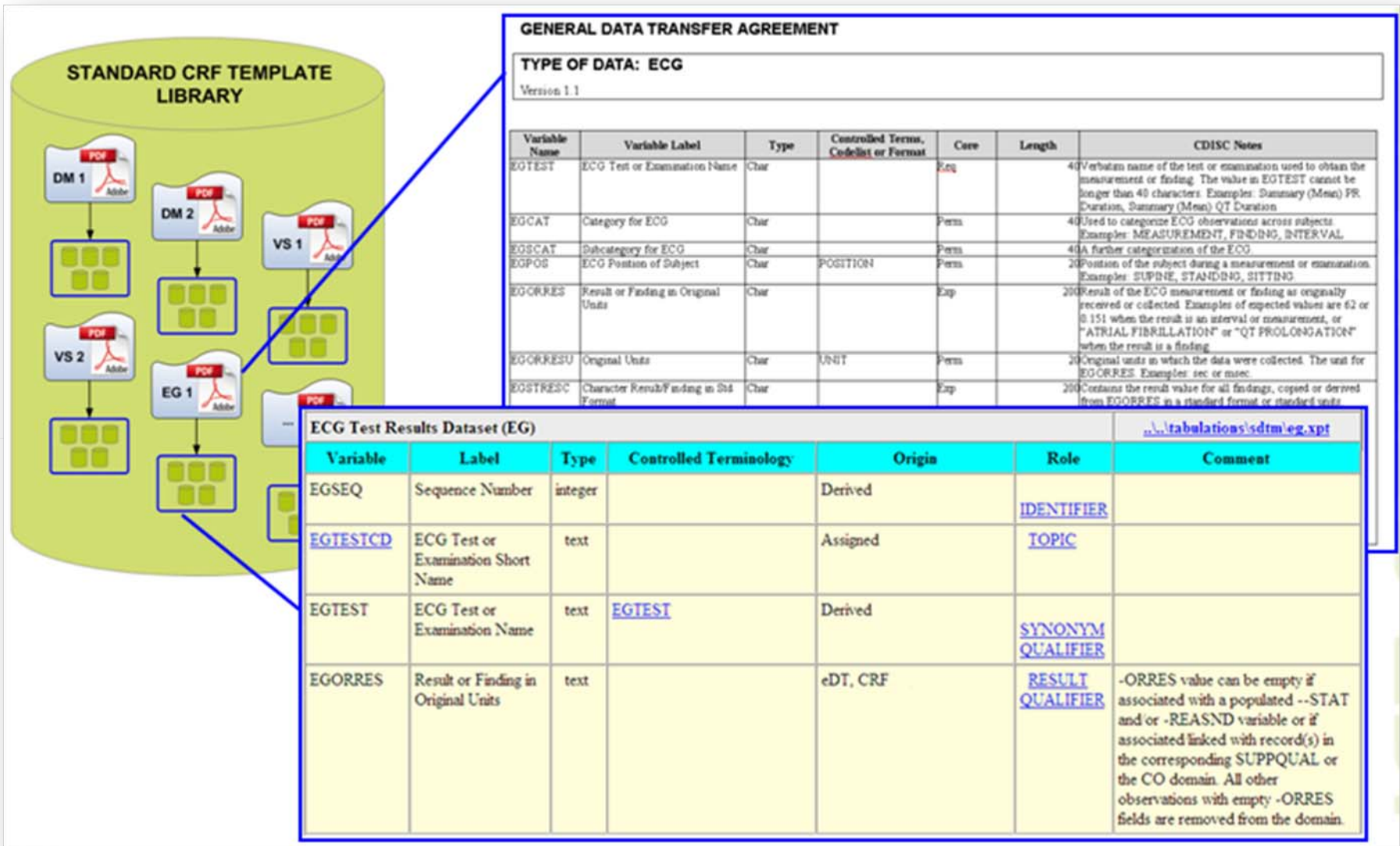
Pulse beats/min **VSORRES where VSTESTCD = "PULSE"**

Blood pressure / systolic/diastolic (mmHg)
VSORRES where VSTESTCD = "SYSBP", "DIABP"

Value Level Metadata (ValueList.VS.VSTESTCD)

Source Variable	Value	Label	Type	Controlled Terminology	Origin	Role	Comments
VSTESTCD	DIABP	DIASTOLIC BLOOD PRESSURE	integer		CRF		
VSTESTCD	PULSE	PULSE RATE	integer		CRF		
VSTESTCD	SYSBP	SYSTOLIC BLOOD PRESSURE	integer		CRF		

