

CDISC Validation

How can we do it right ?

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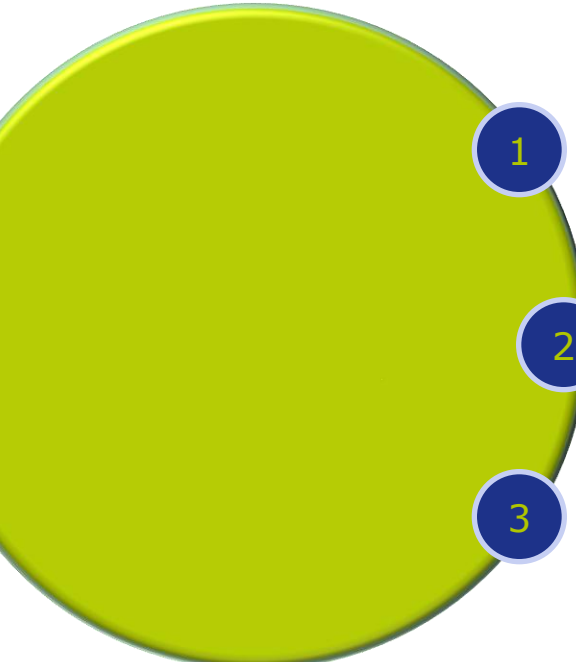
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Topics

- 
- 1 Current Situation
 - 2 Applied CDISC Compliance
 - 3 Summary

Topics

1

Current Situation

2

Applied CDISC Compliance

3

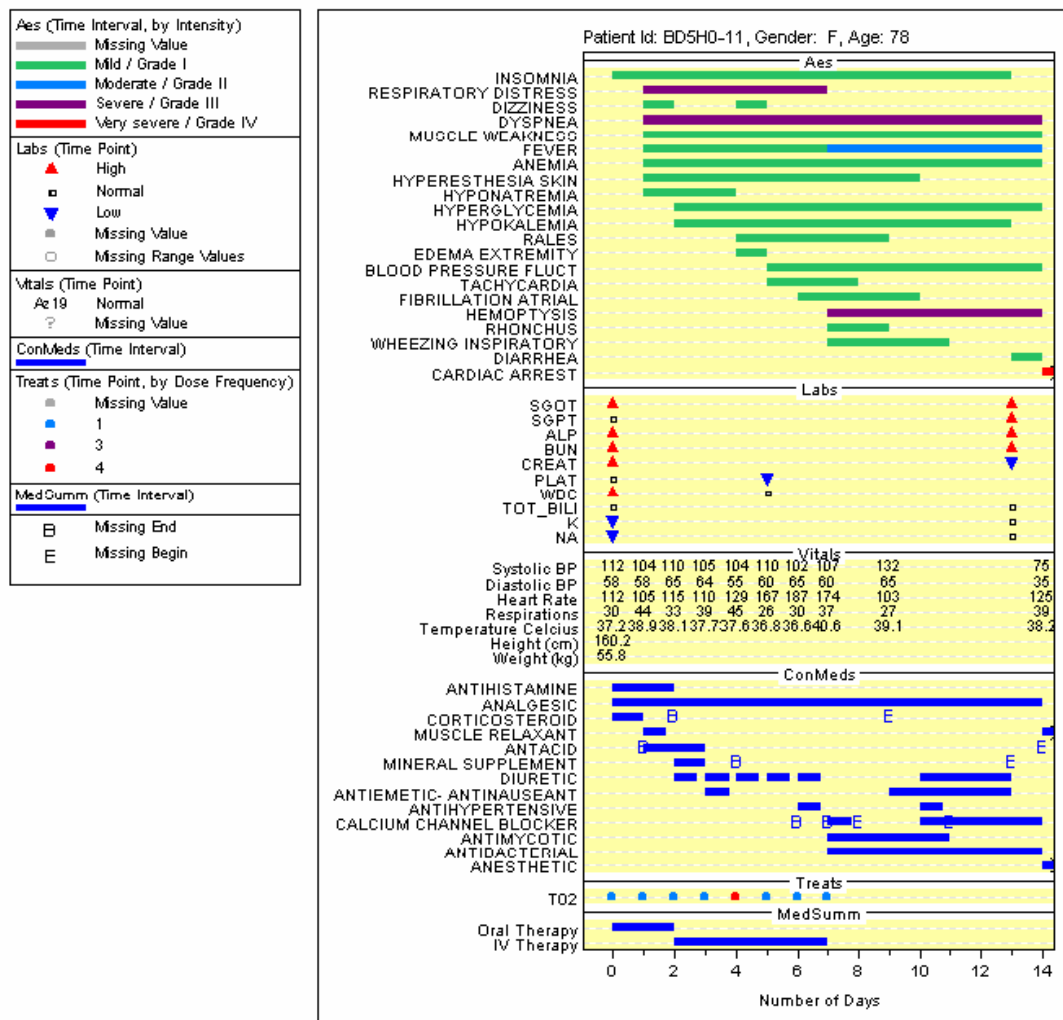
Summary

Submissions of NDAs to the FDA

- It is requested to submit clinical trial data (SDTM) & metadata (Define.xml) according to the SDTMIG V3.1.2 standards
- It is highly recommended to submit analysis data (ADaM) and metadata (Define.xml) according to the ADaMIG V1.0 standards
- Data standards allow the FDA to use standard tools
- CDISC SDTM = standard structure for study data tabulations
- CDISC ADaM = standard structure for analysis datasets

SDTM FDA Tools: Patient Profile Viewer

Subject BD5H0-11



SDTM FDA Tools: JReview (1)

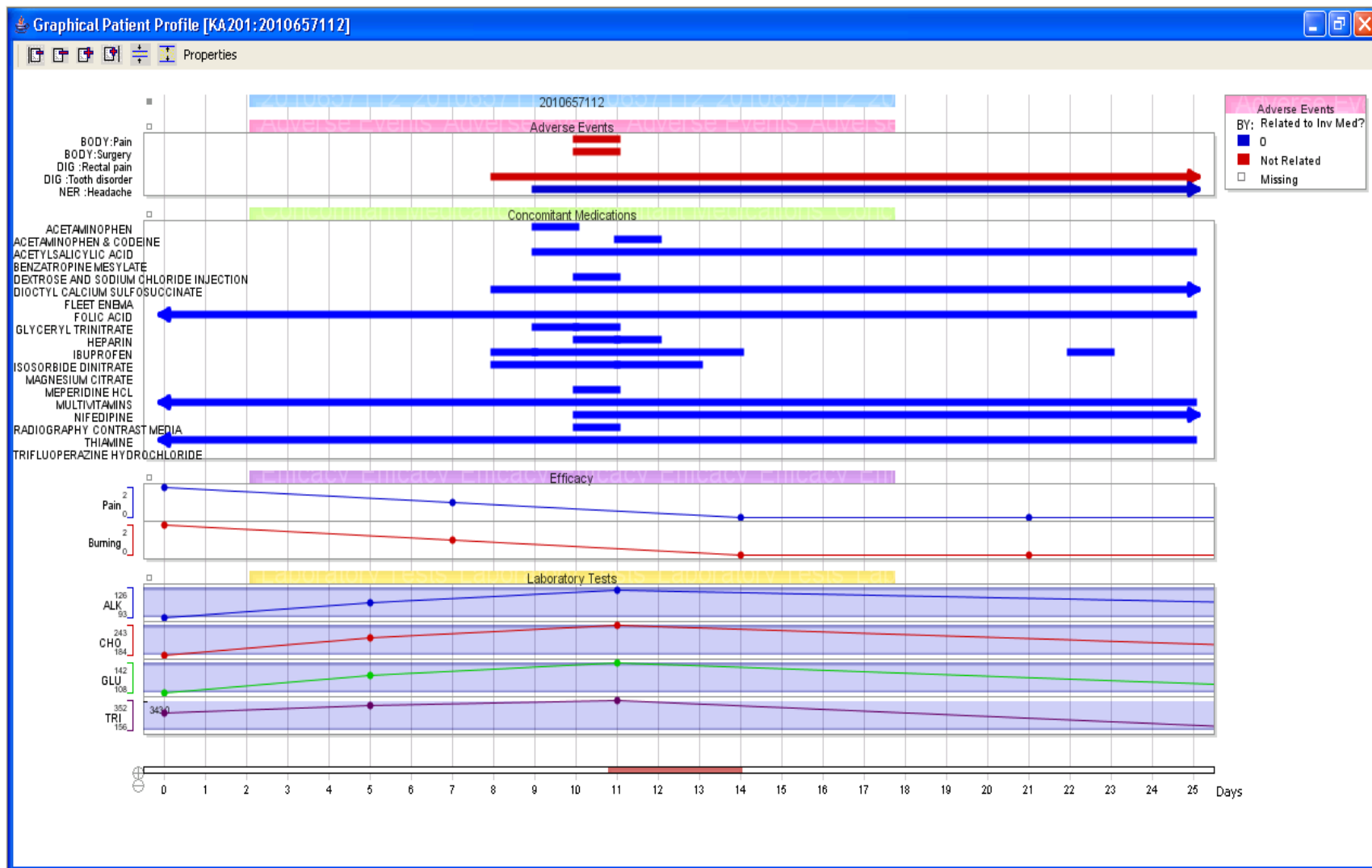
The screenshot displays the JReview 9.0.8 application window. The main menu includes File, Edit, View, Format, Browse, Window, Advanced, and Help. The toolbar contains various icons for file operations and data management. The interface is divided into several panes:

- Studies:** A tree view showing a hierarchy of studies. Under 'KA', there are sub-studies 'KA201', 'KA202', and 'KA203'.
- Patient Subsets:** A section with a dropdown menu set to 'All' and a list of patient subsets including 'All Patients' and 'Training'.
- Output Specifications:** A section with a dropdown menu set to 'All' and a list of output specifications including 'ALERTS', 'SAS Program Training', and 'Training'.
- Patient Selection Criteria [ichpux8:icstrain] (training.i-review.com:22301):** A dialog box for defining selection criteria. It contains four columns:
 - Panels:** A list of panels including '_Define Import SQL_', 'Adverse Events', 'Concomitant Medication', 'Demography', 'Dosage', 'Efficacy Evaluation', 'Final', and 'Lab Chemistry'.
 - Items:** A list of items including '_Define New Item_', '_Define New Range_', 'AE Coded', 'AE Text', 'AE Type (description)', 'Change in Inv Med', 'End Date', and 'End Time'.
 - Functions:** An empty column for defining functions.
 - Operator:** An empty column for defining operators.

