

Getting the most out of CDASH and SDTM

Automating the
specification and validation
process

Jean-Marc Ferran
Consultant & Owner
Mobile +45 60 16 04 56
Email: JMF@qualiance.dk

Qualiance ApS
Guldbergsgade 25, st th
2200 Copenhagen N
www.qualiance.dk

Peter Van Reusel
Business Unit Director
Tel +32 2 774 11 00
Fax +32 2 774 11 99
Mobile +32 476 54 59 17
peter.vanreusel@businessdecision.com

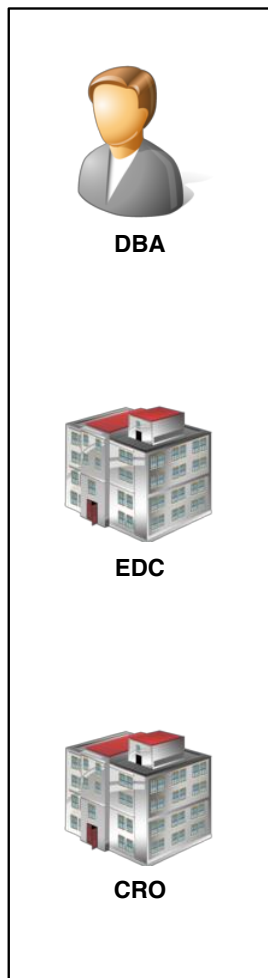
Contract Research Organisation
Business & Decision Life Sciences
Sint-Lambertusstraat 141 Rue Saint-Lambert
1200 Brussels
www.businessdecision-lifesciences.com



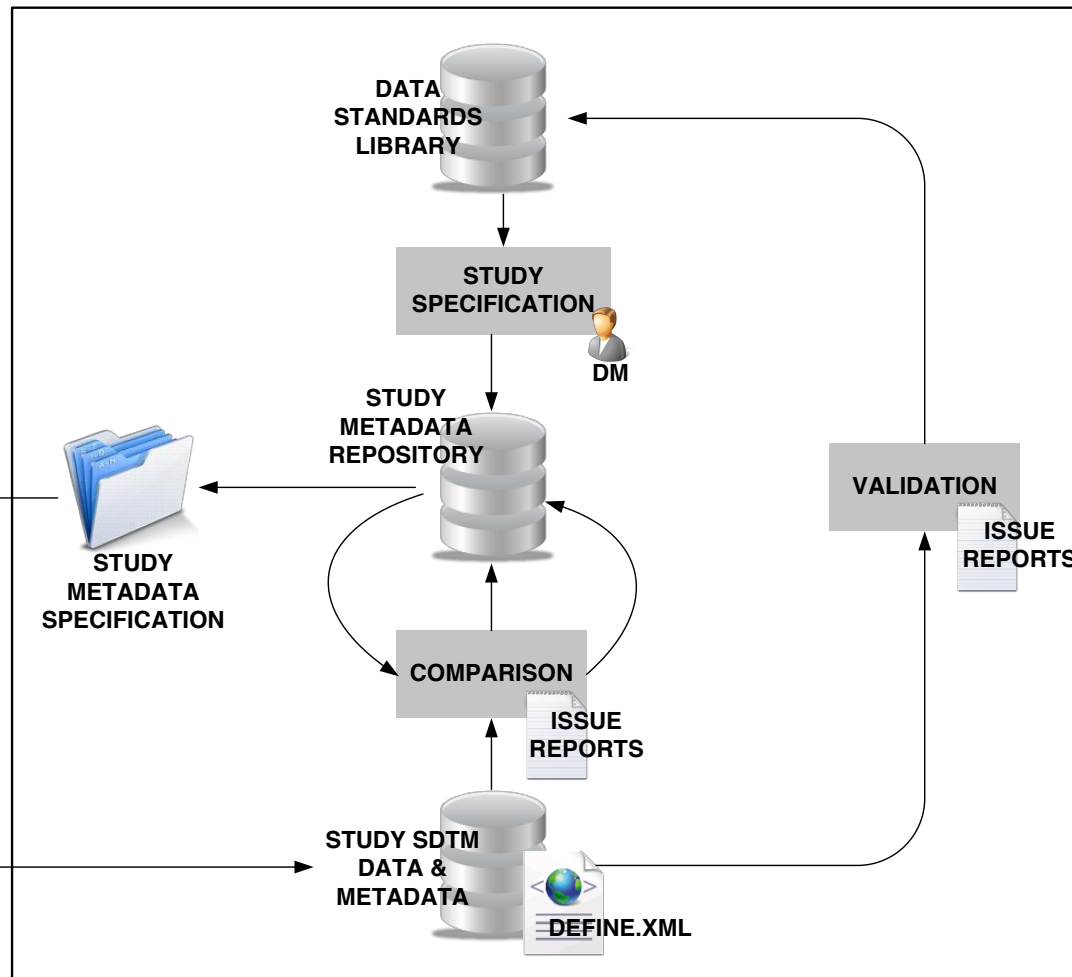
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Process Overview