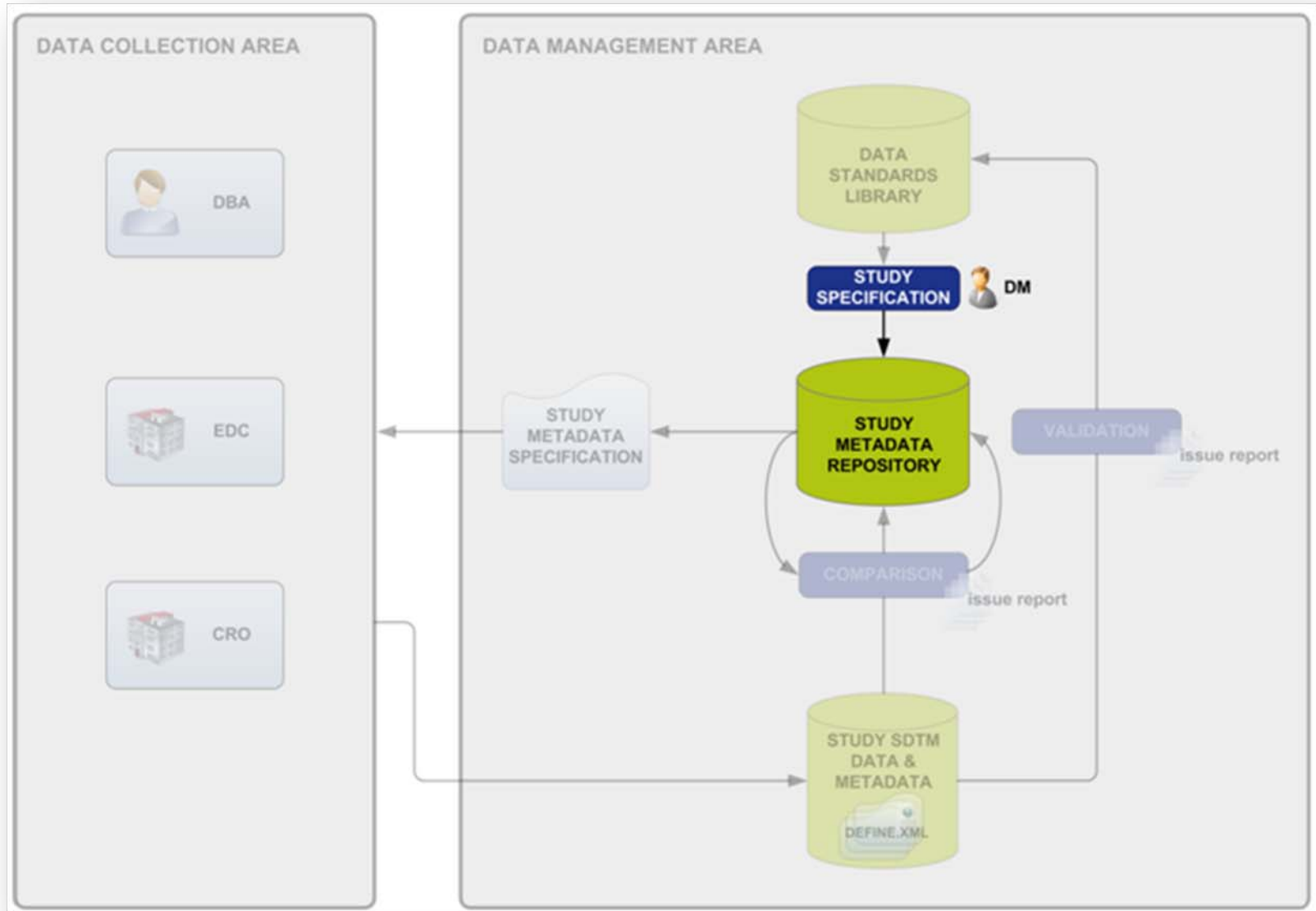
3. Data Standards Library – Standard CRF Templates (Data Collection Modules - Ancillary Data)



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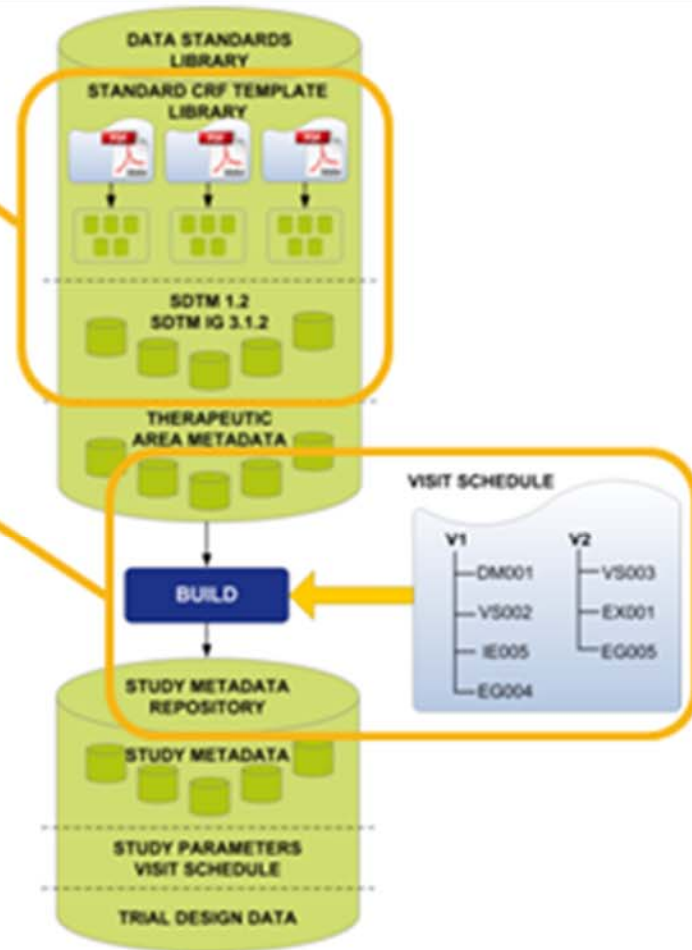
4. Study MetaData Repository

4. Study MetaData Repository



4. Study MetaData Repository

- **Global Standards Library:** metadata clusters corresponding to the CRF templates
- **Generation of study metadata by a *Pick & Select Module* requires :**
 - Visit/Time Point schedule & CRF Templates
 - Study Parameters
 - Trial Design Domains
 - Trial Arms (TA)
 - Trial Elements (TE)
 - Trial Inclusion/Exclusion Criteria (TI)
 - Trial Summary (TS)
 - Trial Visits (TV)