Below the columns are buttons for 'Update Browsers', 'ADD expression', 'Display Stats', 'Display Values', and 'Item Compare'. There are also tabs for 'And/Or', 'Selection Criteria (Text)', and 'Selection Criteria (SQL)'. At the bottom of the dialog, there are checkboxes for 'Exclude patients meeting criteria?' and 'Append to criteria?', and a text field for 'Criteria description:'.

The bottom of the JReview window features an 'Execute' button, a radio button group for 'Order output specifications by:' (with 'Type' selected), and a section for 'Execute object:' with buttons for 'Review Output' and 'Scheduled Jobs'.

SDTM FDA Tools: JReview (2)



SDTM FDA Tools: WebSDM (1)



Variables in Domain

User: BATCHAPP Administrator [admin]

Variable Summary

[Preferences](#)
[Settings](#)
[Feedback](#)
[Exit](#)
[Help](#)

[Home](#)
[Select](#)
[Browse](#)
[Subset](#)
[Report](#)
[Load&Check](#)
[Run History](#)

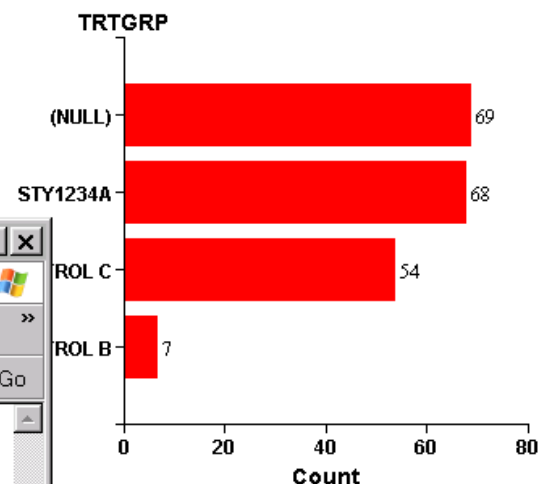
Variable	Description	N	Nulls	Mean	SD	Min	Max	Type	Codelist
<u>AGE</u>	Age in years	198	0	58.313	10.184	25	80	Number	
<u>COUNTRY</u>	Country in which a subject participated in the study	198	0					Character	
<u>DMREFDT</u>	Subject reference date	129	69					Date	
<u>DMREFTM</u>	Subject reference time	128							
<u>RACE</u>	Race of subject	196							
<u>SEX</u>	Sex of subject	198							
<u>SITEID</u>	Uniquely identifies a study site within a particular study	198							
<u>STUDYID</u>	Unique identifier for the study	198							
<u>SUBJID</u>	Subject identification for the study	198							
<u>TRTCD</u>	Treatment code	129							
<u>TRTGRP</u>	Treatment group	129							
<u>USUBJID</u>	Unique identifier for the subject within the application	198							

Subject List - Microsoft Internet Explorer

Address: <http://localhost:8080/BatchApp/subjectListDrilldown.jsp?i>

USUBJID	AGE	SEX	RACE	TRTCD	TRTGRP	SITEID
STY1234AXXX6607	70	M	BLACK	2	CONTROL B	66
STY1234AXXX6906	49	F	BLACK	2	CONTROL B	69
STY1234AXXX7215	56	M	WHITE	2	CONTROL B	72
STY1234AXXX7219	53	M	WHITE	2	CONTROL B	72
STY1234AXXX7312	68	M	WHITE	2	CONTROL B	73
STY1234AXXX7822	55	F	WHITE	2	CONTROL B	78
STY1234AXXX7826	48	M	WHITE	2	CONTROL B	78

[View All as Patient Profiles](#)



SDTM FDA Tools: WebSDM (2)

Web Submission Data Manager - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Home Search Favorites Media Print View Source

Address C:\Demo\Links AE2.htm Go Links

FDA AE Preferences Settings Feedback Exit Help

Home Select Browse Report Subject Lists Advanced Load&Check Run Queue

User: BATCHAPP Administrator [admin], Context: Pilot_1:Pilot_1

374 rows

STUDYID	USUBJID	AGE	SEX	RACE	TRTCD	TRTGRP	AETERM	AFACTSDY	AFACTEDY
STY1234AXXX	STY1234AXXX5603	58	M	WHITE	1	STY1234A	GASTROENTERITIS- PROBABLY VIRAL	50	52
STY1234AXXX	STY1234AXXX5603	58	M	WHITE	1	STY1234A	COMMON COLD SYMPTOMS	190	193
STY1234AXXX	STY1234AXXX5604	62	M	WHITE	3	CONTROL C	ADHESIVE CAPSULITIS OF RIGHT SHOULDER	-3	7
STY1234AXXX	STY1234AXXX5604	62	M	WHITE	3	CONTROL C	HYPERLIPIDEMIA	59	
STY1234AXXX	STY1234AXXX5604	62	M	WHITE	3	CONTROL C	HEMORRHAGE AT DISC MARGIN OF BOTH EYES	186	

STUDYID	AESTDT	AEENDT	AESEQ	AEDECOD	AEBODSYS	AEDUR	AEDURU	AESEV	AESER
STY1234AXXX	04-Dec-1997	06-Dec-1997	1	GASTROENTERITIS	DIGESTIVE SYSTEM	2	DAYS	SEVERE	Y
STY1234AXXX	23-Apr-1998	26-Apr-1998	2	UPPER RESPIRATORY INFECTION	RESPIRATORY SYSTEM	3	DAYS	MILD	N
STY1234AXXX	10-Oct-1997	20-Oct-1997	1	JOINT DISORDER	MUSCULO-SKELETAL SYSTEM	10	DAYS	MILD	N
STY1234AXXX	11-Dec-1997		2	HYPERLIPIDEMIA	METABOLIC & NUTRITIONAL DISORDERS			MILD	N
STY1234AXXX	17-Apr-1998		3	RETINAL HEMORRHAGE	SPECIAL SENSES			MODERATE	N

STUDYID	SAEDTH	SAELIFE	SAEDISAB	SAEHOSP	SAECAN	SAEOD	SAECONG	SAEOTH	AECTRT
STY1234AXXX	N	N	N	Y	N	N	N	N	DOSE NOT CHANGED
STY1234AXXX	N	N	N	N	N	N	N	N	DOSE NOT CHANGED
STY1234AXXX	N	N	N	N	N	N	N	N	DOSE NOT CHANGED
STY1234AXXX	N	N	N	N	N	N	N	N	DOSE NOT CHANGED
STY1234AXXX	N	N	N	N	N	N	N	N	DOSE NOT CHANGED

SDTM FDA Tools: WebSDM (3)

Web Submission Data Manager - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Home Search Favorites Media Print Mail News RSS Feeds Google Search Web

Address http://localhost:8080/BatchApp/ctShowCompositeTable.jsp?savedQueryID=107

Links NewWebCh Norton AntiVirus

FDA Display Report [Home](#) [Select](#) [Browse](#) [Report](#) [Subject Lists](#) [Advanced](#) [Load&Check](#) [Run Queue](#)

User: BATCHAPP Administrator [admin] [Results](#) [Manage Results](#) [Reports](#) [Manage Reports](#) [Create Report](#)

[Preferences](#) [Settings](#) [Feedback](#) [Exit](#) [Help](#)

Report Results [Avg cholesterol for age groups by visit] 4 rows

[Options](#) [Save Results](#) [Edit Definition](#) [Save Definition](#) [Graphs](#) [Download](#)

AGE	Gender																							
	Males												Females											
	Visit Group												Visit Group											
	1, 2, 3, 4						4, 5, 6, 7, 8						1, 2, 3, 4			4, 5, 6, 7, 8								
Tot. CHOL		LDL		HDL		Tot. CHOL		LDL		HDL		Tot. CHOL		LDL		HDL		Tot. CHOL		LDL		HDL		
	%C	%M	%C	%M	%C	%M	%C	%M	%C	%M	%C	%M	%C	%M	%C	%M	%C	%M	%C	%M	%C	%M	%C	%M
20 - 40	5	5.79	5	2.71	5	0.77	6	4.97	6	1.91	6	0.74	2	6.06	2	3.16	2	1.15						
40 - 60	88	4.89	88	2.5	88	1.05	90	4.82	90	2.39	88	1	75	5.48	75	2.89	74	1.22	83	4.92	83	2.46	83	1.21
60 - 80	99	4.94	99	2.61	99	1.05	113	4.73	113	2.48	113	1.02	58	5.31	58	2.78	58	1.33	62	5.27	62	2.57	60	1.27
80 -	1	5.07	1	2.51	1	1.71																		