DATA COLLECTION AREA



DATA MANAGEMENT AREA

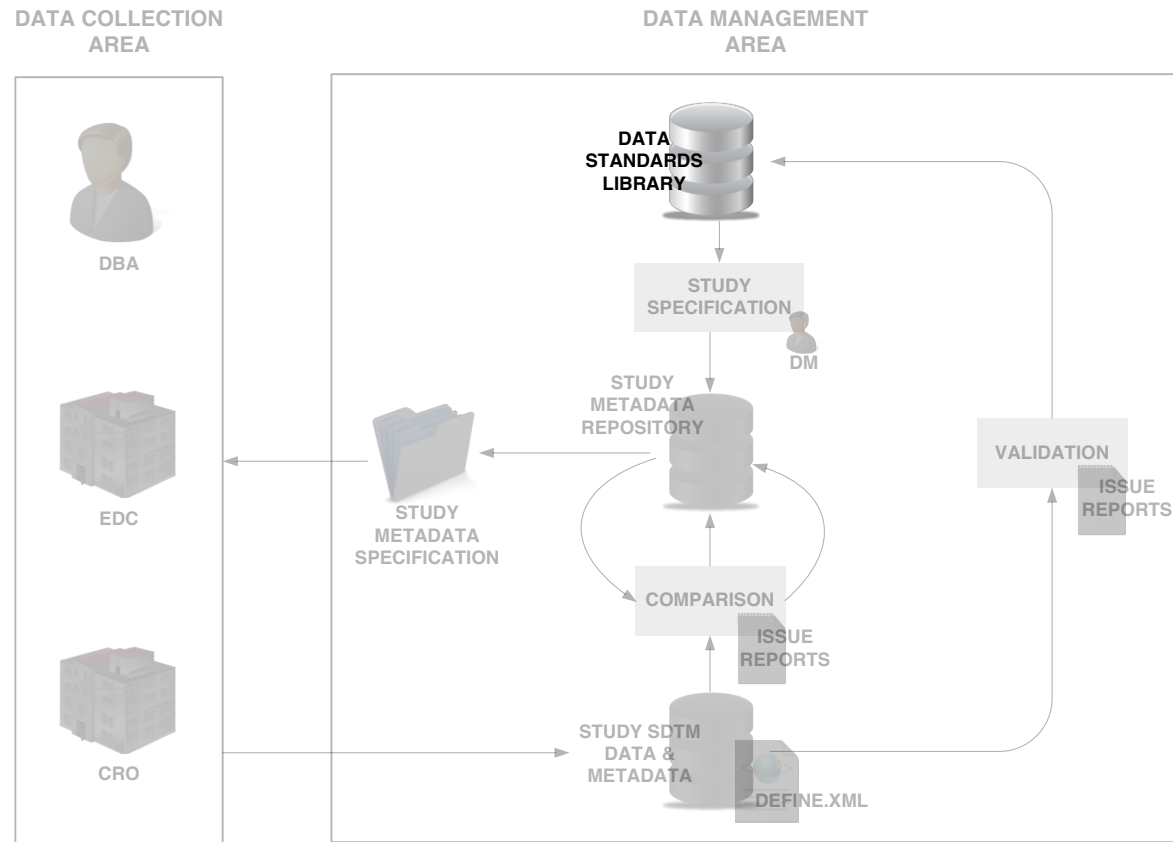


Process Overview

- The Data Standards Library contains :
 - Data Collection Modules (CDASH)
 - Metadata definitions (SDTM, Therapeutic area)

