Business & Decision Life Sciences

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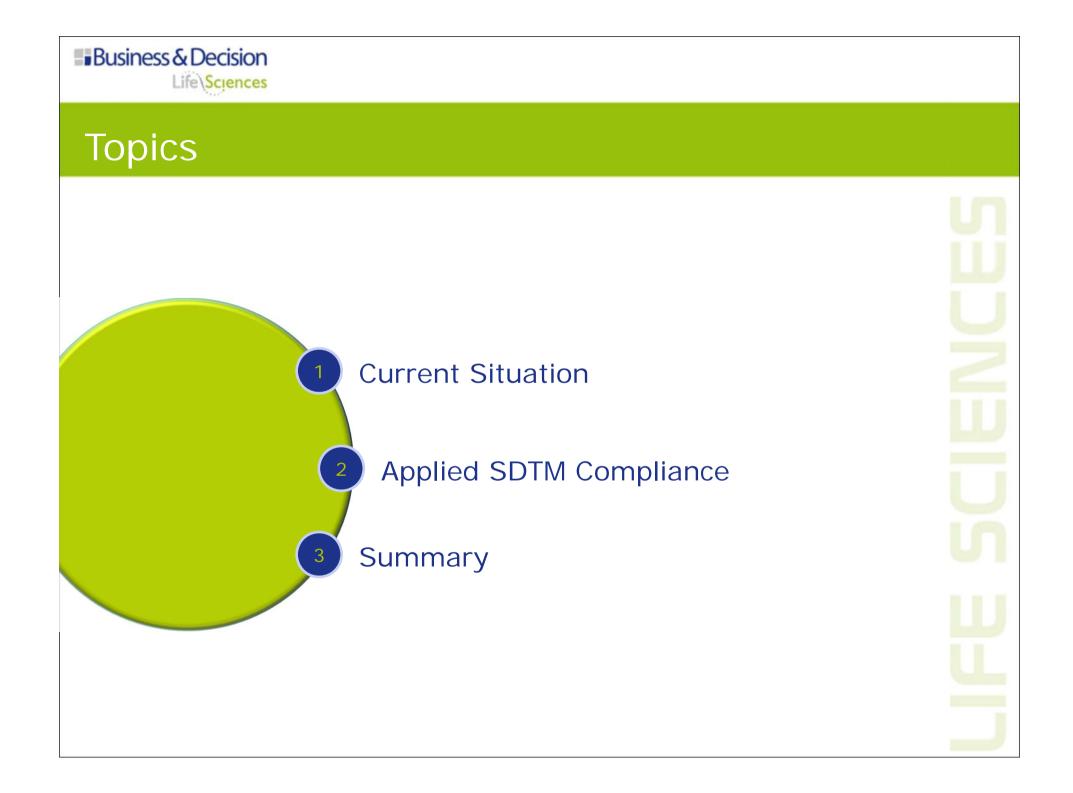
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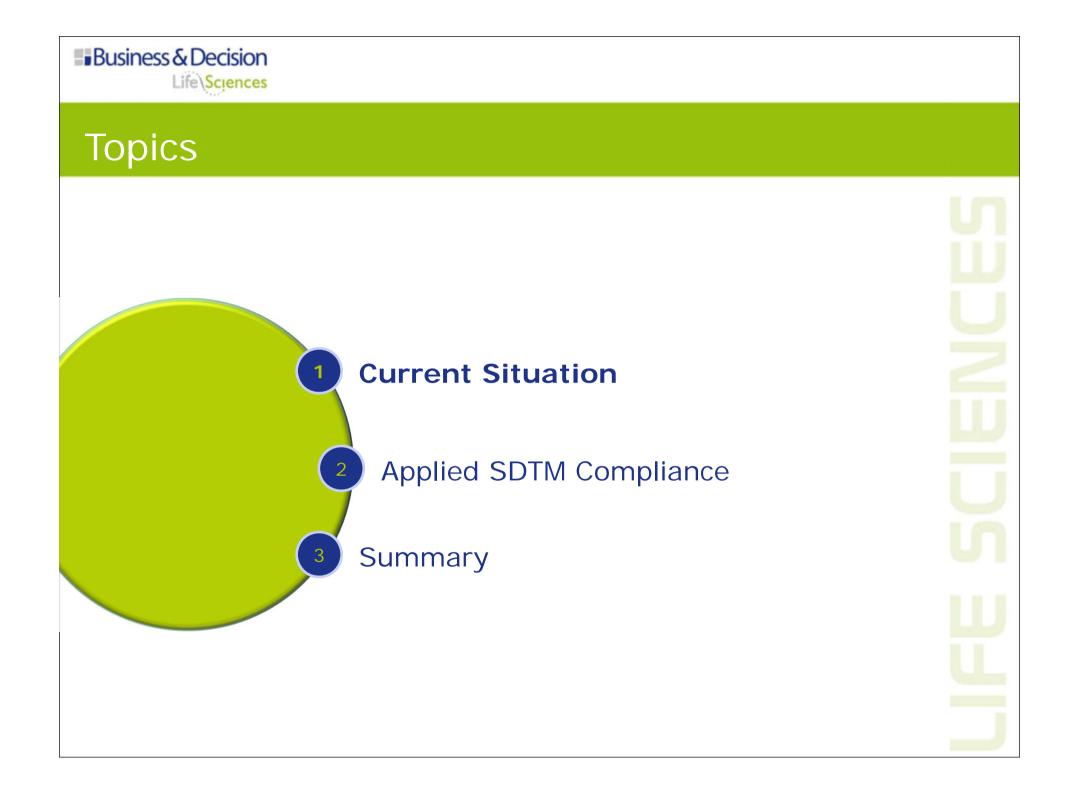
## **SDTM Validation**

#### How can we do it right ?



DRIVE YOUR PERFORMANCE







#### Submissions of NDAs to the FDA

- It is requested to submit clinical trial data (SDTM) & metadata (Define.xml) according to the CDISC standards
- Data standards allow the FDA to use standard tools
- CDISC SDTM = standard structure for study data tabulations