Audit Information
 Data Source: SDM3SAMPJ
 Subject List: null
 Report: Avg cholesterol for age groups by visit
 User: BATCHAPP Administrator
 Date: 09/02/2003 18:28:53 EDT

Done Local intranet

CDISC SDTM versus CDISC ADaM

- SDTM is very prescriptive
- ADaM is more flexible
- SDTM structure, variables, and variable names are pre-specified
- ADaM can include sponsor-defined derived variables
- SDTM Findings structures will be vertical
- ADaM Findings structures will be either vertical or horizontal

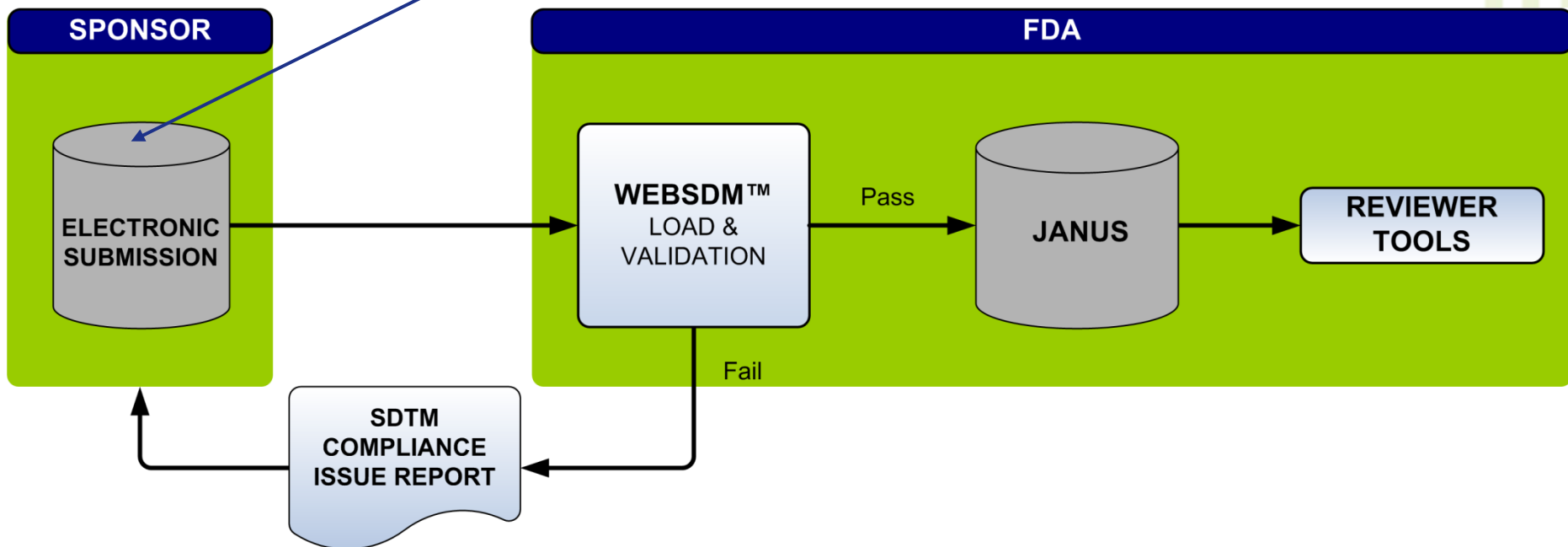
CDISC SDTM Conformance

- Follow **complete metadata structure**
- Follow **CDISC domain models**
- Include all **Required and Expected variables**
- Use CDISC-specified:
 - standard **domain names** and prefixes
 - standard **variable names**
 - **variable labels**
 - **data types** for all variables
 - **controlled terminology** and **format** guidelines
- Currently, adhere to the **SAS V5 XPT limitations**
- Ensure that each dataset includes a set of **keys**
- Ensure that each record in a dataset includes a **topic variable**
- Conform to all **business rules**

CDISC CRT Submission Process

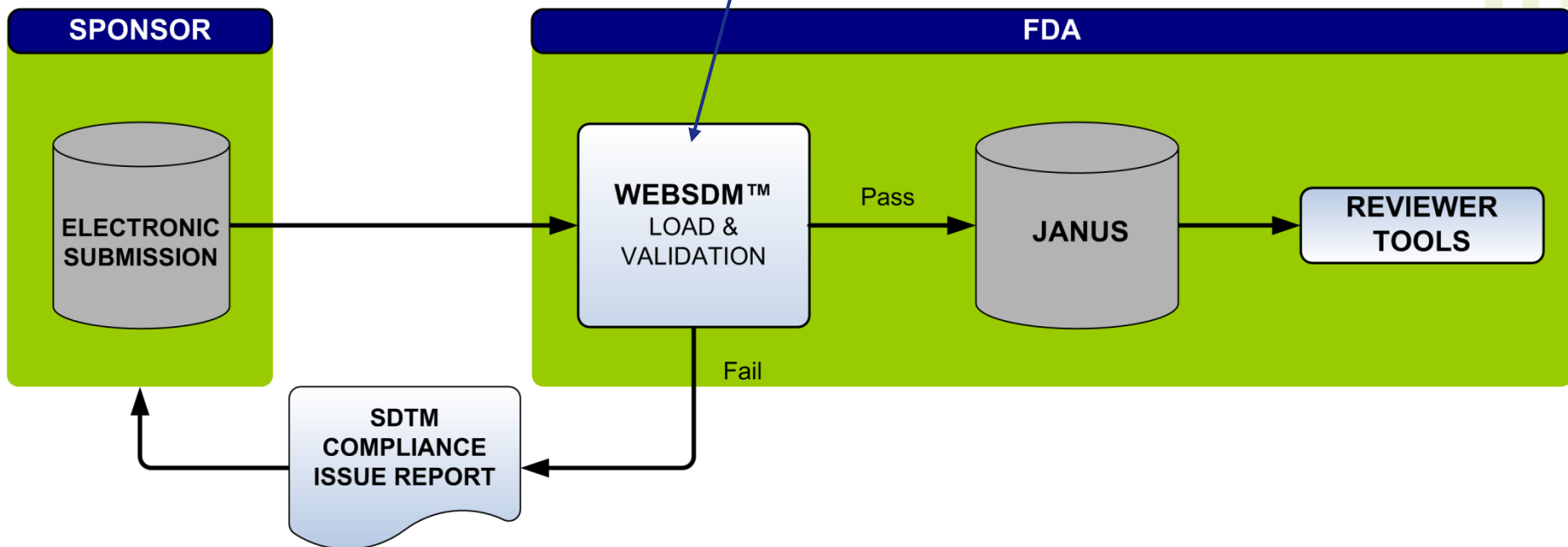
Data Tabulation Components:

- SDTM annotated CRFs
- SDTM datasets
- ADaM datasets
- Define.xml metadata



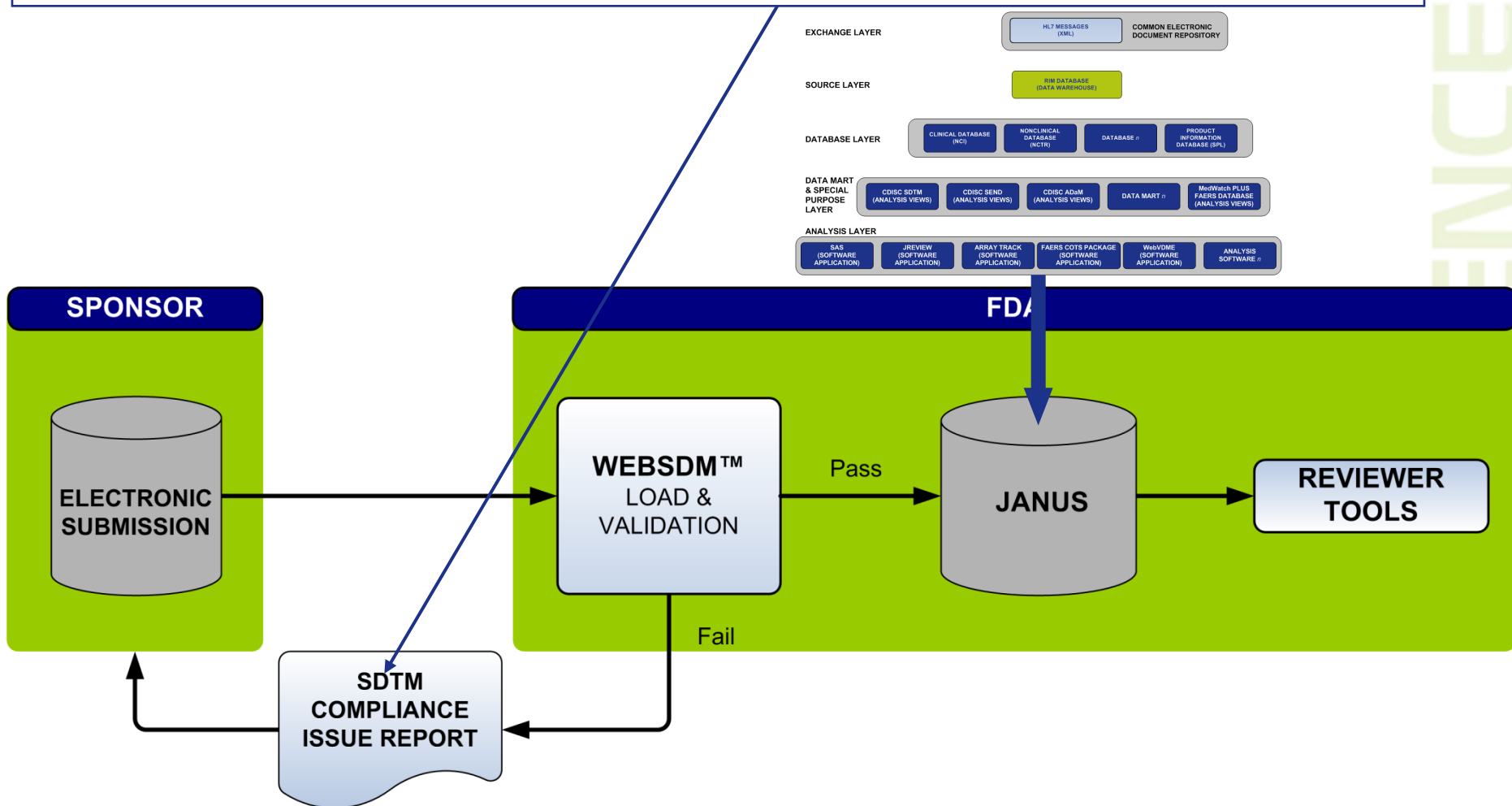
CDISC CRT Submission Process

WebSDM™ tool checks the CDISC SDTM data & metadata to ensure standard FDA tools can be used

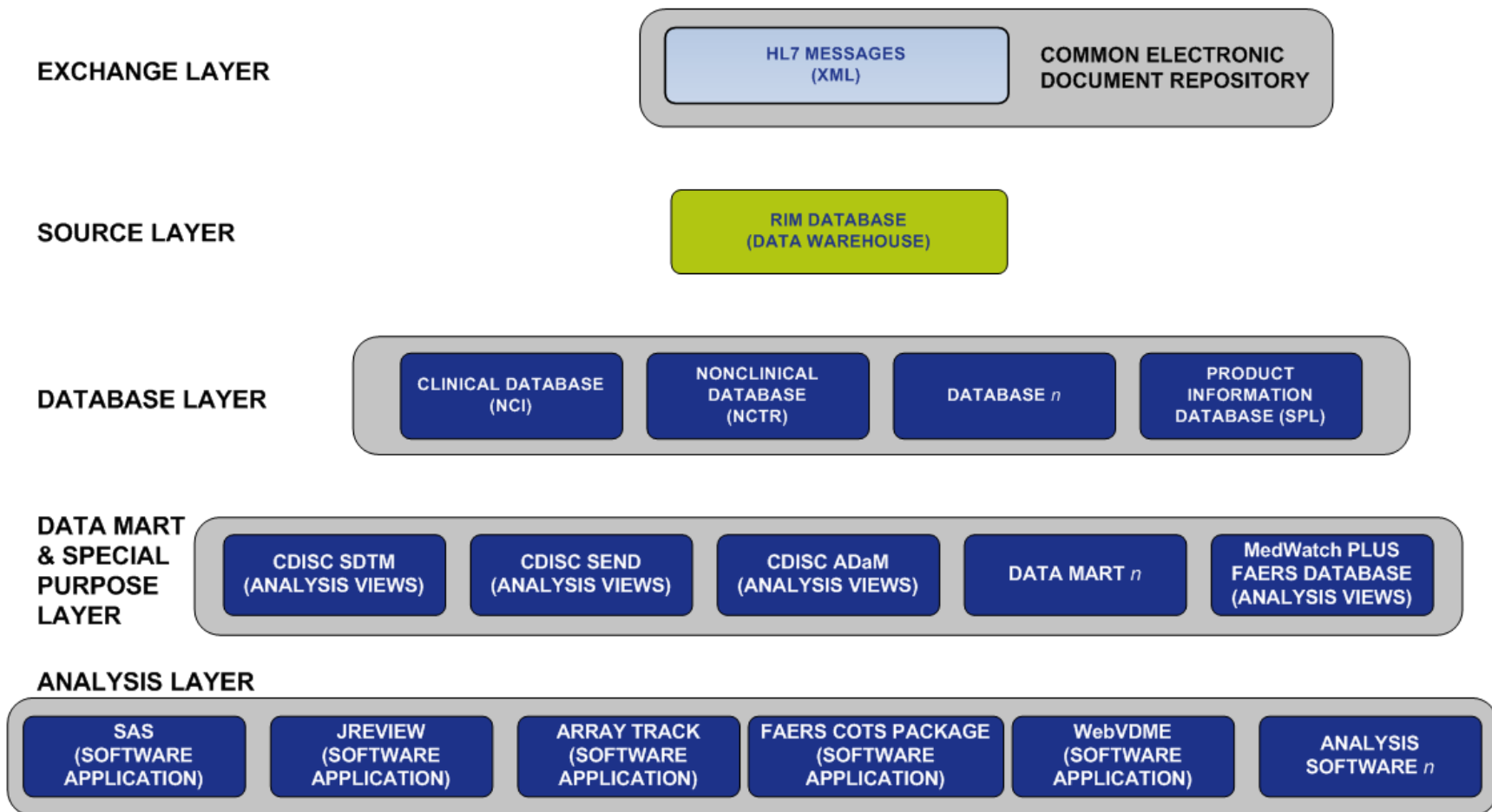


CDISC CRT Submission Process

CDISC SDTM compliance issues are reported to the sponsor



Janus layers



Source:

« CDISC Standards, Present & Future », Dave Iberson-Hurst, CDISC, VP Technical Strategy

WebSDM™ Load & Validation

WebSDM™ V3.0 Validation Checks:

- 154 Checks
- Severity definition: High – Medium – Low

<http://www.phaseforward.com>

SDTM Compliance Issues Report

- OBPS provides an SDTM issue list to the sponsor
- OBPS = Office of Business Process Support
- Loading issues can be caused by
 - Data & Metadata Inconsistency
 - Non conformity with:
 - » SDTM Model
 - » SDTM IG business rules
 - » Controlled Terminology

Topics

1

Current Situation

2

Applied CDISC Compliance

3

Summary

CDISC Compliance Checks

We have created an expanded & enhanced list of checks

- 154 WebSDM TM checks
- Total check package:

	SDTMIG V3.1.1	SDTMIG V3.1.2	ADaMIG V1.0
Data checks	141	219	45
Metadata checks	68	117	51
Mapping checks	56	57	12
Project consistency checks	20	20	20