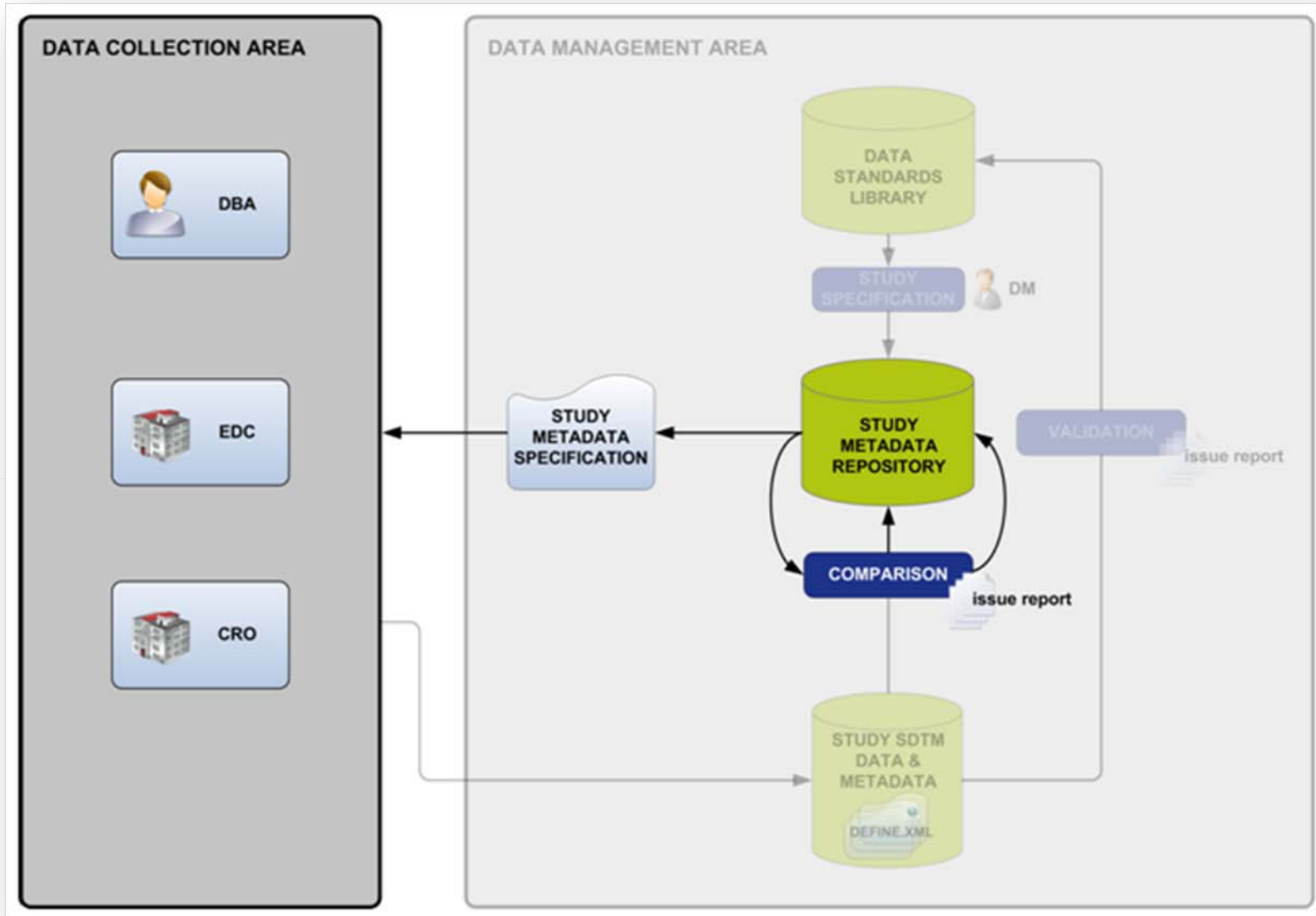
4. Study MetaData Repository (example study level '*define.xml*' parameters)

STUDYID	PAR_NAME	PAR_VALUE	PAR_ID	PAR_DESCRIPTION
ABC-0001	StudyOID	ABC-0001	Header	Study Identifier(Required Internal ODM key used to uniquely identify the entity)
ABC-0001	StudyName	ABC-0001	Header	Study Name (Part of the Globalvariables in ODM markup (required section))
ABC-0001	StudyDescription	ABC-0001	Header	Sudy title (Part of the Globalvariables in ODM markup (required section))
ABC-0001	ProtocolName	ABC-0001	Header	Name of the Protocol (Part of the Globalvariables in ODM markup (required section))
ABC-0001	ExternalDictionary	MedDRA	Footer	Name of the External Dictionary (Optional)
ABC-0001	DictionaryVersion	13.0	Footer	Version of the External Dictionary (Optional)
ABC-0001	DictionaryOID	MEDDRA	Footer	Unique Identifier for an External Dictionary (Optional)
ABC-0001	DictionaryDesc	ADVERSE EVENT DICTIONARY	Footer	Description of External Dictionary
ABC-0001	ExternalDictionary	WHO Drug	Footer	Name of the External Dictionary (Optional)
ABC-0001	DictionaryVersion	WHO-DD 10:MAR	Footer	Version of the External Dictionary (Optional)
ABC-0001	DictionaryOID	WHODRUG	Footer	Unique Identifier for an External Dictionary (Optional)
ABC-0001	DictionaryDesc	DRUG DICTIONARY	Footer	Description of External Dictionary
ABC-0001	DictionaryOID	ISO 8601	Footer	Unique Identifier for an External Dictionary (Optional)
ABC-0001	DictionaryDesc	ISO 8601	Footer	Description of External Dictionary
ABC-0001	DictionaryOID	ISO 3166	Footer	Unique Identifier for an External Dictionary (Optional)
ABC-0001	DictionaryDesc	ISO 3166	Footer	Description of External Dictionary

An abstract background featuring a horizontal band of color. The band is composed of various shades of blue, red, and orange, with a textured, almost painterly appearance. The colors are blended together, creating a sense of depth and movement. The text is overlaid on this band.

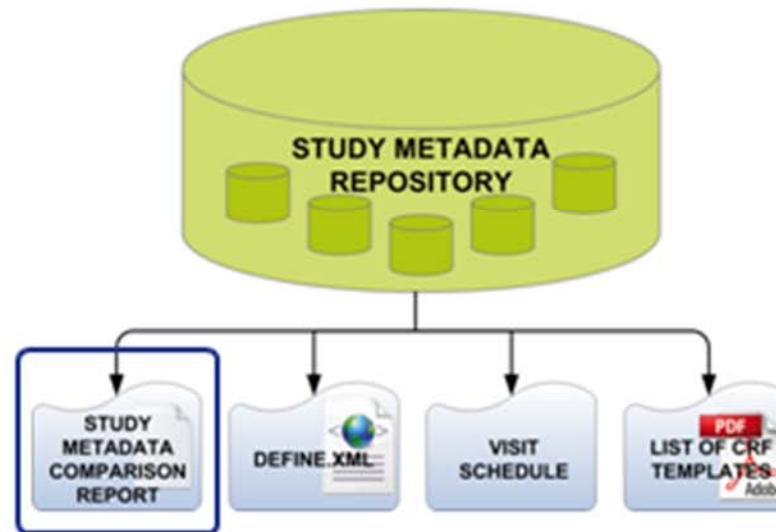
5. Generating Study MetaData Specifications & Reports

5. Generating Study MetaData Specifications & Reports



5. Generating Study MetaData Specifications & Reports

- **Comparison reports**
 1. To compare study metadata against the Data Standards Library
 2. To measure metadata consistency within studies (different versions of metadata) and between studies.