#### SDTM FDA Tools: Patient Profile Viewer

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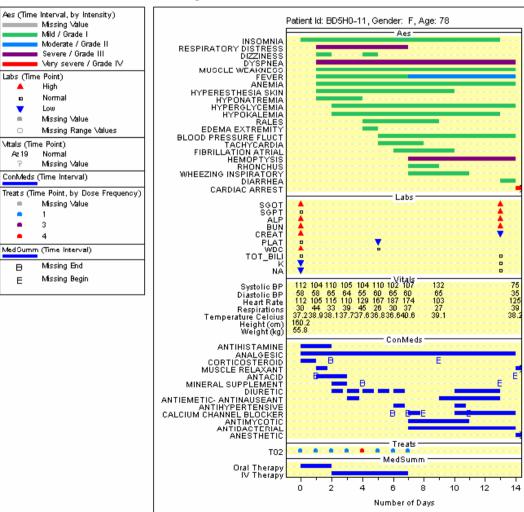
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Subject BD5H0-11

# Business & Decision

#### SDTM FDA Tools: Web SDM (1)

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# Business & Decision

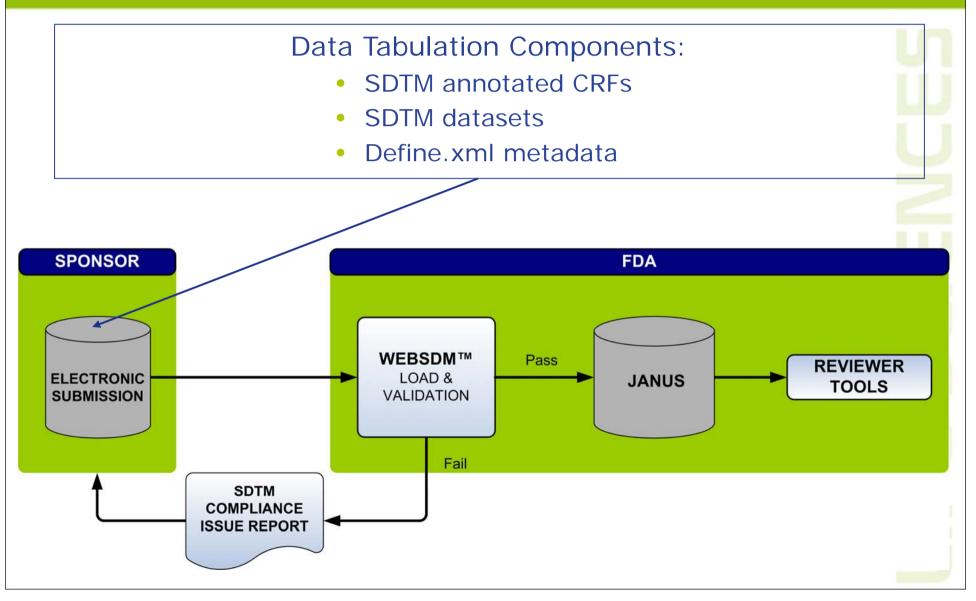
#### SDTM FDA Tools: Web SDM (2)

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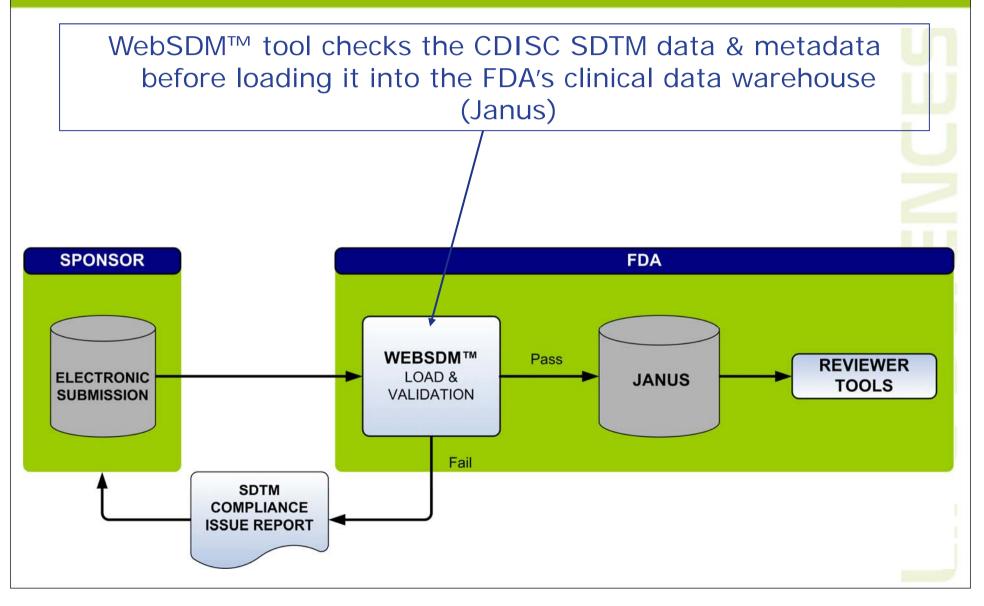
#### **CDISC SDTM Conformance**