CDISC compliance checks list is growing continuously

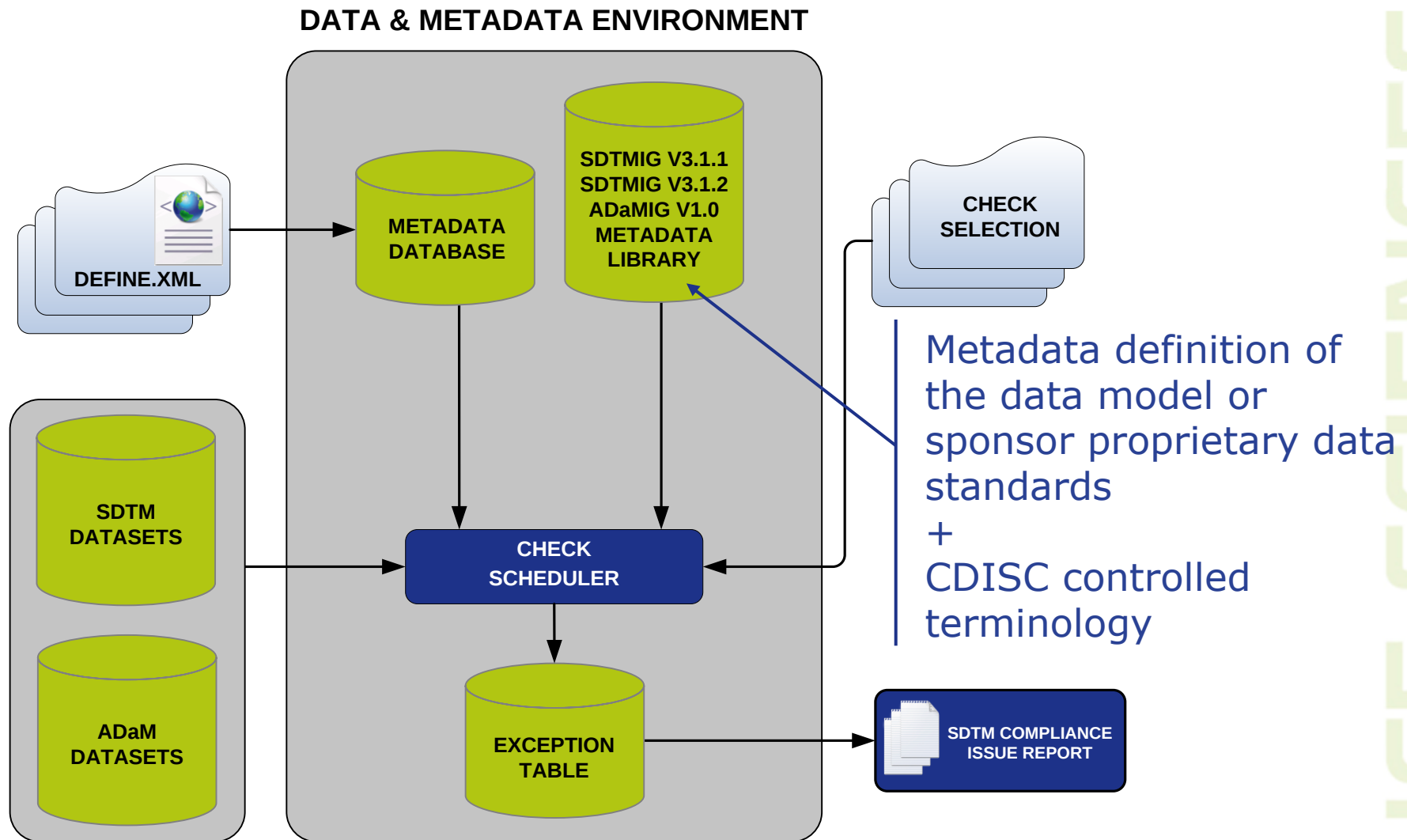
Categorization

CDISC Compliance Checks Categories

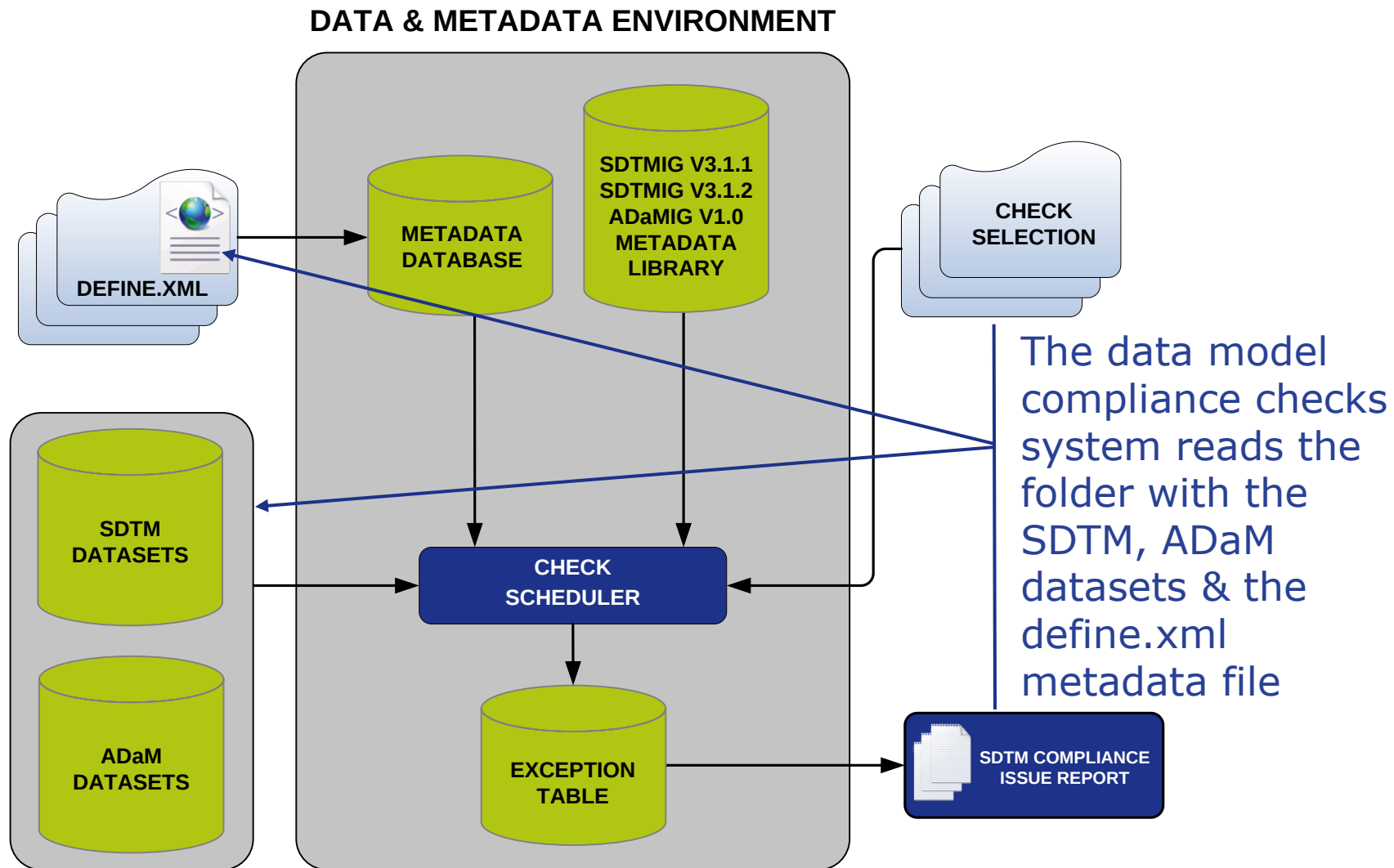
- Data
- Class
- Mapping
- Data model version
- Metadata
- Domain
- Timing variables
- Check version

				Categorization												
CheckID	Sub CheckID	Check Description	Error Message	Data Checks	Metadata Checks	Programming checks	Mapping Checks	All Class Checks	Events Checks	Intervention s Checks	Finding Checks	Trial Design Checks	Special Purpose Checks	Findings About Checks	Project Consistency Checks	SDTM_Versi on
0001		Check if all the date variables (DTC, --STDTC, ENDTC, RFSTDTC, RFENDTC) have a ISO 8601 standard format.	DATE VARIABLE does not have a ISO 8601 format.	X		X		X	X	X	X	X	X			SDTMIG V3.1.1
0002		Check per LBTESTCD if the LBSTRESU is consistent within the trial limited to records where (LBORRES <> NULL AND LBSTRESU <>)	The STANDARD UNIT is not consistent per LAB TEST or EXAMINATION.	X							X					SDTMIG V3.1.2
0003	1	Check if AESER = "Y" that (AESCAN= "Y" or AESCONG= "Y" or AESDISAB= "Y" or AESDTH= "Y" or AESHOSP= "Y" or AESLIFE= "Y"	The AE is serious, but none of the serious criteria is answered "Y".	X					X							SDTMIG V3.1.3
0003	2	Check if (AESCAN= "Y" or AESCONG= "Y" or AESDISAB= "Y" or AESDTH= "Y" or AESHOSP= "Y" or AESLIFE= "Y" or AESMIE= "Y"	The AE is not serious, but one of the serious criteria is answered "Y".	X					X							SDTMIG V3.1.4
0004	1	Check if -- STRESC <> NULL that -- STAT = NULL.	A STANDARD RESULT is completed, but the STATUS is completed.	X		X					X					SDTMIG V3.1.5