Comparison done across all the levels of metadata existing in the Study Metadata Repository

5. Generating Study MetaData Specifications & Reports (example report)

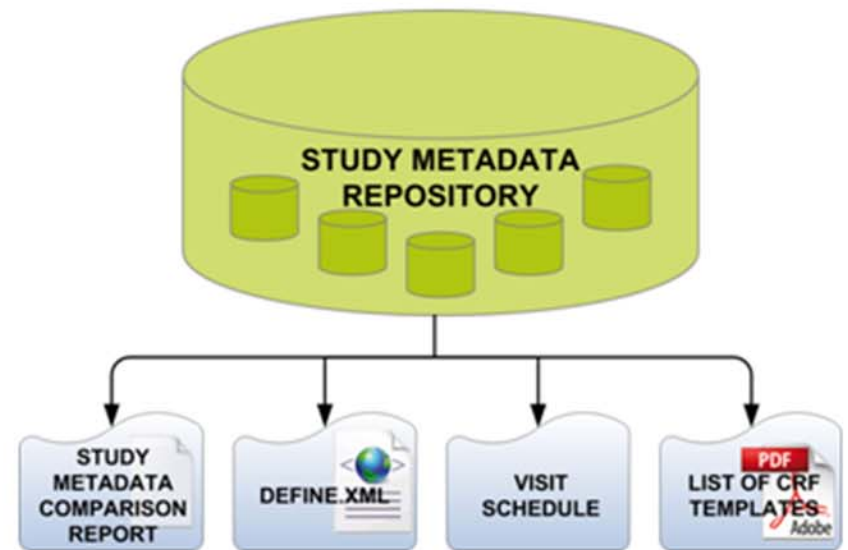
- 2 different statuses:
 - Ok** : no metadata conflict
 - Difference** : difference in metadata value between studies

Status	Dataset	Label	A1000_0000	A1000_0001	A1000_0002
Ok	AE	Adverse Events	X	X	X
Status	Reference	Computational algorithm	A1000_0000	A1000_0001	A1000_0002
Difference	DM.AGE	Equal to (DS.DSSTDTC-DM.BRTHDTC)/365.25 where DSTERM = 'INFORMED CONSENT OBTAINED'		X	
Difference	DM.AGE	Equals to (DS.DSSTDTC-DM.BRTHDTC)/365.25 where DSTERM = 'INFORMED CONSENT OBTAINED'	X		X
Difference	DM	Demographic		X	
Ok	DS	Disposition	X	X	X

5. Generating Study MetaData Specifications & Reports

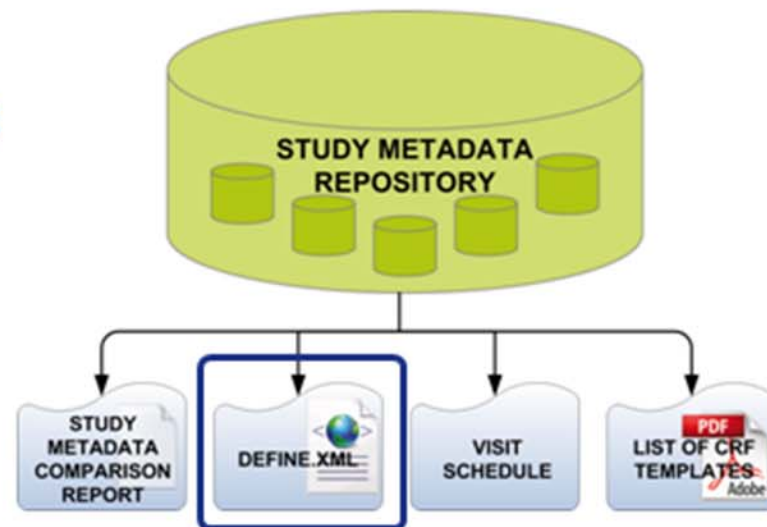
- Study metadata specifications

1. 5 levels of metadata
2. define.xml
3. list of CRF templates
4. visit schedule



5. Generating Study MetaData Specifications & Reports

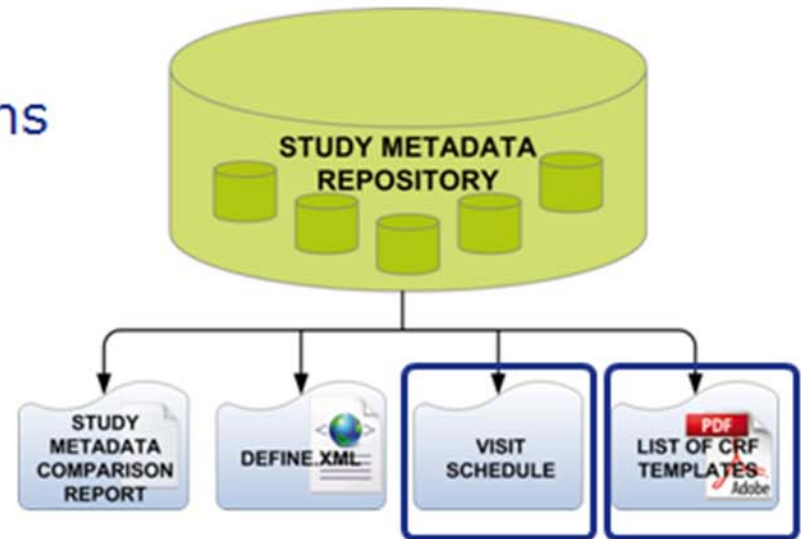
- Study metadata specifications
 1. 5 tables, one for each level of metadata
 2. Define.xml