- 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 SDTM Submission Process

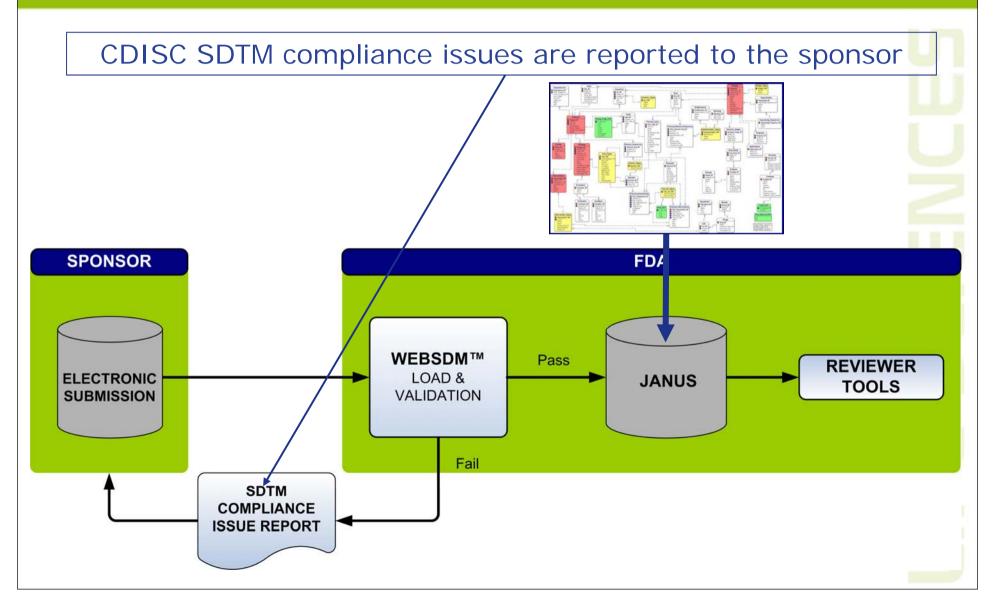


#### CDISC CRT Submission Process



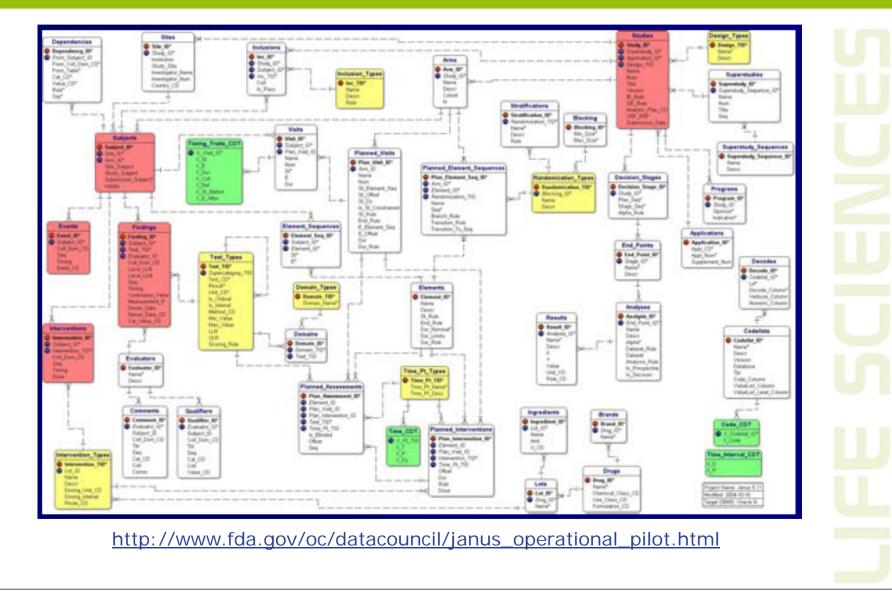


#### CDISC CRT Submission Process





#### Janus





#### WebSDM<sup>™</sup> Load & Validation

WebSDM<sup>™</sup> V2.6 Validation Checks:

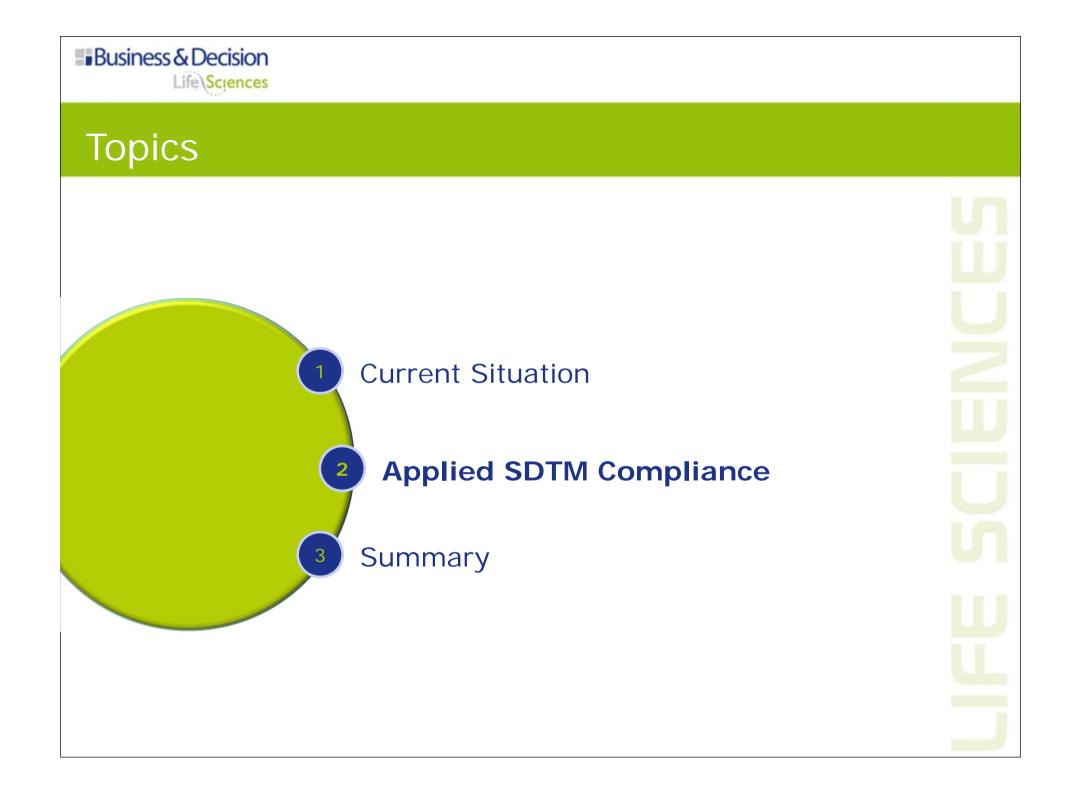
- 108 Checks
- Severity definition: High Medium Low

http://phaseforward.com/resource/whitepapers/Validation%20Checks%202.6/WebSD M%20V2.6%20Validation%20Checks%20FINAL.pdf



#### 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





#### SDTM Compliance Checks

We have created an expanded & enhanced list of checks

- 108 WebSDM <sup>™</sup> checks
- Total check package:

	SDTM 3.1.1	SDTM 3.1.2
Data checks	135	214
Metadata checks	68	85
Mapping checks	55	55

SDTM compliance checks list is still growing

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#### Categorization

#### **SDTM** Compliance Checks Categories

– Data

- Class
- Metadata Domain
- Mapping
  Controlled Terminology
- Timing variables
- SDTM IG version - Check version