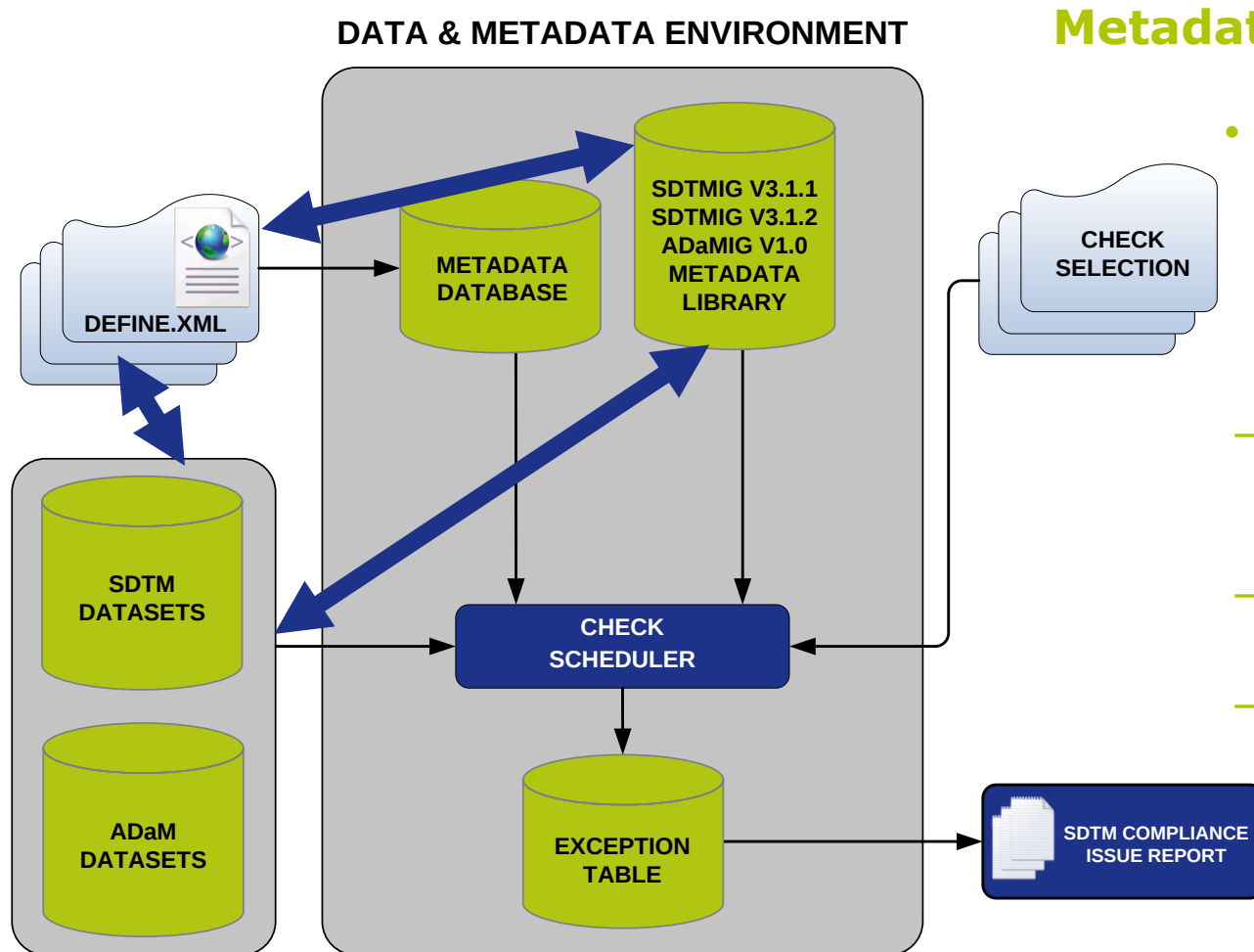
Application Flowchart



Application Flowchart



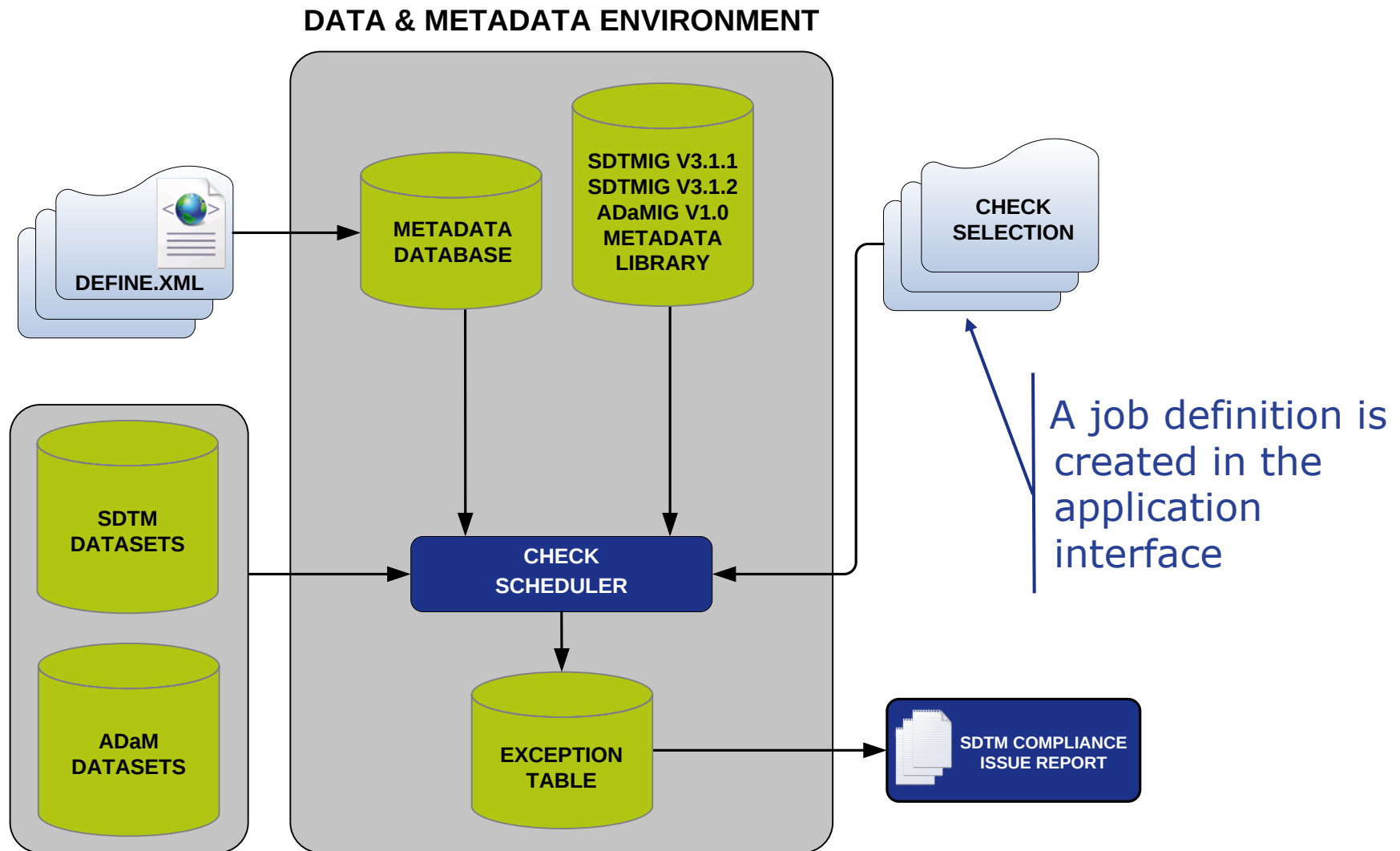
Application Flowchart



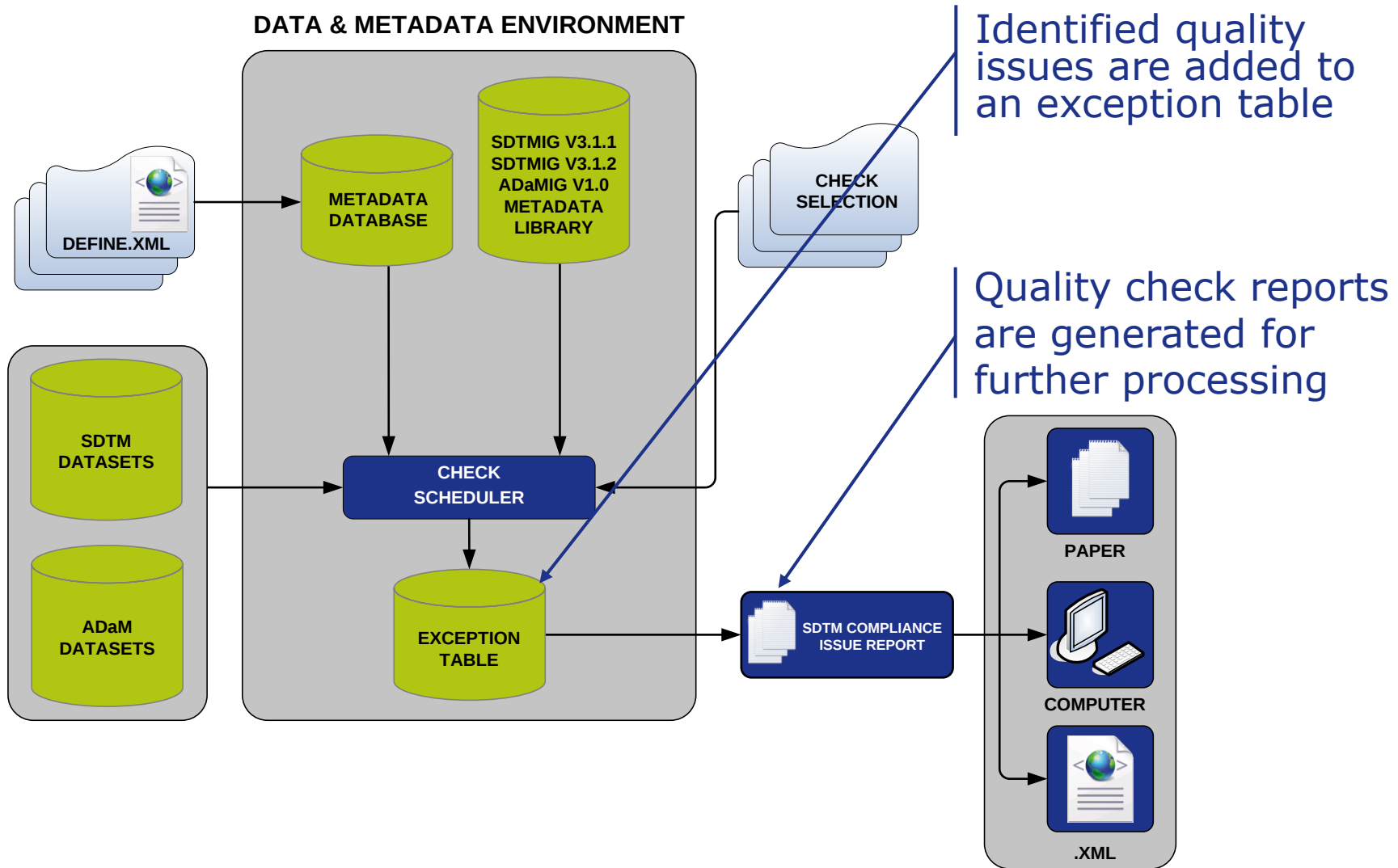
Metadata Cross Checks

- Data Model Compliance Checks cross-check for consistency between:
 - CDISC SDTM or ADaM datasets definition
 - Metadata reported in the Define.xml
 - CDISC SDTM, ADaM or sponsor proprietary data standards in the metadata library