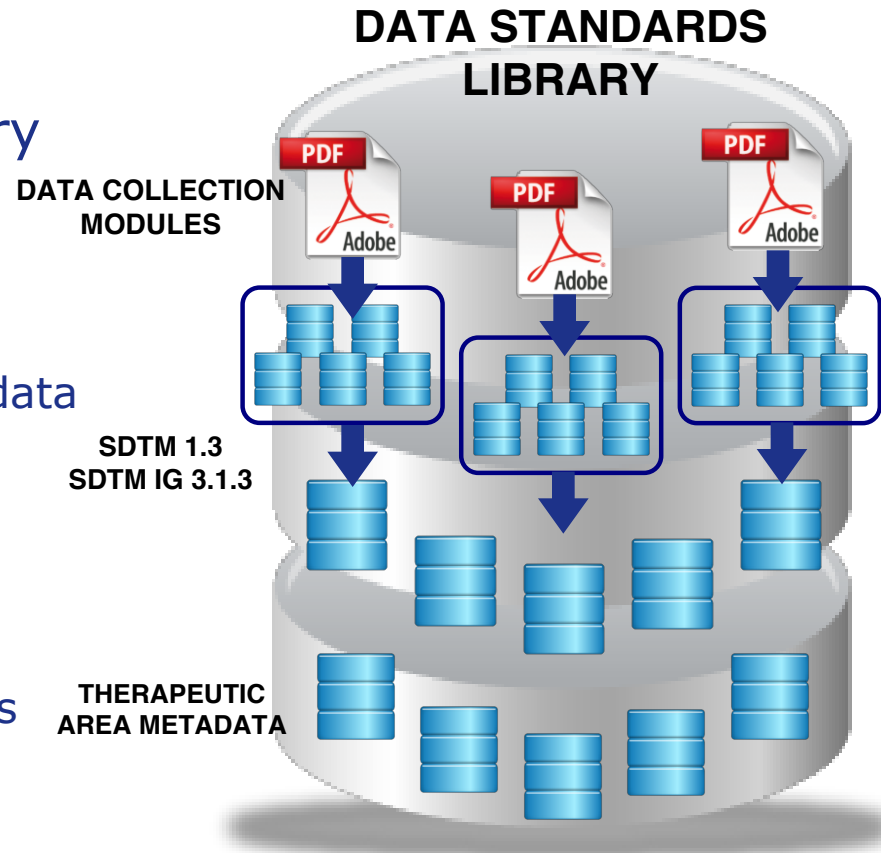


*used to
create study
metadata*



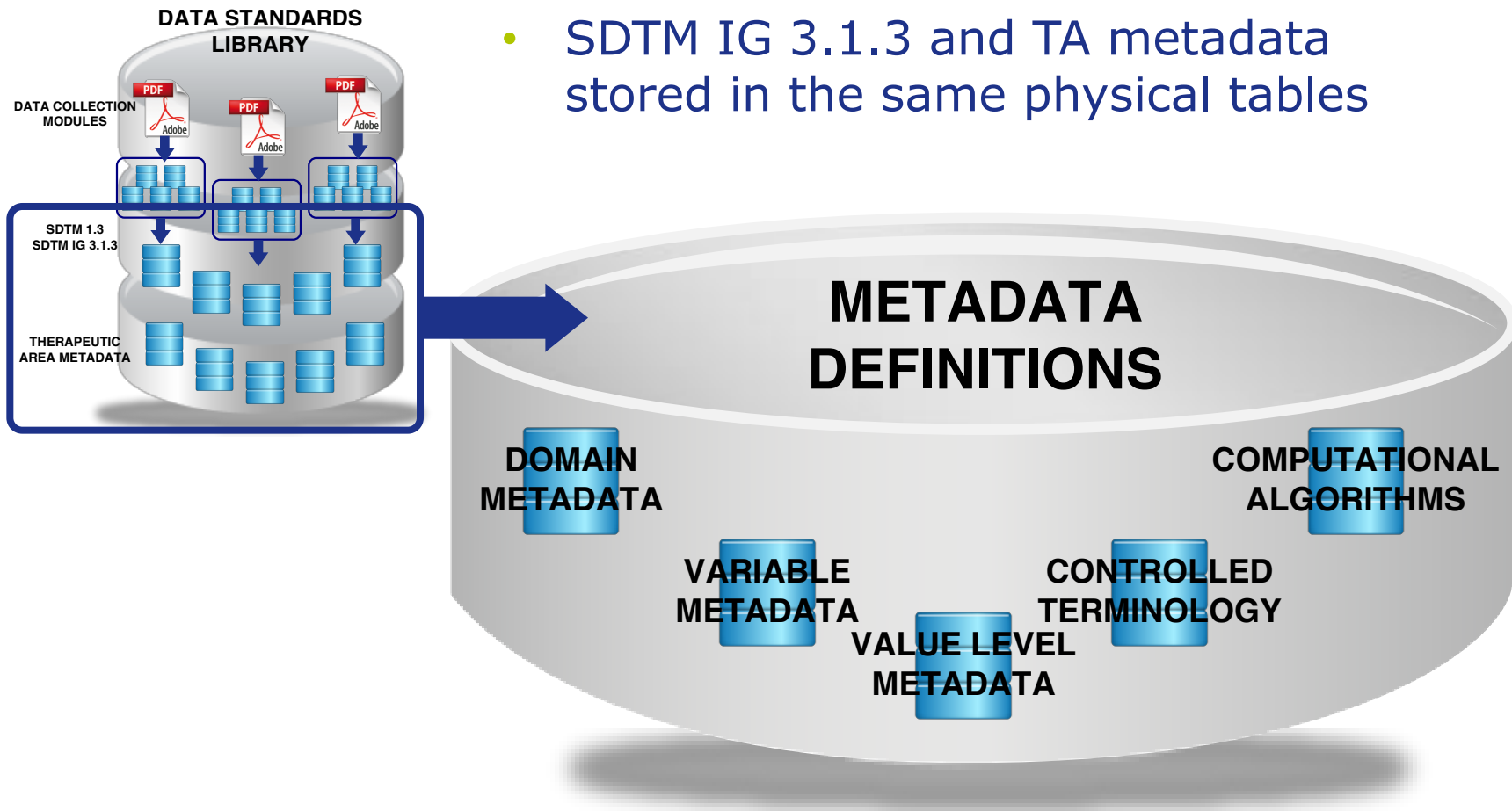
Data Standards Library

- The Data Standards Library contains :
 - Data Collection Modules:
 - using CDASH metadata
 - with clustered SDTM metadata
 - annotated for CDASH
 - annotated for SDTM
 - Metadata Definitions :
 - SDTM Standards
 - Therapeutic Area Standards



Metadata Definitions

- 5 levels of metadata
- SDTM IG 3.1.3 and TA metadata stored in the same physical tables



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

Metadata Definitions

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	..Tabulations\ex.xpt
AE	Adverse Events					

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-ZZZZ', where 'XXXX' indicates the 4-digit compound code, 'YYYY' the 4-digit study code and 'ZZZZ' the 4-digit subject code

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	

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	

Computational Algorithms (VS.BMI)