							CATEGOR	ZING			SDTM	
CHECKID	SUB CHECKID	CHECK DESCRIPTION	ERROR MESSAGE	DATA	METADATA	MAPPING SHEET	CLASS	DOMAIH	CONTROLLED TERMINOLOGY	TIMING VARIABLES	IMPLEMENTATION GUIDE VERSION	CHECK
0001		Check it off the date variables (DTC,STDTC,ENDTC, RFSTDC, RFENDTC) have a SO 8601 standard format.	DATE VARIABLE does not have a ISO 8501 format.	x			ALL	ALL	N	¥	3.1.1	0.1
0002		Check ker LBTESTCD if the LBSTRESU is consistent within the trial.	The STANDARD UNIT is not consistent per LAB TEST or EXAMINATION.	x			FINDINGS	LB	N	N	3.1.1	0.1
0003	ì	Check it AESER ='Y' that IAESCAN='Y' or AESCONG='Y' or AESDISAB='Y' or AESDISAB='Y' or AESDITH='Y' or AESH0SP='Y' or AESJFE='Y' or AESME='Y' or AESOD='Y'] (Check only applies if serious oriteria are completed).	answered 'Y'.	x			EVENTS	ĄĘ	N	N	3.1.1	0.1
0003	2	Check if [AESCAN="Y" or AESCONG="Y" or AESDISAB="Y" or AESDIH="Y" or AESH0SP="Y" or AESJFE="Y" or AESME="Y" or AESOD="Y"] that AESER ="Y".	The AE is not serious, but one of the serious critera is answered 'Y'.								3.1.1	6 <b>t.0</b>
	-	Check itSTRESC ⇔ NULL	A STANDARD RESULT is									

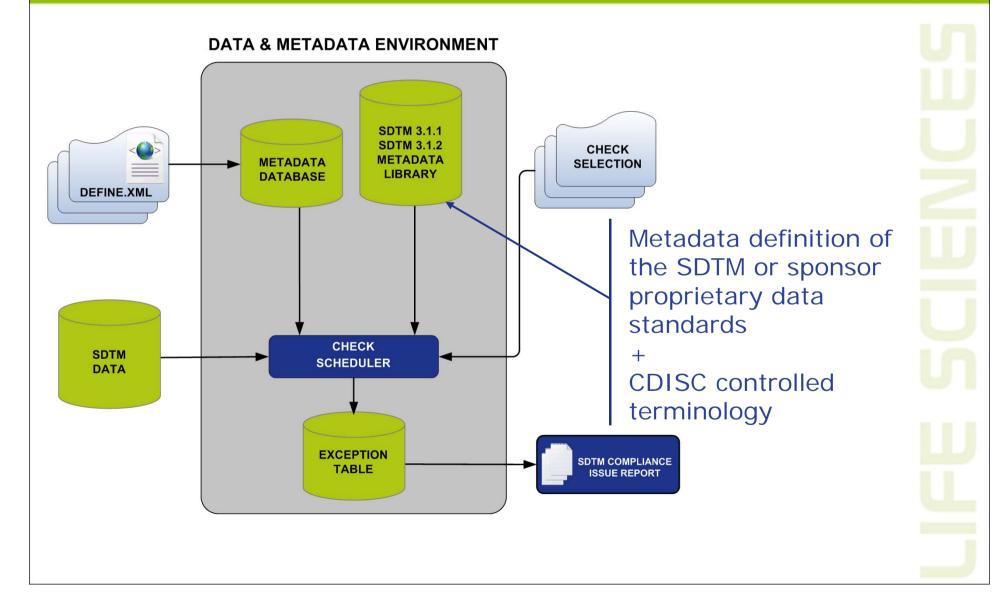
#### How is the categorization used?

A subset of checks can be created :

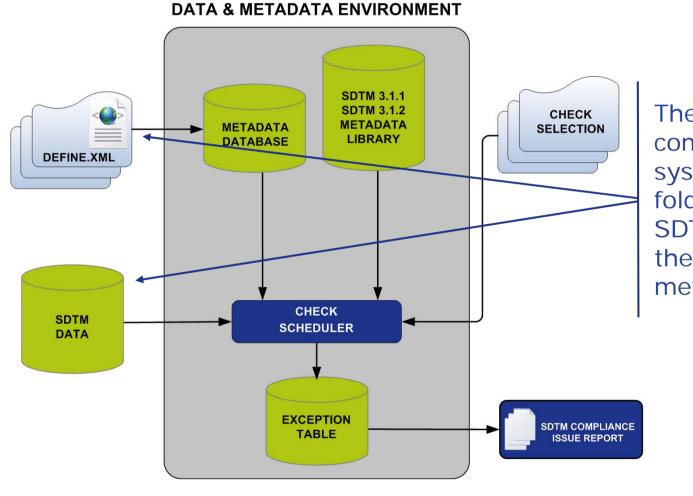
BY DATA STANDARD VERSION
BY CHECK TYPE
BY DOMAIN TYPE

- SDTM IG 3.1.1
- SDTM IG 3.1.2
- Proprietary
- All check types
- Data checks
- Metadata checks
- All domains, one specific domain
- All Findings class domains
- All Interventions class domains
- All Events class domains
- All special purpose domains
- All Trial Design domains

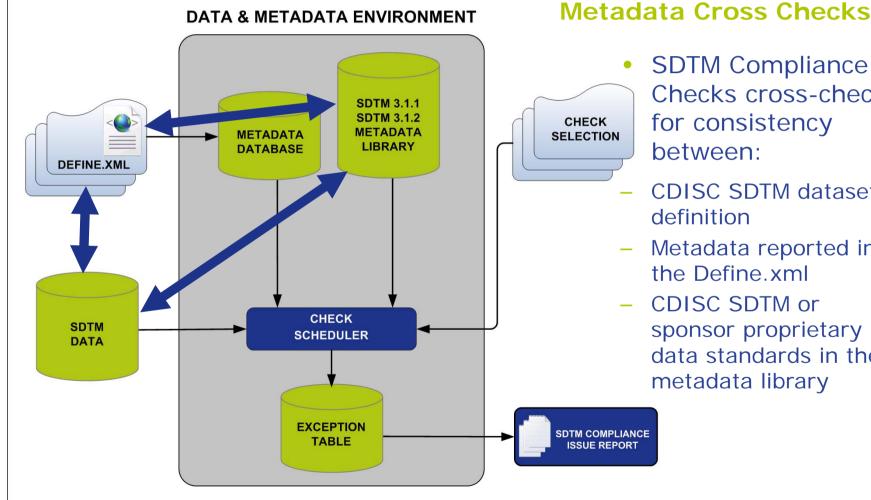








The SDTM compliance checks system reads the folder with the SDTM datasets & the define.xml metadata file