Application Flowchart



Application Flowchart



Application Interface

 Entry Screen



DATA MODEL COMPLIANCE CHECKER

Create Job

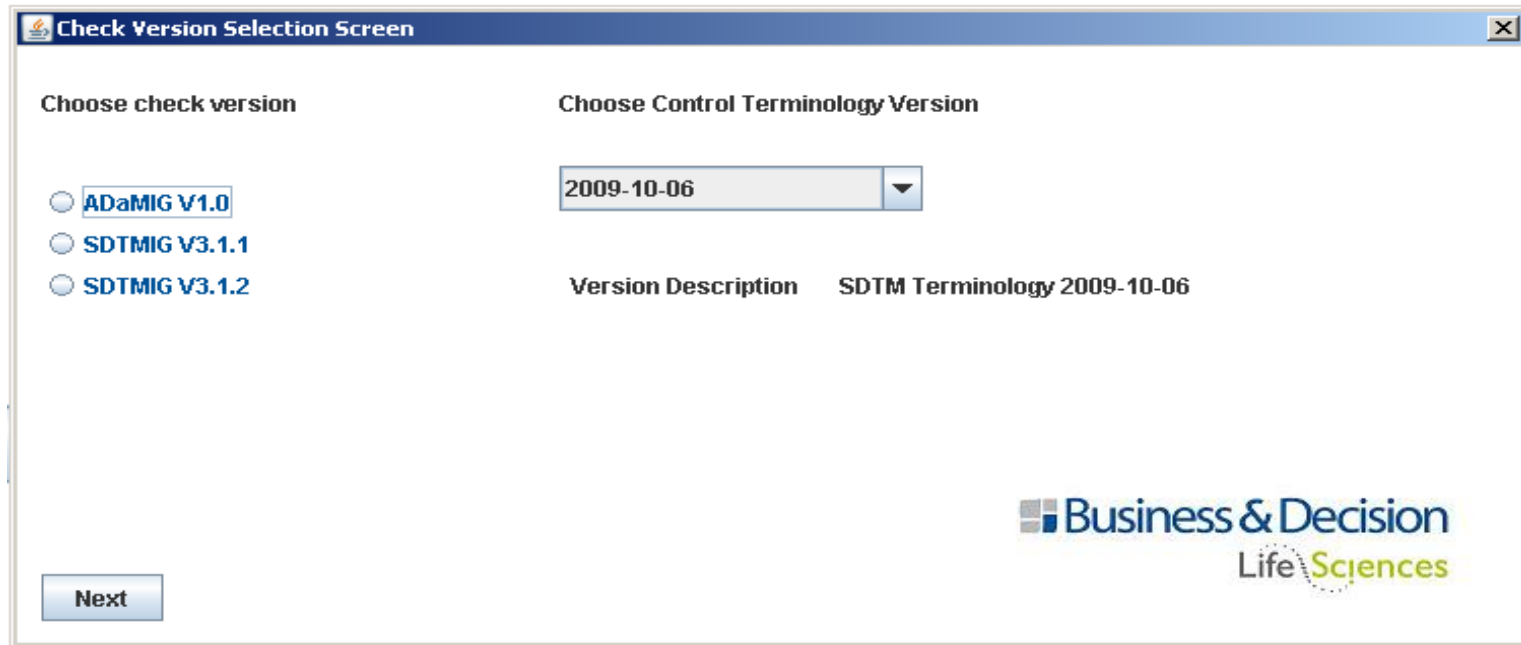
Run Job

Parameter Database

Application Interface

- Data Model Selection Screen
 - Select Data Model
 - Possibility to add proprietary data models
 - Select Controlled Terminology
 - CDISC Controlled Terminology
 - Possibility to include sponsor-defined controlled terminology

Application Interface



Check Version Selection Screen

Choose check version

☒ ADaMIG V1.0

☐ SDTMIG V3.1.1

☐ SDTMIG V3.1.2

Choose Control Terminology Version

2009-10-06

Version Description SDTM Terminology 2009-10-06

Next

 Business & Decision
Life Sciences

Application Interface

- Job Creation Screen
 - Check Selection :
 - Select Project and Study
 - Select Checks based on
 - Class – Events, Interventions, Findings, Trial Design, Special Purpose
 - Type – Data, Metadata, Programming
 - Individual
 - Select from dynamically created list of domains
 - Creates Job ID
 - Check Description :
 - Detailed description of all checks
 - Possibility of adding/modifying check descriptions

Application Interface

- Check Selection :

Check Selection Form

Check Selection Screen Check Description Screen

Choose Project: 1084 Enter Job Description: NEXT

Choose StudyID: TMC278-TIDP6-C106

☐ Select All
☒ Data Checks
☐ Metadata Checks
☐ Mapping Checks
☐ Programming Checks

☐ All Class Checks
☐ Events Checks
☐ Interventions Checks
☒ Findings Checks
☐ Trial Design Checks
☐ Special Purpose Checks

☐ Project Consistency Checks

CheckId	Select
Check1001	☒
Check1002	☒
Check1003	☒
Check1004	☒
Check1005	☒
Check1006	☒
Check1007	☒
Check1008	☒
Check1009	☒
Check1010	☒
Check1011	☒
Check1012	☒
Check1013	☒
Check1014	☒
Check1015	☒
Check1016	☒
Check1017	☒
Check1018	☒
Check1019	☒
Check1020	☒
Check1021	☒
Check1022	☒
Check1023	☒
Check1024	☒
Check1025	☒
Check1026	☒
Check1027	☒
Check1028	☒
Check1029	☒
Check1030	☒
Check1050	☒
Check1051	☒
Check1052	☒
Check1053	☒
Check1054	☒
Check1055	☒
Check1056	☒

Domains	Select
AE	☒
CM	☒
CO	☒
DM	☒
DS	☒
DV	☒
EG	☒
EX	☒
FA	☒
IE	☒
LB	☒
MH	☒
ML	☒
PC	☒
PE	☒
PP	☒
QS	☒
RD	☒
RELREC	☒
RF	☒
SC	☒

Application Interface

- Run Job Screen
 - Job List :
 - » Lists Job ID, Job description, Job owner, Job creation date
 - » Select the job to run
 - Job Description :
 - » Lists project and studyid for the selected job
 - » Lists checks to run for the selected job
 - » Lists domains on which selected checks run

Application Interface

- Job List

Job Selection Screen

Job List Screen Job Description Screen

Job_ID	Rep_ID	Study_ID	Job_Owner	Job_Description	Job_Creation_Date	VERSION
1	865	1160-0025	rbanga	25 Data & Metadata	2009-06-22T09:35	2
2	865	1160-0024	rbanga	24 Data & Metadata without	2009-06-22T09:50	2
3	865	1160-0025	rbanga	25 Data&Metadata without 15	2009-06-22T09:51	2
4	865	1160-0025	rbanga	TEST	2009-06-22T11:10	2
5	865	1160-0024	ndedonder	Final run	2009-06-22T12:43	2
6	865	1160-0028	scid	Final run	2009-06-22T16:24	2
7	865	1160-0028	scid	Final Run2	2009-06-23T09:43	2
9	865	1160-0024	ndedonder	24 - Final run	2009-06-23T13:31	2
10	865	1160-0025	ndedonder	25 - Final run	2009-06-23T14:14	2
11	865	1160-0048	ndedonder	48 - Final run	2009-06-23T14:15	2
12	865	1160-0026	athielemans	testho	2009-06-23T16:13	2
13	865	1160-0026	athielemans	testho1	2009-06-23T16:27	2
14	865	1160-0042	dbaele	data/metadata 42	2009-06-23T16:33	2
15	865	1160-0026	mjuneja	DATA CHECKS	2009-06-23T16:43	2
16	865	1160-0019	ndedonder	19 - Final run	2009-06-25T09:34	2
17	865	1160-0001	hdevroye	Mapping checks	2009-06-29T08:07	2
18	865	1160-0001	hdevroye	Mapping checks	2009-06-29T08:12	2
19	865	1160-0026	athielemans	checks_apbtce	2009-06-29T10:39	2
20	865	1160-0026	athielemans	checks_oevsc	2009-06-29T10:46	2
21	865	1160-0020	scid	Data and Metadata Checks	2009-06-29T11:22	2
22	865	1160-0050	ndedonder	50 - data & metadata	2009-06-29T16:21	2
23	865	1160-0026	rbanga	RELY - AP,BT,CE,OE,EV,SC,	2009-06-30T17:59	2
24	865	1160-0075	hdevroye	Final run	2009-07-01T11:42	2
25	865	1160-0006	dbaele	mapping checks 1160-0006	2009-07-02T14:07	2
26	865	1160-0026	athielemans	rely_c_to_m	2009-07-02T15:46	2
27	865	1160-0026	athielemans	rely_ae_dm_test	2009-07-02T15:57	2
28	865	1160-0026	athielemans	rely_events_test	2009-07-02T16:03	2
29	976	1218-0032	ndedonder	Mapping checks	2009-07-03T08:59	2
30	976	1218-0032	ndedonder	Mapping checks	2009-07-03T09:32	2
31	865	1160-0026	athielemans	rely_selectdomain	2009-07-03T14:07	2
32	865	1160-0026	athielemans	rely_selectdomainallchecks	2009-07-03T14:11	2
33	865	1160-0026	athielemans	Rely_6domains_data	2009-07-06T15:13	2
34	865	1160-0026	athielemans	Rely_5domains	2009-07-06T15:53	2
35	865	1160-0020	ndedonder	20 - Final checks	2009-07-06T16:32	2