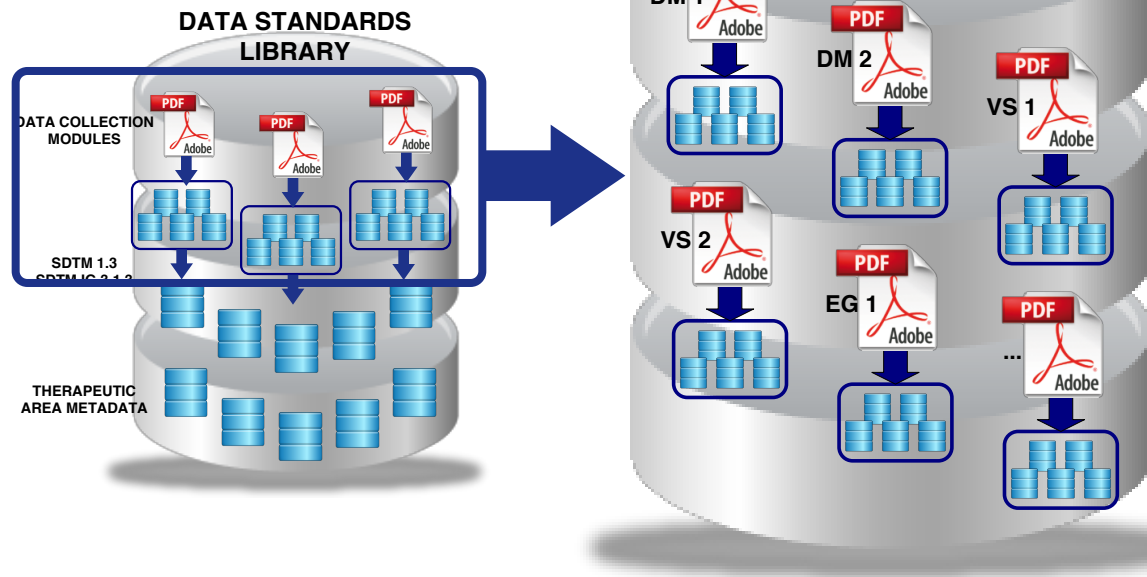
Reference Name	Computation Method
VS.BMI	Equals to WEIGHT DIVIDED BY HEIGHT SQUARED

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

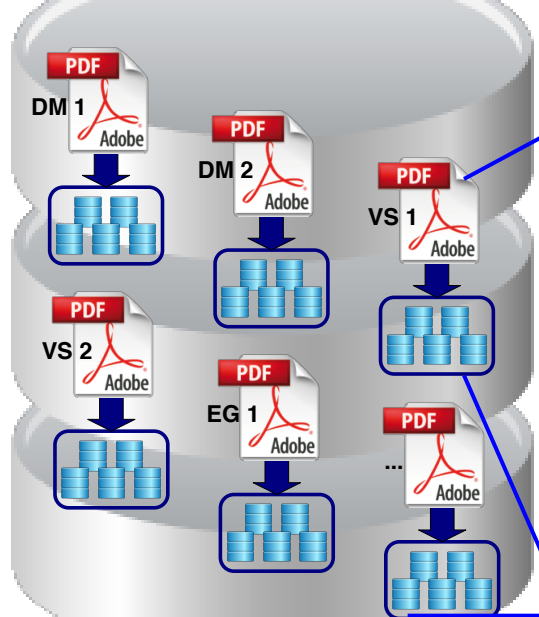
Data Collection Modules

- Data Collection Modules Library :
 - using CDASH metadata
 - with clustered SDTM metadata
 - annotated for CDASH
 - annotated for SDTM



Data Collection Modules - CDASH

DATA COLLECTION MODULES LIBRARY



Vital Signs

Vital signs

Date and time performed

VSDAT dd mmm yy VSTIM hh mm (24 h time clock)

Weight VSORRES kg **Height** VSTEST cm VSORRESU

Pulse

Supine* VSORRES beats/min VSORRESU

Standing* VSPOS VSORRESU

Blood pressure

Supine* VSORRES systolic/diastolic (mmHg) VSORRESU

Standing* VSORRESU systolic/diastolic (mmHg)

* (supine: after ≥ 5 min. rest; standing: after ≥ 1 min. standing)