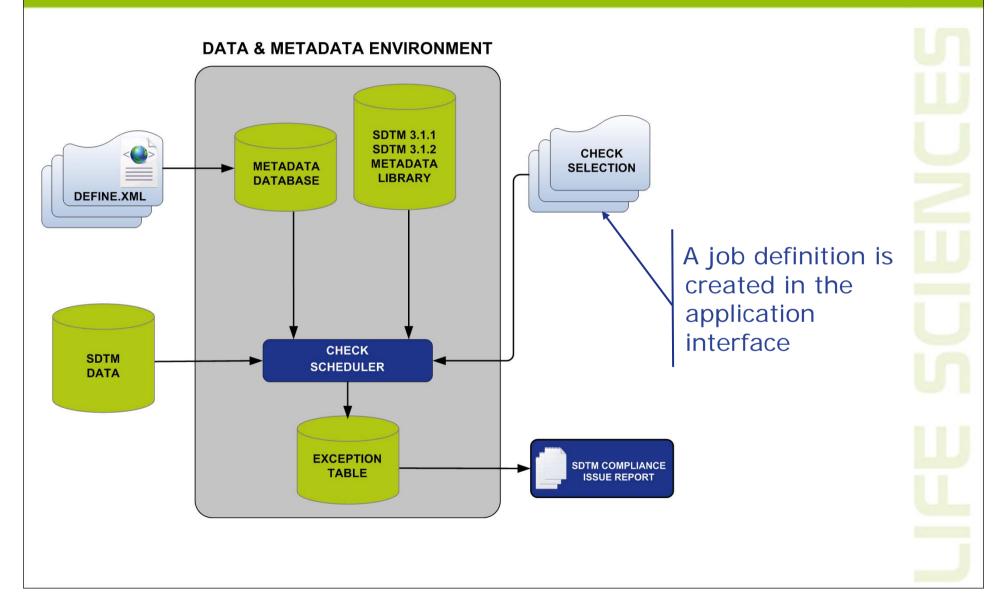


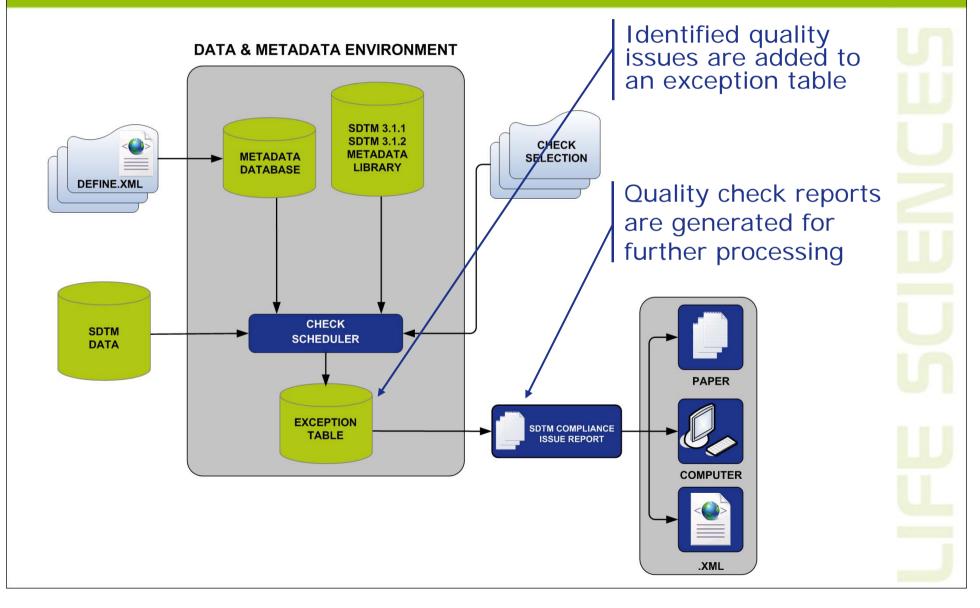
#### **DATA & METADATA ENVIRONMENT**

# • SDTM Compliance Checks cross-check

- for consistency between:
- **CDISC SDTM dataset** definition
- Metadata reported in the Define.xml
- CDISC SDTM or sponsor proprietary data standards in the metadata library









- 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 JobID
  - Check Description :
    - Detailed description of all checks
    - Possibility of adding/modifying check descriptions

• Check Selection :

Choose Project	805	<b>a</b>	Enter Job Description	Data Check	o on interventions	NEXT		
Choose StudyID	1160-0007	-						
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Select At			Check0001 Check0003	Ki -	AP NP		-	
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• Check Description:

Check Name	ChecktD	Sub Che.,	Check Description
heck0001	0001	1.	Check if all the cale variables (-DTC,ETDTC,ETDTC, RESTOR, REFERENCE) have a 150 6601 standard formal.
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heck0003	0003	1	Creck Integer = Y first AESCAN= Y to AESCONG= Y to AESCIEND= Y crives DT+= Y crives DT
heckDOC3	0003	2	CRECK/ITAESCANEY OF AESCONDERY OF AESDISAE*** OF AESDITE*** OF AESHIOSPE*** OF AESLIFE*** OF AESDIE*** OF AESDIE*** OF AESDIE*** OF AESDIE**** OF AESDIE**** OF AESDIE**** OF AESDIE**** OF AESDIE**** OF AESDIE***** OF AESDIE***** OF AESDIE***** OF AESDIE***********************************
heck0004	0004	1	Check IfSTRESC -> NUL, IhmSTAT = NUL,
heckOCCd	0004	2	Check # RTAT +> NULL the STRESC 1 NULL
heck0005	0005	1	Check if   STOTC ++ (JULL and -ENDTC ++ NULL that - STOTC ++ ENDTC) (Check its same +++ of procision of both cales, it may
heckboog	0005		Check if -000UR ++ NULL that -000UR+Y if -000UR+V()
heck3007 heck3008	0007	-	Checkel - TEST ++ ETEST Ind LENST-I,-TEST) ++ 40 sharelers)
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heck3008	0008	1	Check IF TESTCO APROD ETCE contains social characters careerscens are alwards Creck IF TESTCO APROD ETCE contains social characters careerscens are alwards
heck0010	0010		Check for each code is related we also had the study of the study opecific codelist stached to that variable
heckoold	0013		Creek for each comein that all Regi and Top' variables are included in the dataset
heck3013	0012		Creck for each corruin if a value is corrulated for all Teer ver ables
Rection a	0013		Check if each domain present in the databalts is preprint in the Defineum.
heck 3014	0014		Creck/Isac-UB_8.ID - VISIT+ VISIT+LK torr tination can be build in the EV domain.
heck0016	0015	11	Check (the ROOMIN value of the CO company's profesence to a praticipation dataset.
heck0016.	0015	2	Check per subject Pine IDVAR value of the CO domain is a reference to a versible in the re-sted calaset.
heck0016	0015	15	Check per subject Pitre (DWRWA) value of the CO convolution are ference to a value in the related dataset
heck0010	0015	1	Check (the ROOWN value of the RELREC domain is a reference to englated decase)
heckoote	0015	Z	Check per subject Pine IO-WR value of the RELIRED common is a reference to a variable influential of dataset.
hechool e :	0015	3	Check per subject Pine IDW/PVM, value of the RELINEC domain is a reference to a value in the rotated dataset
heckport?	0017	1	Check (The ROOMIN value of the SUPPOUAL comain is a reference to a rolated dataset.
heck0017	0017	2	Check per subject Pfre IDVAR value of the SUPPOURL domain (except for 3UPPDM) is a prenence to a variable in the related cataset.
heck0017	0017	3	Check per subject Fine (DAREVAL volue of the EUPPOUAL complexity) SUPPORt is a reference to a value in the related dataset.
heck0018	0.018	12	Check If USUEJD <> NULL in the DM domain that USUBJD is unique
heckOOl S	0019		Check (Fibe COLUTEY value in the DM domain can be found in the SDTM code(at COLUTEY)
heck0030	0029	1	Check for the SUPPOLAL domains that the 'STUDY'E, USUBJID, IDWRY, EVARYAL, GNAM' combination is unique.
hack0021	0021		Check in the DM comain (FARMOD) == "BORNEAL" Fail #"STDTD == NULL, YCE VEREAV?
heck0032	0022		Check in the DM commin (FARKCD <> SCRNFAL*) SR R*SNDTC <> NULL
heck0020	0023	1	Chick (AEO, FA-ATAL Y JI AEO TH-Y
heck0023 heck0024	0023	6	Check if AESDTHLY that AECV/TEPATAL
heck003ft	0025		Check (I-TEST ) & ETEST Inst LENGTH(-TEST) 42 20 (Handlers. Check (ILINGTH(-TEST20) +8 Extenders)
heckboold	0025	-	Creach or and calculated main data related variable that he value is bund in the value sive metadata stached to that variable.
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heck0.01	0101		Check that the Contain Abbreviation column matches with the name of Domain
heck0:02	0102		Check that the values to - EEG are under within a publicit
heck3 CS	0103		Check if E-STOY is not null and -ENDY is not null him (E-STOY less than or equal to -ENDY).
heck0104	0104		Creck IT ENBE a not null that ENBE & OFFORE DURING WELES DURINGAPTER, UI
heck0105	0105		Check (F)-STRF is not null have -STRF is (DEFORE, DURING, WETER, U)]
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hecho: C7	0107	1	Check(FLEF)CTH(CSFAR(CD) = 3 characters)
heck0107	0102	2	Check in TSPARMOD about start with a number to
heck0: C?	0102	3	Check # SPARED tombins no social thatacters
heck0108	0108	20	Check ( ) EN2TO Is rul ( 1 st.) ENRE cinx null
heck0 09	0109	199	Check (C-STOTC is null first )-STRF e not null
heck0110	0110		Check ([-STNRH) is not rull and -STNRLO is not rul ] that ESTNRH == -STNRLO
i con			the second s

- 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

#### • Job List

Job ID	Rep	3D Study ID	Joh Owner	Job Description	Joli Creation Date
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	825	1 62 0222	manga	20 Clataó Vietariata without 16,16	2009-06-22703:04
	856	1 60 0024	inde dans er	Finalization	2009-00-22713:43
	859	1 03 0028	ocid	Factors	- 2000/06/22742:34
	800	1 63 0025	or M	Enri Rin2	2010 16 28703:48
	865	1 60 0024	indedander	24 Finalitum	2029 06 23712:31
	800	1 05 0525	n de dans er	22 Endiruo	12009-06-28714: 4
	855	1 00 0048	inderlander	48 Finalitun	2029 06 23714: 6
	850	1 03 0042	dbacie	datav metaclata 42	2020 20 28712:28
	855	1 60 0025	mjuneja	DATA CHECKS	2009-06-28712:43
					Business & Decisio

#### • Job Description

					ob List Job Description
	List_Of_Domains	List_Of_Checks	Study_ID	Rep_ID	Job_ID
-	ALL	Check0001	1160-0028	865	5
	ALL	Check0002	1160 0028	885	
	ALL	Check0003	1160-0028	065	8
-	ALL	Check0004 Check0005	1160-0028	005	8
	ALL	Check0005	1160-0028	865	
	ALL	Check0007	1160-0028	005	8
	ALL	Check0008	1160-0028	865	6
_	ALL	Check0009	1160-0028	865	8
	ALL	Check0010	1160-0028	865	6
	ALL	Check0011	1160 0028	865	И
	ALL	Check0012	1160-0020	065	6
	ALL	Check0013	1160-0028	865	8
	ALL	Check0014	1160-0020	065	8
	ALL	Check0015	1160-0028	865	6
	ALL	Check0018	1160-0028	965	8
	ALL	Check0017	1160-0028	865	6
	ALL	Check0018	1180-0028	885	8
	ALL	Check0019	1160-0028	865	6
	ALL	Check0020	1160.0028	885	a .
	ALL	Check0021	1160-0020	065	8
	ALL	Check0022	1160-0028	885	1
6	ALL	Check0023	1160-0028	085	8
	ALL	Check0024	1160-0028	865	fi
	ALL	Check0025	1160-0029	985	3
	ALL	Check0026	1160-0028	865	5
	ALL	Check0100	1180-0028	865	8
	ALL	Check0101	1160-0028	865	5
	ALL	Oheck0102	1180-0028	865	4
	ALL	Check0103	1160-0020	065	5
	ALL	Check0104	1160-0028	865	6
*	ALL	Check0105	1160-0020	065	1

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- Parameter Database
  - Central table for project and study parameters