Run Delete Job ☐ Refresh Metadata from Define.xml

Application Interface

- Job Description



Job_ID	Rep_ID	Study_ID	List_Of_Checks	List_Of_Domains
6	865	1160-0020	Check0001	ALL
8	865	1160-0028	Check0002	ALL
8	865	1160-0020	Check0003	ALL
8	865	1160-0028	Check0004	ALL
8	865	1160-0020	Check0005	ALL
6	865	1160-0028	Check0006	ALL
8	865	1160-0020	Check0007	ALL
6	865	1160-0028	Check0008	ALL
8	865	1160-0020	Check0009	ALL
6	865	1160-0028	Check0010	ALL
8	865	1160-0020	Check0011	ALL
6	865	1160-0028	Check0012	ALL
8	865	1160-0020	Check0013	ALL
6	865	1160-0028	Check0014	ALL
8	865	1160-0020	Check0015	ALL
6	865	1160-0028	Check0016	ALL
8	865	1160-0020	Check0017	ALL
6	865	1160-0028	Check0018	ALL
8	865	1160-0020	Check0019	ALL
6	865	1160-0028	Check0020	ALL
8	865	1160-0020	Check0021	ALL
6	865	1160-0028	Check0022	ALL
8	865	1160-0020	Check0023	ALL
6	865	1160-0028	Check0024	ALL
8	865	1160-0020	Check0025	ALL
6	865	1160-0028	Check0026	ALL
8	865	1160-0020	Check0100	ALL
6	865	1160-0028	Check0101	ALL
8	865	1160-0020	Check0102	ALL
6	865	1160-0028	Check0103	ALL
8	865	1160-0020	Check0104	ALL
6	865	1160-0028	Check0105	ALL

Reporting Tool (1)

- 3 reports are created:
 - Exception log**
 - Exception summary
 - Exception report
- > 50 exceptions per check per domain: only 3 exceptions are reported

LIST_OF_CHECKS	ERROR_LEVEL	COMPLETION_TIME	ELAPSED_TIME
Check1001	The Check Completed Successfully	2010-02-12T18-57-58	.
Check1002	The Check Completed Successfully	2010-02-12T18-57-58	0:00:00
Check1003	The Check Completed Successfully	2010-02-12T18-57-59	0:00:01
Check1004	The Check Completed Successfully	2010-02-12T18-57-59	0:00:00
Check1005	The Check Completed Successfully	2010-02-12T18-58-00	0:00:01
Check1006	The Check Completed Successfully	2010-02-12T18-58-00	0:00:00
Check1007	The Check Completed Successfully	2010-02-12T18-58-01	0:00:01
Check1008	The Check Completed Successfully	2010-02-12T18-58-02	0:00:01
Check1009	The Check Completed Successfully	2010-02-12T18-58-03	0:00:01
Check1010	The Check Completed Successfully	2010-02-12T18-58-19	0:00:16
Check1011	The Check Completed Successfully	2010-02-12T18-58-20	0:00:01
Check1012	The Check Completed Successfully	2010-02-12T18-58-37	0:00:17
Check1013	The Check Completed Successfully	2010-02-12T18-58-37	0:00:00
Check1014	The Check Completed Successfully	2010-02-12T18-58-40	0:00:03
Check1015	The Check Completed Successfully	2010-02-12T18-58-41	0:00:01
Check1016	The Check Completed Successfully	2010-02-12T18-58-41	0:00:00
Check1017	The Check Completed Successfully	2010-02-12T18-58-43	0:00:02
Check1018	The Check Completed Successfully	2010-02-12T18-58-43	0:00:00
Check1019	The Check Completed Successfully	2010-02-12T18-58-44	0:00:01
Check1020	The Check Completed Successfully	2010-02-12T18-58-44	0:00:00
Check1021	The Check Completed Successfully	2010-02-12T18-58-44	0:00:00
Check1022	The Check Completed Successfully	2010-02-12T18-58-45	0:00:01
Check1023	The Check Completed Successfully	2010-02-12T18-58-45	0:00:00

Reporting Tool (2)

- 3 reports are created:
 - Exception log
 - Exception summary**
 - Exception report
- > 50 exceptions per check per domain: only 3 exceptions are reported

LIST OF CHECKS	DOMAIN	VARIABLE1	EXCEPTIONS COUNT	CHECK TYPE
Check0009	LB	LBORRES	73	DATA
Check0010	LB	LBORRESU	84	METADATA
Check0010	VS	VSORRESU	56	METADATA
Check0010	VS	VSSTRESU	56	METADATA
Check0015	CO	IDVAR	73	DATA
Check0100	IE	DOMAIN	1	DATA
Check0268	CM	COLUMN	1	METADATA
Check0271	VS	COMPALGO	5	METADATA

Reporting Tool (3)

- 3 reports are created:
 - Exception log
 - Exception summary
 - Exception report**
- > 50 exceptions per check per domain: only 3 exceptions are reported

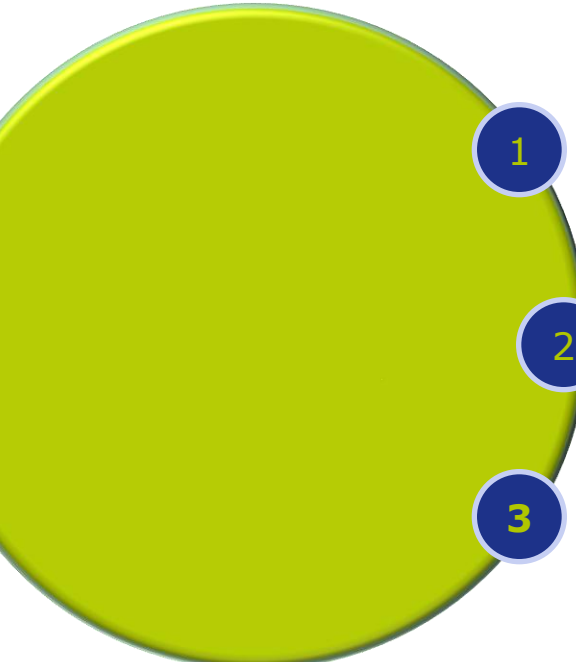
Reported Exception

Record Identifiers

Exception Attributes

CHECKID	ERRORMSG	STUDYID	DOMAIN	USUBJID	KEY1CD	KEY1	VAR1CD	VAR1	VAR2CD	VAR2
9	An ORIGINAL RESULT is completed but the STANDARD RESULT (CHARACTERISTIC) is missing.	1234-5678	LB	1234-5678-00002	LBSEQ	29	LBORRES	32,4	LBSTRESC	
9	An ORIGINAL RESULT is completed but the STANDARD RESULT (CHARACTERISTIC) is missing.	1234-5678	LB	1234-5678-00002	LBSEQ	13	LBORRES	19	LBSTRESC	
9	An ORIGINAL RESULT is completed but the STANDARD RESULT (CHARACTERISTIC) is missing.	1234-5678	LB	1234-5678-00001	LBSEQ	52	LBORRES	1,1	LBSTRESC	
9	TOO MANY FAILURES (73)									
10	The value cannot be found in the codelist attached to the variable.	1234-5678	LB	1234-5678-00016	LBSEQ	55	LBORRESU	10*6/uL		
10	The value cannot be found in the codelist attached to the variable.	1234-5678	LB	1234-5678-00027	LBSEQ	54	LBORRESU	10*6/uL		
10	The value cannot be found in the codelist attached to the variable.	1234-5678	LB	1234-5678-00008	LBSEQ	55	LBORRESU	10*6/uL		
10	TOO MANY FAILURES (84)									
10	The value cannot be found in the codelist attached to the variable.	1234-5678	VS	1234-5678-00024	VSSEQ	16	VSORRESU	kg		
10	The value cannot be found in the codelist attached to the variable.	1234-5678	VS	1234-5678-00020	VSSEQ	16	VSORRESU	kg		
10	The value cannot be found in the codelist attached to the variable.	1234-5678	VS	1234-5678-00012	VSSEQ	16	VSORRESU	kg		
10	TOO MANY FAILURES (56)									

Topics

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- 1 Current Situation
 - 2 Applied CDISC Compliance
 - 3 **Summary**

Summary

- CDISC compliance will help us adhere to the data standards
- CDISC Compliance Checks will facilitate the use of FDA tools
- Running these checks do not necessarily solve all findings but sponsor is prepared for FDA feedback
 - Consider documenting confirmed issues in FDA Reviewers' Guide
- FDA will not reject your submission!



Thank you for your attention

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