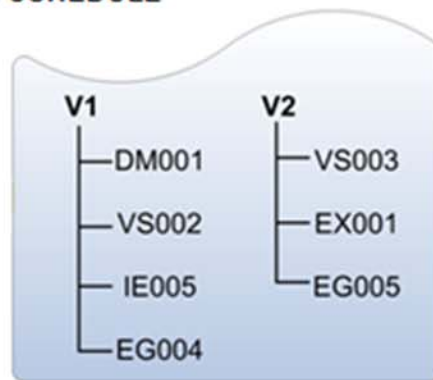
Demographics Dataset (DM)						..\Tabulations\dm.xpt
Variable	Label	Type	Controlled Terms or Format	Origin	Role	Comment
STUDYID	Study Identifier	text		Protocol, CRF	<u>IDENTIFIER</u>	Unique identifier for a study within the submission.
DOMAIN	Domain Abbreviation	text	<u>DOMAIN</u>	Assigned	<u>IDENTIFIER</u>	Two-character abbreviation for the domain most relevant to the observation.
USUBJID	Unique Subject Identifier	text		Derived	<u>IDENTIFIER</u>	Unique subject identifier within the submission. This is the concatenation of STUDYID, SITEID and SUBJID.
SUBJID	Subject Identifier for the Study	text		CRF	<u>TOPIC</u>	Unique subject identifier within the study.

5. Generating Study MetaData Specifications & Reports

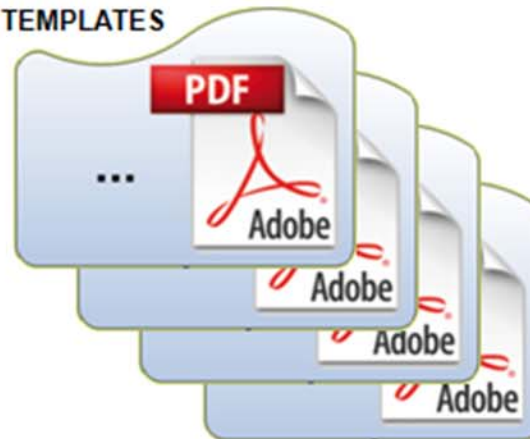
- Study metadata specifications
 - 3. Visit schedule
 - 4. CRF templates



VISIT SCHEDULE



CRF TEMPLATES

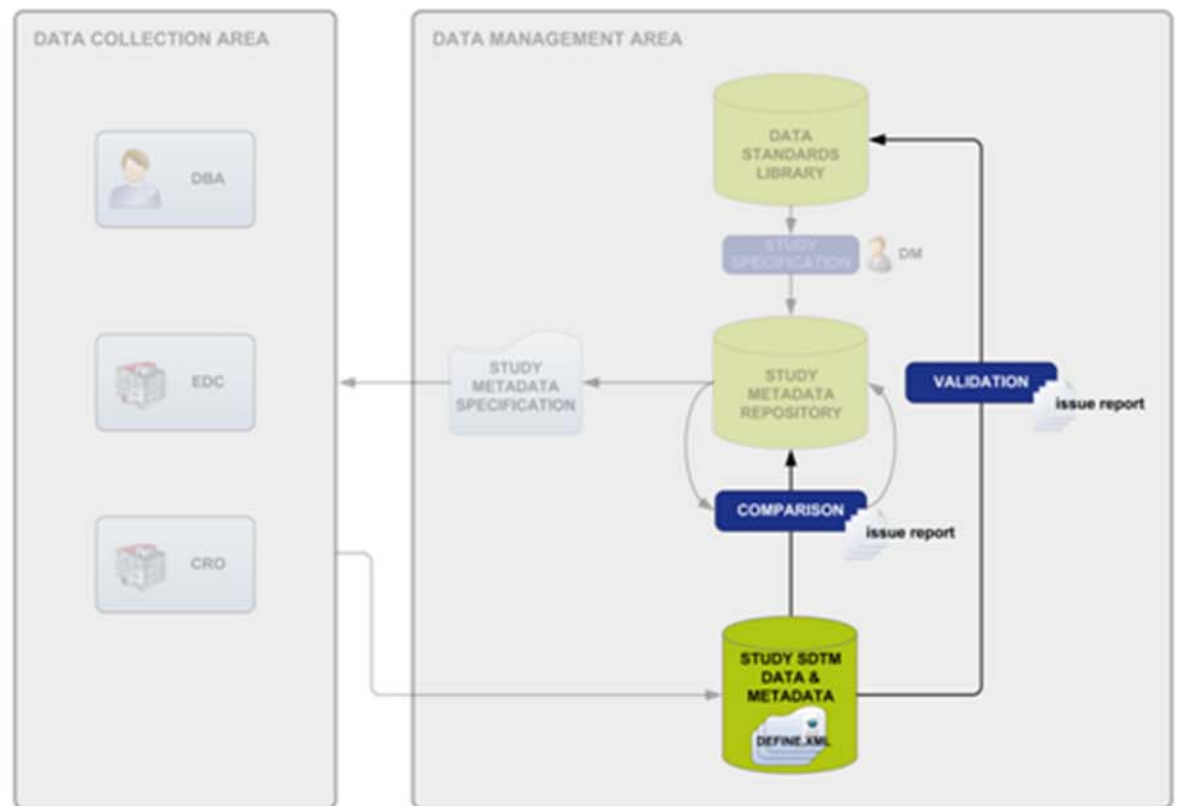


An abstract, textured background featuring a mix of vibrant blue, deep red, and warm orange hues, resembling a close-up of a colorful fabric or a digital art piece.