Reg_ID	Thudy ID	BRC_DATA_PATH	EDTM_DATA_PATH	SOTH_CHECK_PATH	DEFINE_PATH
19	1100-0007	NBRU-S-P2K3-1654/CR0/StahD atal.	NBRU-S-P2K3-16540CRO/BtattData	(IBRU-B-P2K3-1654ICROVStatiData).	0ERU-S-P2K3-1654/CR0tStatiOa
	1100-0011	DERU-S-F2K3-1654/CROIBtabOatal	NERU-S-P2K3-16540CRO08tet0wbs	GERU-S-P2K3-1654/CROIStanData)	MERU-S-P2K3-1854/CROIStatiOn
	1100-0019	X0RU-IS-P2FG-1654/CFLOUISHO MM	MERU-S-P2K3-1654/CRO/SHIDuba	GERU-S-P2K3-165400780103ahData	SERU-S-P2ICI-16540CR0ISbahO
	1186-0920	DERU-B-P2K3-1654KCROBNAD MM.	NBRU-S-P2KI-1654/CRO/BlatData	KERVL-B-P2H3-1654ICROBIAND ato.	http://www.benuese.com/delation/
	1160-0023	06RU-8-P2K3-1654KCR OlStahD atal.	IBRU-S-P2K3-1654/CRO/BtatData	(BRU-8-P3K3-1654(CRO)StahData)	MBRU-8-P2K3-1654/CROIStatio
	1160-0024	VERU S-P2K3-1654/CROIBtabDatal	IBRU-S-P2k3-1654/CRO(BtattData	(ERU-8-P2K3-1654(CRO)StahData).	MERU-8-P2K3-1654/CR01StabD
	1160-0025	0BRU-8-P2k3-1654/CRO(StatiO stat.	IBRU-S-P2k3-1654/CRO(BtatiData	(IBRU-8-P2K3-1054ICROIStanData).	NERU-8-P2K3-1654/CR0(Statio
	1160-0026	NERU-S-P2K3-1654/CR0(StatiOntal.	NERU-S-P2k3-1654/CROIStatData	KERU-B-P2K3-1654(CRO)StatData)	NERU-8-P2K3-1654(CR01Stat0)
<u>6</u>	1160-0028	DERU-S-P2K3-1654/CRO/BbitO atsi.	NERU-S-P2K3-1654VCRO49tatiData	REPU-S-P2K3-1654/CRO/StahData)	KERU-S-P2K3-1654/CR0/SbnD
	1100-0029	SORU-S-P2K3-1654/CROBINO MM	https://www.communication.com/	0879J-8-P2K3-1850/CR068bahDatat	MERU-S-PORT-1654/CROMMON
	1180-0040	06RU-6-F2K3-1654/CROIBIADD at al.	NBRU-8-P2k3-16540CRO(BtattData	tBRU-8-P2K3-1854/CRO/StanData.	XERU-8-P2K3-1654/CROIStanD
	1160-0042	USRU-S-P2K3-1654/CRO/StatOatak	MBRU-8-P2k3-1854/CRO8hatData	(BRU-8-P2K3-1654(CRO)StahData).	MERU-8-P3K3-1654/CR0/StatD
7	1160-0048	UBRU-S-P2K3-1654/CRO/BtatiD atak.	MBRU-S-P2k3-1654/CRO/BtatiData	(BRU-8-P2k3-1654)CR0(StahData)	KERU-S-P2K3-1654/CR0(Statio
	1160-0049	0BRU S-F2K3-1654/CR0/BtatiO atal.	NBRU-S-P2K3-1654/CRO/BtattData.	(ERU-8-P2k3-1854(CRO)StatiOata).	NERU-8-P2K3-1654/CR01StatiO
	1160-0050	DBRU-S-F2K3-1654/CRC49tatiOntal.	NBRU-S-P2k3-1654/CR04StatiOata	NERU-S-P2K3-1664/CROIStanData).	NERU-S-P2K3-1654/CR0(Statio
	1100-0051	DERU-S-F2H3-1654/CROIDMONTM	NERU-S-P2-CI-16540CROUBINData	GERU-S-P2K3-18540CPO1StafiData	DERU-S-P2K3-1654/CR05ba00
	1160-0054	DBRU-5-P2I-0-1654/CROShinD at al.	MBRU-S-P2k3-16540CROUBIatOaha	GBRU-B-P2H3-1654ICROBIADData	50RU-S-P2K3-165400R065ab0
	1160-0056	UBRU-E-P2K3-1654/CRO/BtabDatal.	hBRU-6-P2k3-1654/CRO(BlatCode	kBRU-8-P2k3-165402R0/StahData	16RU-8-P2K3-1654/CR0(Statio
	1160-0057	06RU-6-P2K3-1654/CRO/BtahDatal	ISRU-S-P2K3-16540CRO(BtattData	IdBRU-8-P2k3-1654(CRO)StahData)	MERU-8-P2K3-16540CR0IStahD
	1160-0059	DBRU-S-P2K3-1654/CRO/BtahDatal	NBRU-S-P2K3-1654/CRO/BtattData	(ERU-8-P2K3-1654(CRO)StahData).	hERU-6-P2K3-1654/CR0IStaND
5	1160-0059	0BRU-S-P2K3-1654/CR04StatiO atal.	NBRU-S-P2K3-1654/CRO48tattData	(BRU-9-P2K3-16640 R0(StafiData).	NERU-S-P2K3-1654/CR048twhO
	1100-0061	06RU-S-P2K3-1654/CRO/Statio atal.	NERLI-S-P2KI-16540CR04BtatiData	(BRU-S-P2K3-1654)CRO(StanData)	NERU-S-P2K3-1614ICROISING
	1160-0080	ODRU-G-P25G-1654/CRC/05MO MM.	MORU-S-P2K3-1654KCRO(StatiCala)	KERRU-S-P 24CB-165 (CCRC)/StahDatas	MERU-S-P2K3-1654/CROBINO
	1380-0068	06RU-6-P2K3-1654/CROIStatiO at al.	MERU-S-P2k3-18546CRO(BlattData	(6RU-9-P2K3-1654)CROVStanData	KERU-8-P2KI-16540CROIStaND
	1160-0070	06RU-8-P2K3-1654/CR0(StatiData).	MBRU-S-P2k3-1654/CRO(BtattData	(BRU-8-P2K3-1654/CR0)StatiData).	KERU-8-P2K3-1654(CROIStanD
	1160-0074	NERU 6 P2K3-1654(CROBIND atal.	NERU-S-P2K3-16541CR OlBtatiD ata	KERU-8-P2K3-165440R01StatDatat.	KERU 8 P2ICI 16540 ROIStatO
	1160-0075	NERU-S-P2K3-1654\CR04StatDatal.	NBRU-S-P2k3-1654/CRO/BtattData	(BRU-8-P2K3-1654(CR0)StatiData).	NERU-S-P2K3-1654/CR0tStatiO
	1560-0082	NERU-S-P2K3-1654/CRO(Statio atal.	NBRU-S-P2K3-16540CRO(Btation/a	INERU-S-P2K3-1654/CROIStanData).	NERU-S-P2K3-1654/CR0IStMD
	1160-0090	DERU-S-P2K3-1654/CRO(StanDatal	hERU-S-P2ICI-1654/CROUStatiData	INSRU-S-P24C3-1654/CROStahData	SERU-S-P2K3-3654ICROISIMD