Collected CDASH Variables	CRF Prompt	Codelist	Preprinted values
VSDAT	Date		
VSTIM	Time		
VSPOS	Position	POSITION	
VSTEST	Test	VLM VSTESTCD	Height
VSTEST	Test	VLM VSTESTCD	Weight
VSTEST	Test	VLM VSTESTCD	Pulse
VSTEST	Test	VLM VSTESTCD	Systolic Blood Pressure
VSTEST	Test	VLM VSTESTCD	Diastolic Blood Pressure
VSORRESU	Unit	VSRESU	cm
VSORRESU	Unit	VSRESU	kg
VSORRESU	Unit	VSRESU	beats/min
VSORRESU	Unit	VSRESU	mmHg

MODULES LIBRARY

The diagram illustrates a 'MODULES LIBRARY' structure. It features a large, light gray cylinder representing the library. Inside the cylinder, several PDF documents are arranged in a hierarchical manner. Each document is represented by a white icon with a red 'PDF' label and the Adobe logo. The documents are labeled as follows: DM 1, DM 2, VS 1, VS 2, EG 1, and an ellipsis (...). Each document is connected by a blue arrow to a corresponding data block, which is depicted as a stack of blue cylinders. The data blocks are also arranged in a hierarchical manner, with some blocks containing more sub-blocks. A blue line points from the top right towards the VS 1 document, and another blue line points from the bottom right towards the data block associated with the ellipsis (...).