6. Verifying Study Data & MetaData

6. Verifying Study Data & MetaData

- The data and metadata are verified by a two-step process :
 - Comparison against the Study Metadata Library
 - Validation against the Data Standards Library



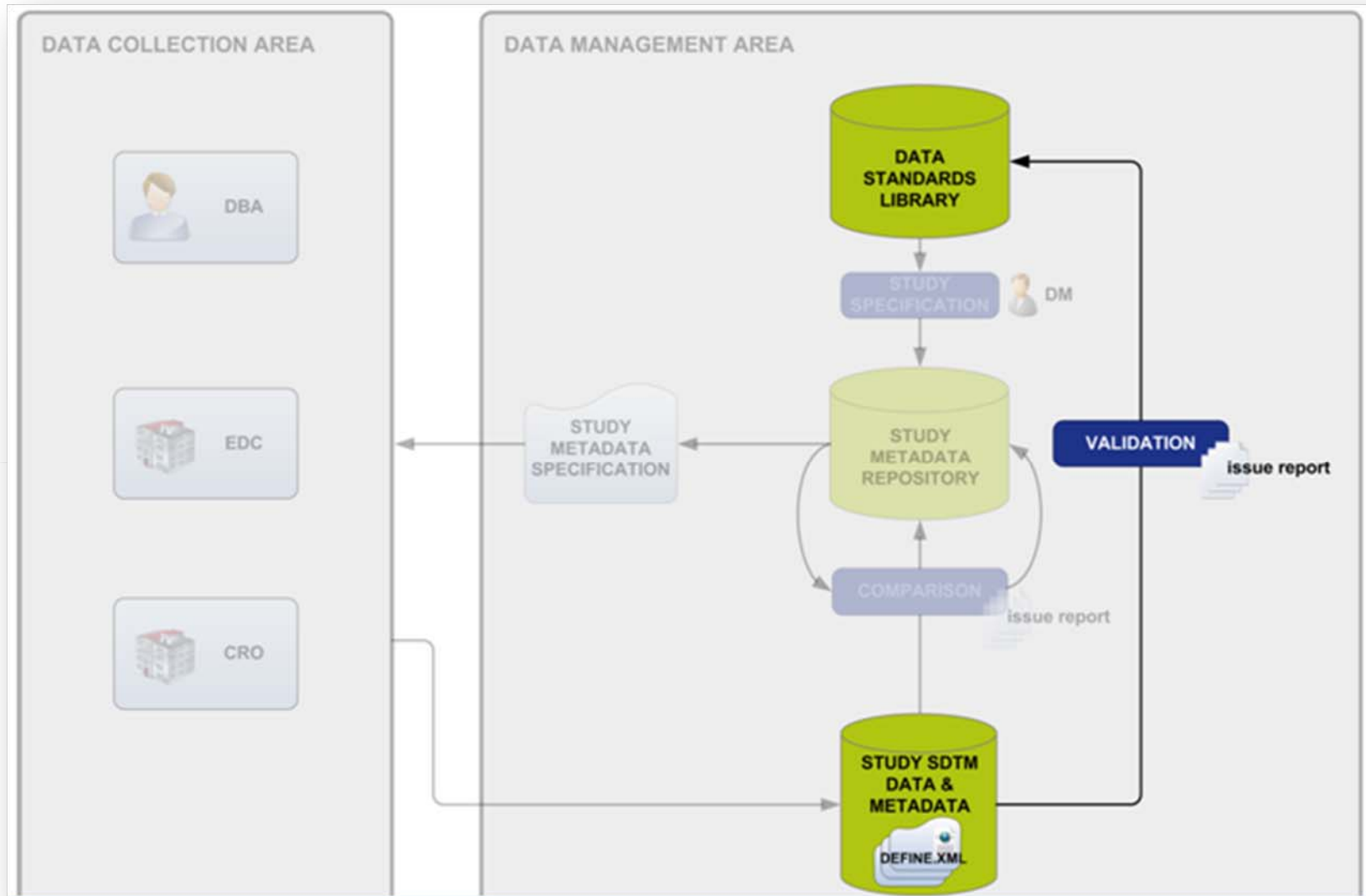
6. Verifying Study Data & MetaData (Comparison against Study MetaData Library)

✓ Compared against Study Definitions (*Study MetaData Repository*)
and Trial Design Domains

- 4 different statuses :
 - Ok** : no conflict in metadata
 - Difference** : difference in the metadata value
 - Missing** : metadata not in study data
 - Addition** : metadata not in study specifications

Status	Dataset	Variable	<i>Label</i>	Specifications	Study
Difference	AE	AEACN	Action Taken with Study Trtment		X
Difference	AE	AEACN	Action Taken with Study Treatment	X	
Ok	AE	AEBODSYS	Body System or Organ Class	X	X
Missing	AE	AECAT	Category for Adverse Event	X	
Addition	AE	AECOM	Comment about Adverse Event		X
Ok	AE	AECONTRT	Concomitant or Additional Trtmnt Given	X	X