Business & Decision



## Reporting Tool (1)

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

CHECK LIST	ERROR LEVEL	COMPLETION TIME	-
Check0001	The Check Completed Successfully	2009-01-27T9-55-00	
Check0002	The Check Completed Successfully	2009-01-27T9-55-00	
Check0003	The Check Completed Successfully	2009-01-27T9-55-00	
Check0004	The Check Completed Successfully	2009-01-27T9-55-00	
Check0005	The Check Completed Successfully	2009-01-27T9-55-00	
Check0006	The Check Completed Successfully	2009-01-27T9-55-00	
Check0007	The Check Completed Successfully	2009-01-27T9-55-00	
Check0008	The Check Completed Successfully	2009-01-27T9-55-00	
Check0009	The Check Completed Successfully	2009-01-27T9-55-00	
Check0010	The Check Completed Successfully	2009-01-27T9-55-00	
Check0011	The Check Completed Successfully	2009-01-27T9-55-00	
Check0012	The Check Completed Successfully	2009-01-27T9-55-00	
Check0013	The Check Completed Successfully	2009-01-27T9-55-00	
Check0014	The Check Completed Successfully	2009-01-27T9-55-00	
Check0015	The Check Completed Successfully	2009-01-27T9-56-00	
Check0016	The Check Completed Successfully	2009-01-27T9-56-00	
Check0017	The Check Completed Successfully	2009-01-27T9-56-00	
Check0018	The Check Completed Successfully	2009-01-27T9-56-00	
Check0019	The Check Completed Successfully	2009-01-27T9-56-00	
IChack0020	The Check Completed Successfully	2009-01-2779-56-00	

## Reporting Tool (2)

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

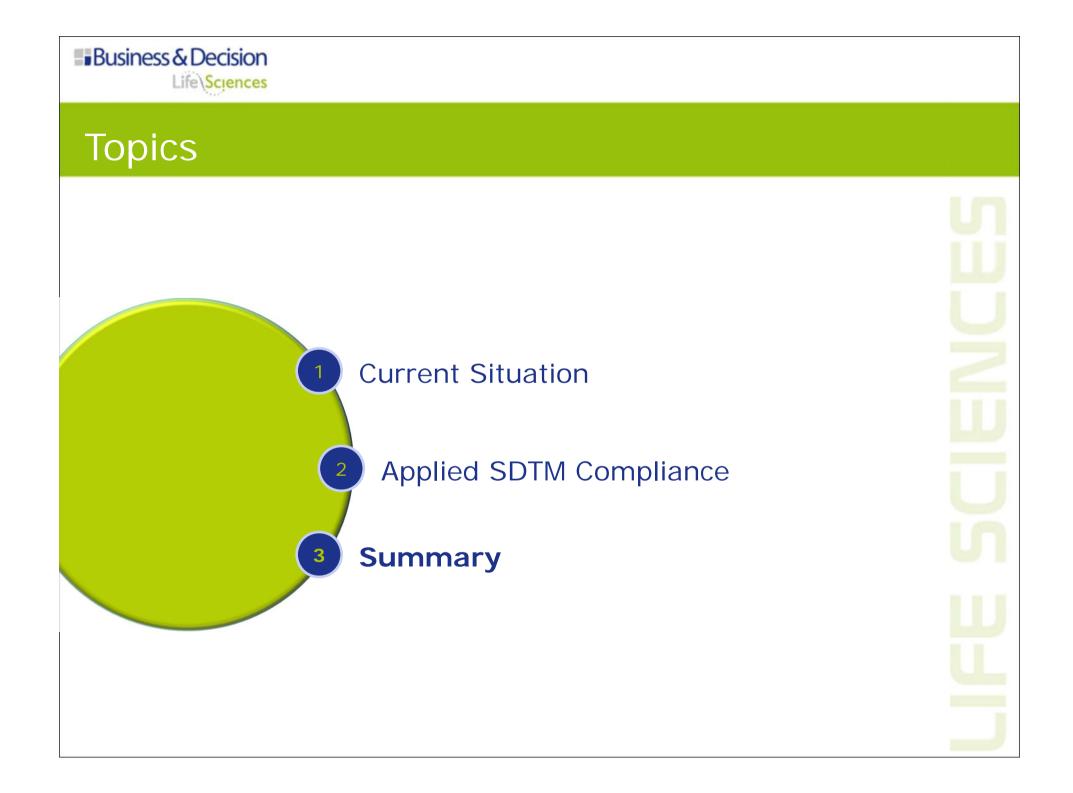
LIST_OF_CHECKS	DOMAIN	VARIABLE1	EXCEPTIONS_COUNT	CHECK TYPE	-
Check0009	LB	LBORRES		73 DATA	
Check0010	LB	LBORRESU		84 METADATA	
Check0010	VS	VSORRESU		56 METADATA	
Check0010	VS	VSSTRESU		56 METADATA	
Check0015	CO	IDVAR		73 DATA	
Check0100	IE	DOMAIN		1 DATA	
Check0268	CM	COLUMN		1 METADATA	
Check0271	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

					KEY1CD		MADACD .	VAR1 🔽	VAR2CD	
CHECKID	ERRORINISG			USUBJID 💌	METTCD -	NET I	VARICD	VARI	VARZED	VARZ
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)									

Reported Exception Record Identifiers Exception Attributes



#### Summary

- SDTM compliance will help us adhere to the data standards
- SDTM Compliance Checks will facilitate loading into Janus
- 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!



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# Thank you for your attention



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