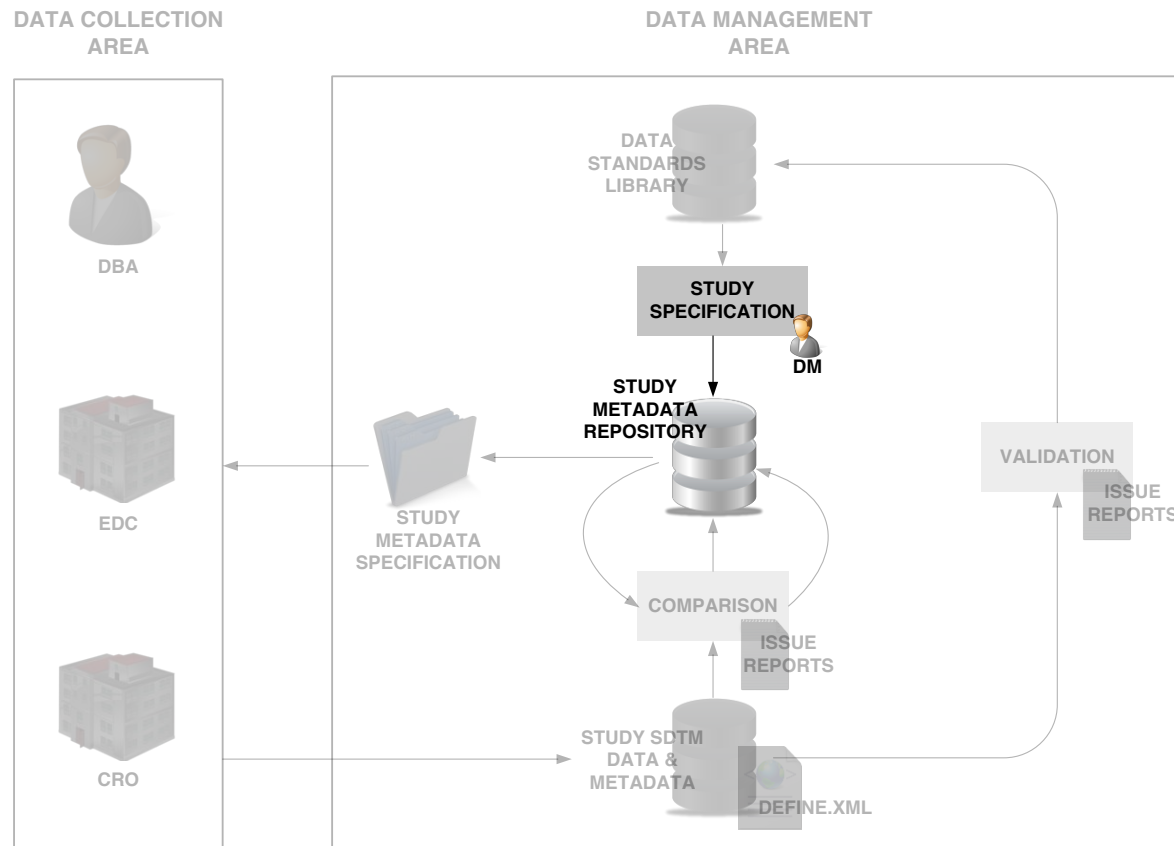
Vital Signs

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VSTESTCD	HEIGHT	HEIGHT	integer		CRF		
VSTESTCD	PULSE	PULSE RATE	integer		CRF		
VSTESTCD	SYSBP	SYSTOLIC BLOOD PRESSURE	integer		CRF		
VSTESTCD	WEIGHT	WEIGHT	integer		CRF		

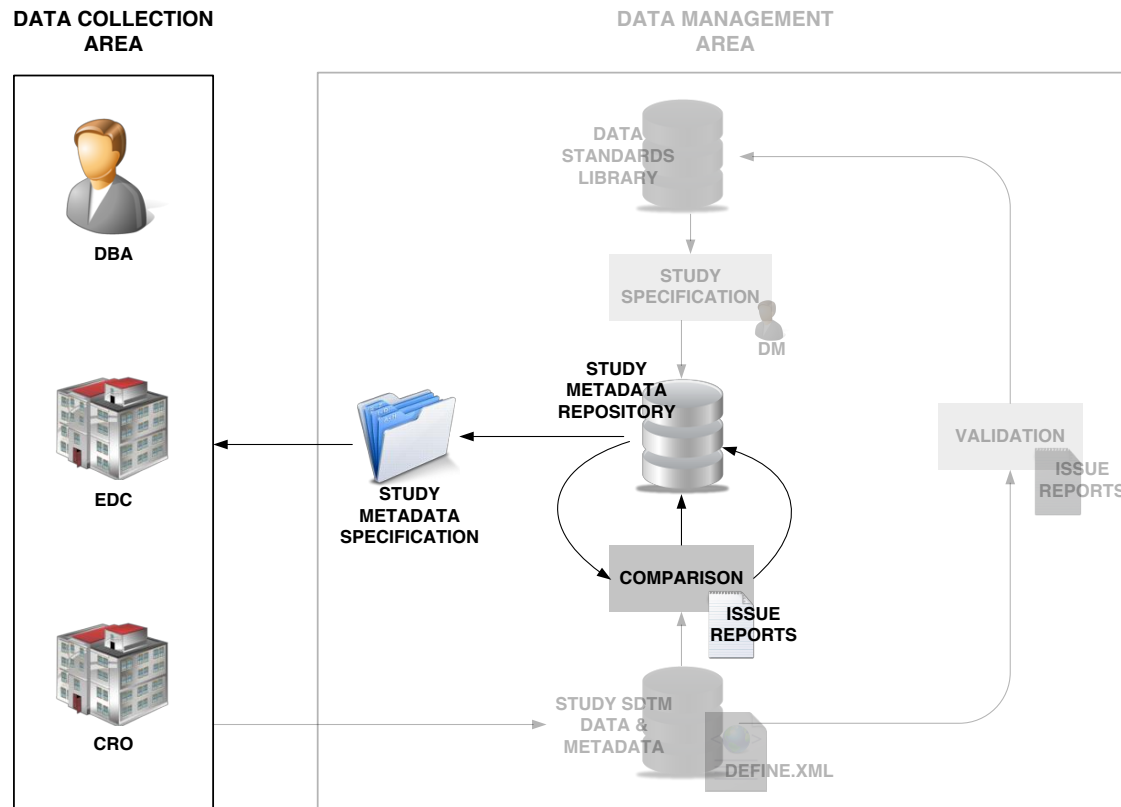
Process Overview

- Generating study metadata by selecting Data Collection Modules from the Data Standards Library