6. Verifying Study Data & MetaData (Validation against Data Standards Library)



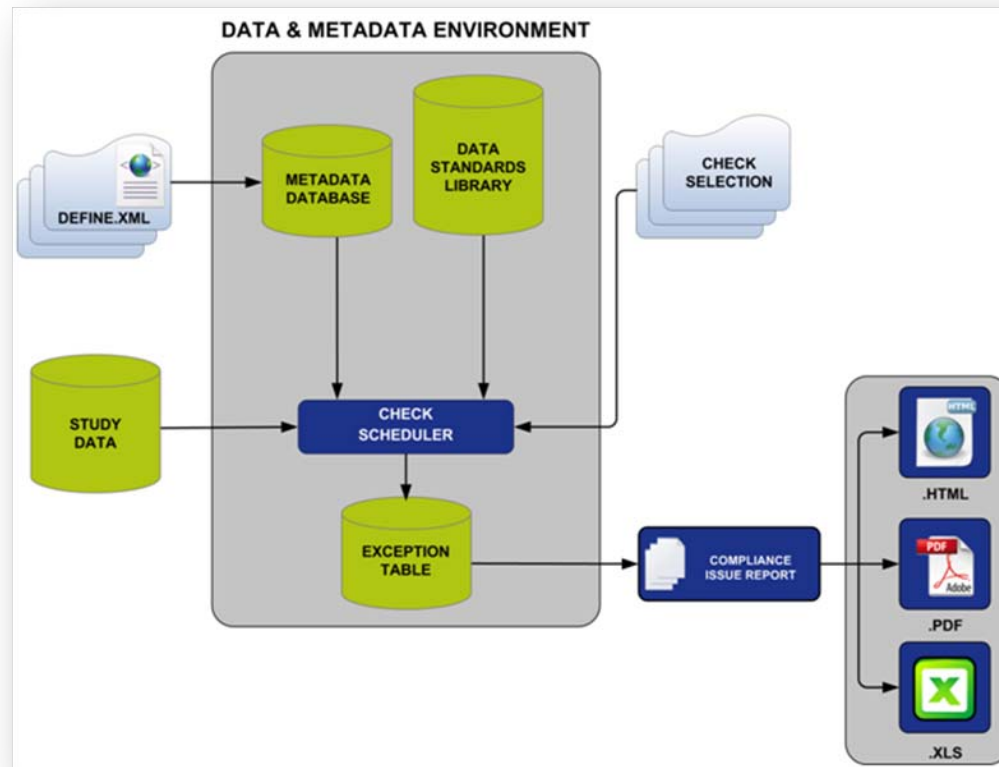
6. Verifying Study Data & MetaData (Validation against Data Standards Library)



Data Model Version	Check	Sub CheckID	Error_Message	Type	Applies to	Severity	WebSDM	WebSDM Rule Description
SDTMIG V3.1.2	1001		DATE VARIABLE does not have a ISO 8601 format.	Data	All observation classes, TD, Special Purpose	Medium	IR5002	Identifies records where the DATE VARIABLE does not conform to the ISO 8601 standard.
SDTMIG V3.1.2	1002		The STANDARD UNIT is not consistent per LAB TEST or EXAMINATION.	Data	Findings	High	IR5006	Identifies Measurement, Test or Examination records where the STANDARD UNIT is not consistent with the standard units value (Standard Units List).
SDTMIG V3.1.2	1003	1	The AE is serious, but none of the serious criteria is answered "Y".	Data	Events	Medium	IR5008	Identifies records where Seriousness is "Y" but none of the criteria (Seriousness, Death, Death Date, Death Time, Death Cause, Death Location, Death Outcome, Death Status, Death Reason, Death Date, Death Time, Death Cause, Death Location, Death Outcome, Death Status, Death Reason) are answered "Y".
SDTMIG V3.1.2	1003	2	The AE is not serious, but one of the serious criteria is answered "Y".	Data	Events	Medium	IR5008	Identifies records where Seriousness is "N" but one of the criteria (Seriousness, Death, Death Date, Death Time, Death Cause, Death Location, Death Outcome, Death Status, Death Reason, Death Date, Death Time, Death Cause, Death Location, Death Outcome, Death Status, Death Reason) is answered "Y".
SDTMIG V3.1.2	1004	1	A STANDARD RESULT is completed, but the STATUS is not completed.	Data	Findings	Medium		
SDTMIG V3.1.2	1004	2	No STANDARD RESULT is completed, but STATUS is not completed.	Data	Findings	Low		
SDTMIG V3.1.2	1005		START DATE/TIME OF OBSERVATION falls after the END DATE/TIME OF OBSERVATION.	Data	All observation classes, Special Purpose	High	IR5101	Identifies records that violate the rule: Observation less than or equal to records where [Start Date/Time of Observation is not null] and [End Date/Time of Observation is not null].
SDTMIG V3.1.2	1006		The OCCURRENCE is completed differently from "Y" or "N".	Data	Events, Interventions	High	IR5106	Identifies records that violate the rule: Occurrence is not "Y" or "N".
SDTMIG V3.1.2	1007		The LENGTH of the --TEST variable is more than 40 characters.	Data	Findings	High	IR5113	Identifies records that violate the rule: Measurement, Test or Examination Short Name length is more than 40 characters.
SDTMIG V3.1.2	1008	1	The --TESTCD starts with a number.	Data	Findings	High	IR5114	Identifies records that violate the rule: Measurement, Test or Examination Short Name (1st character) is not a number.
SDTMIG V3.1.2	1008	2	The --TESTCD contains special characters.	Data	Findings	High	IR5114	Identifies records that violate the rule: Measurement, Test or Examination Short Name contains special characters.
SDTMIG V3.1.2	1009		An ORIGINAL RESULT is completed but the STANDARD RESULT (CHARACTERISTIC) is missing.	Data	Findings	High	IR5135	Identifies records where the ORIGINAL RESULT is completed but the STANDARD RESULT (CHARACTERISTIC) is missing.

6. Verifying Study Data & MetaData (Validation against Data Standards Library)

- ✓ Structure Checks based on Industry Standards
- ✓ Business Rules and Data Checks



6. Verifying Study Data & MetaData (Validation Reports)

- 3 reports are created:
 - **Exception log**
 - Exception summary
 - Exception table

LIST_OF_CHECKS	ERROR_LEVEL	COMPLETION_TIME	ELAPSED_TIME
Check1002	The Check Completed Successfully	2011-03-02T11-39-37	.
Check1005	The Check Completed Successfully	2011-03-02T11-39-37	0:00:00
Check1007	The Check Completed Successfully	2011-03-02T11-39-38	0:00:01
Check1008	The Check Completed Successfully	2011-03-02T11-39-38	0:00:00
Check1009	The Check Completed Successfully	2011-03-02T11-39-38	0:00:00
Check1011	The Check Completed Successfully	2011-03-02T11-39-41	0:00:03
Check1012	The Check Completed Successfully	2011-03-02T11-39-48	0:00:07
Check1102	The Check Completed Successfully	2011-03-02T11-39-49	0:00:01
Check1103	The Check Completed Successfully	2011-03-02T11-39-49	0:00:00
Check1122	The Check Completed Successfully	2011-03-02T11-39-49	0:00:00
Check1132	The Check Completed Successfully	2011-03-02T11-39-49	0:00:00
Check1242	The Check Completed Successfully	2011-03-02T11-39-50	0:00:01
Check1243	The Check Completed Successfully	2011-03-02T11-39-51	0:00:01
Check1249	The Check Completed Successfully	2011-03-02T11-39-51	0:00:00
Check1251	The Check Completed Successfully	2011-03-02T11-39-51	0:00:00
Check1414	The Check Completed Successfully	2011-03-02T11-39-52	0:00:01

6. Verifying Study Data & MetaData (Validation Reports)

- 3 reports are created:
 - Exception log
 - **Exception summary**
 - Exception table

LIST_OF_CHECKS	EXCEPTIONS_COUNT	CHECK TYPE
Check1002	5	DATA
Check1005	8	DATA
Check1007	2	DATA
Check1008	1	DATA
Check1009	3	DATA
Check1010	1	METADATA
Check1011	8	DATA
Check1012	44	DATA
Check1102	1	DATA
Check1103	3	DATA
Check1122	1	DATA
Check1132	2	DATA
Check1242	4	DATA
Check1243	1	DATA
Check1249	4	DATA
Check1251	1	DATA
Check1414	2	DATA

6. Verifying Study Data & MetaData (Validation Reports)

- 3 reports are created:
 - Exception log
 - Exception summary
 - Exception table**

Reported Exception		Record Identifiers				Exception Attributes					
CHECKID	ERRORMSG	SEVERITY	STUDYID	DOMAIN	USUBJID	KEY1CD	KEY1	VAR1CD	VAR1	VAR2CD	VAR2
1002	The STANDARD UNIT is not consistent per TEST or EXAMINATION.	High	1000-0000	LB				LBTESTCD	LPASE	LBSTRESU	%
1002	The STANDARD UNIT is not consistent per TEST or EXAMINATION.	High	1000-0000	LB				LBTESTCD	LPASE	LBSTRESU	mmol/L
1002	The STANDARD UNIT is not consistent per TEST or EXAMINATION.	High	1000-0000	LB				LBTESTCD	ALKP	LBSTRESU	U
1002	The STANDARD UNIT is not consistent per TEST or EXAMINATION.	High	1000-0000	LB				LBTESTCD	ALKP	LBSTRESU	U/L
1002	The STANDARD UNIT is not consistent per TEST or EXAMINATION.	High	1000-0000	LB				LBTESTCD	LPASE	LBSTRESU	U/L
1005	START DATETIME OF OBSERVATION falls after the END DATETIME OF OBSERVATION.	High	1000-0000	AE	1000-0000-00019	AESEQ	1	AESTDTC	1998-12-01T17:00	AEENDTC	1998-12-01T16:30
1005	START DATETIME OF OBSERVATION falls after the END DATETIME OF OBSERVATION.	High	1000-0000	AE	1000-0000-00037	AESEQ	1	AESTDTC	1998-12-15T07:40	AEENDTC	1998-11-25T08:00
1005	START DATETIME OF OBSERVATION falls after the END DATETIME OF OBSERVATION.	High	1000-0000	SE	1000-0000-00004	SESEQ	2	SESTDTC	1998-11-17T08:06:00	SEENDTC	1998-11-17T07:07:00
1005	START DATETIME OF OBSERVATION falls after the END DATETIME OF OBSERVATION.	High	1000-0000	SE	1000-0000-00009	SESEQ	2	SESTDTC	1998-11-24T08:00:00	SEENDTC	1997-11-24T08:01:00
1005	START DATETIME OF OBSERVATION falls after the END DATETIME OF OBSERVATION.	High	1000-0000	SV	1000-0000-00022			SVSTDTC	1998-12-03	SVENDTC	1998-12-02
1005	START DATETIME OF OBSERVATION falls after the END DATETIME OF OBSERVATION.	High	1000-0000	SV	1000-0000-00010			SVSTDTC	1998-11-24	SVENDTC	1998-11-22
1005	START DATETIME OF OBSERVATION falls after the END DATETIME OF OBSERVATION.	High	1000-0000	SV	1000-0000-00014			SVSTDTC	1998-11-16	SVENDTC	1998-10-16
1005	START DATETIME OF OBSERVATION falls after the END DATETIME OF OBSERVATION.	High	1000-0000	SV	1000-0000-00035			SVSTDTC	1998-12-17	SVENDTC	1997-12-17
1007	The LENGTH of the --TEST variable is more than 40 characters.	High	1000-0000	LB	1000-0000-00001	LBSEQ	35	LBTEST	ERY. MEAN CORPUSCULAR HB CONCENTRATION MEAS	LENGTH	43
1007	The LENGTH of the --TEST variable is more than 40 characters.	High	1000-0000	LB	1000-0000-00030	LBSEQ	54	LBTEST	PARTIAL THROMBOPLASTINE TIME MEASUREMENTS	LENGTH	41
1008	The --TESTCD starts with a number.	High	1000-0000	LB	1000-0000-00001	LBSEQ	3	LBTESTCD	2AMYL		
1009	An ORIGINAL RESULT is completed but the STANDARD RESULT (CHARACTERSTIC) is missing.	High	1000-0000	IE	1000-0000-00006	IESEQ	1	IEORRES	N	ESTRES	

7. Conclusion



7. Conclusion

- A multi layered data standards library (CDASH and SDTM) that facilitates building the study metadata
- The use of a study metadata repository to generate vendor specifications and increase consistencies across compounds
- Comparing standard data and metadata against the data collection's data standard and the study metadata
- Complex data management processes can be automated through workflows
- Implement data governance defined as the organizational structure that creates and enforces policies & procedures for the business use and management of data across the research & development organizations
- Export data management best (next) practices from clinical to other functions in the organization and leverage expertise, practices, tools, procedures,...
- Is there an opportunity for the industry to work more together in a pre-competitive environment on these type of solutions
- Similar process can be designed for ADaM

Q&A



srogiers@its.jnj.com