Process Overview

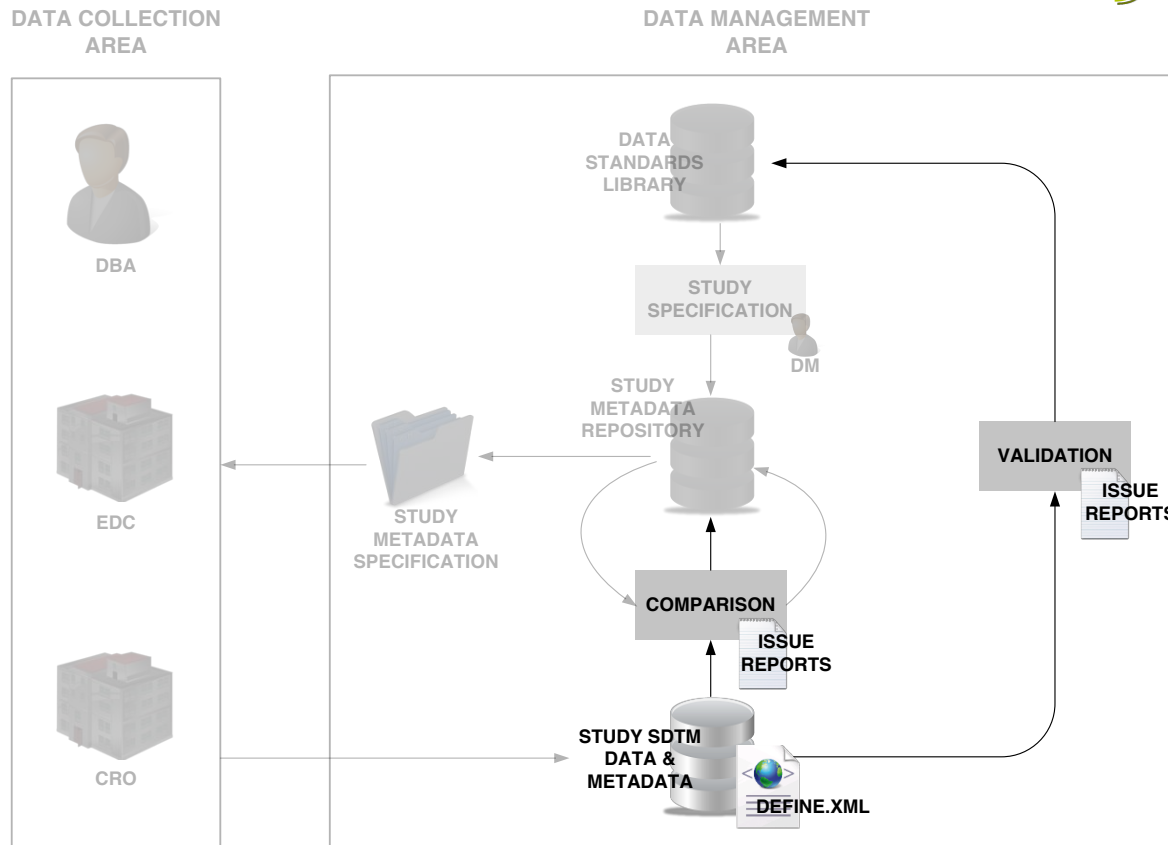
- Study Metadata Repository is used to measure the consistency of metadata
- Study metadata is sent to external or internal partners for database build



Process Overview

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

Verification



Conclusion (Process)

- Data standards library (CDASH, SDTM & ADaM) facilitates building the study metadata
- Reduce study specification cycle times
- Generate define.xml upfront
- Increase consistencies across compounds
- Automatically compare collected data against specifications
- Run the SDTM validation checks against sponsors' therapeutic data standards library
- Similar process can be designed for ADaM

Process Overview - Extension

