

***EFFECTIVE AND OPERATIONAL USE OF
CDISC STANDARDS & STUDY METADATA
THROUGH SAS LIFE SCIENCE ANALYTICS FRAMEWORK***

CAMBRIDGE - PHUSE SDE (MAY2016)



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HEALTH & LIFE SCIENCES (GLOBAL PRACTICE)**

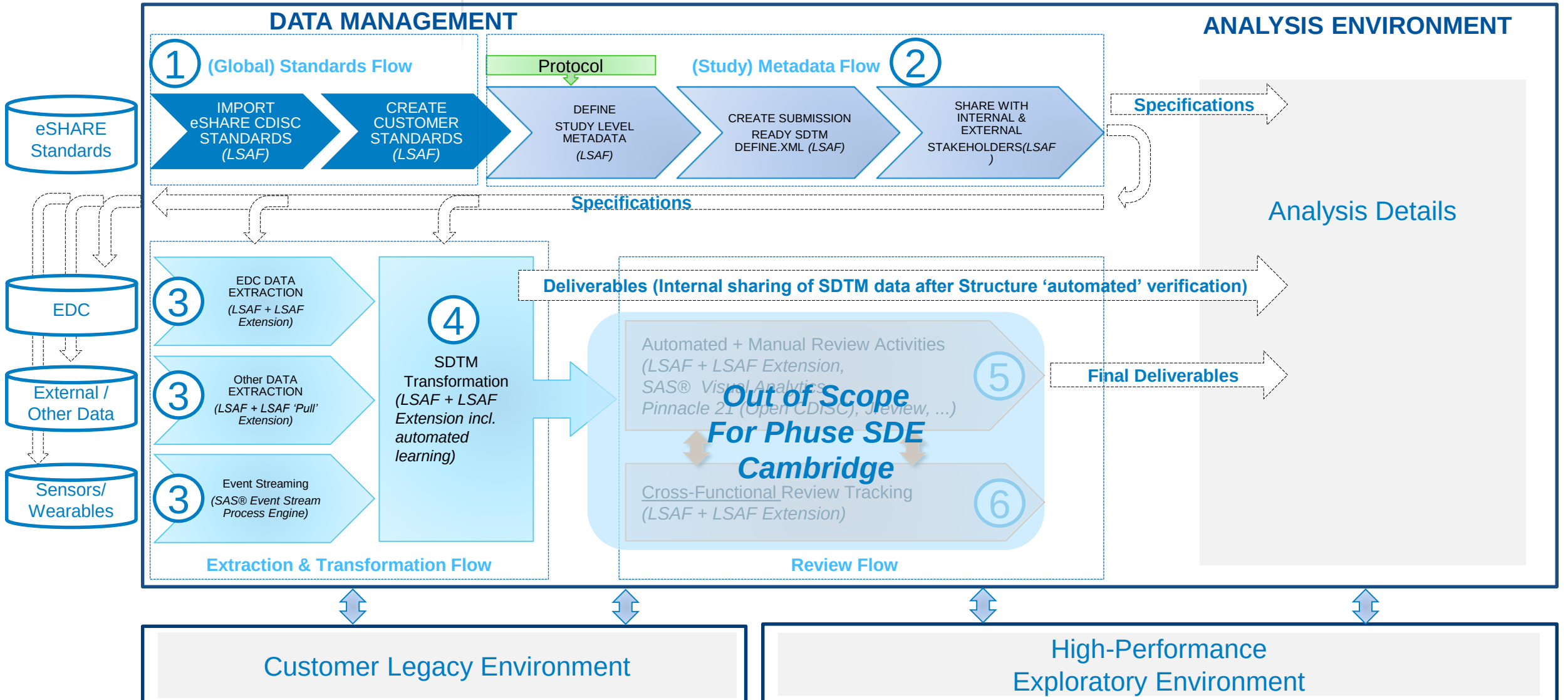
AGENDA

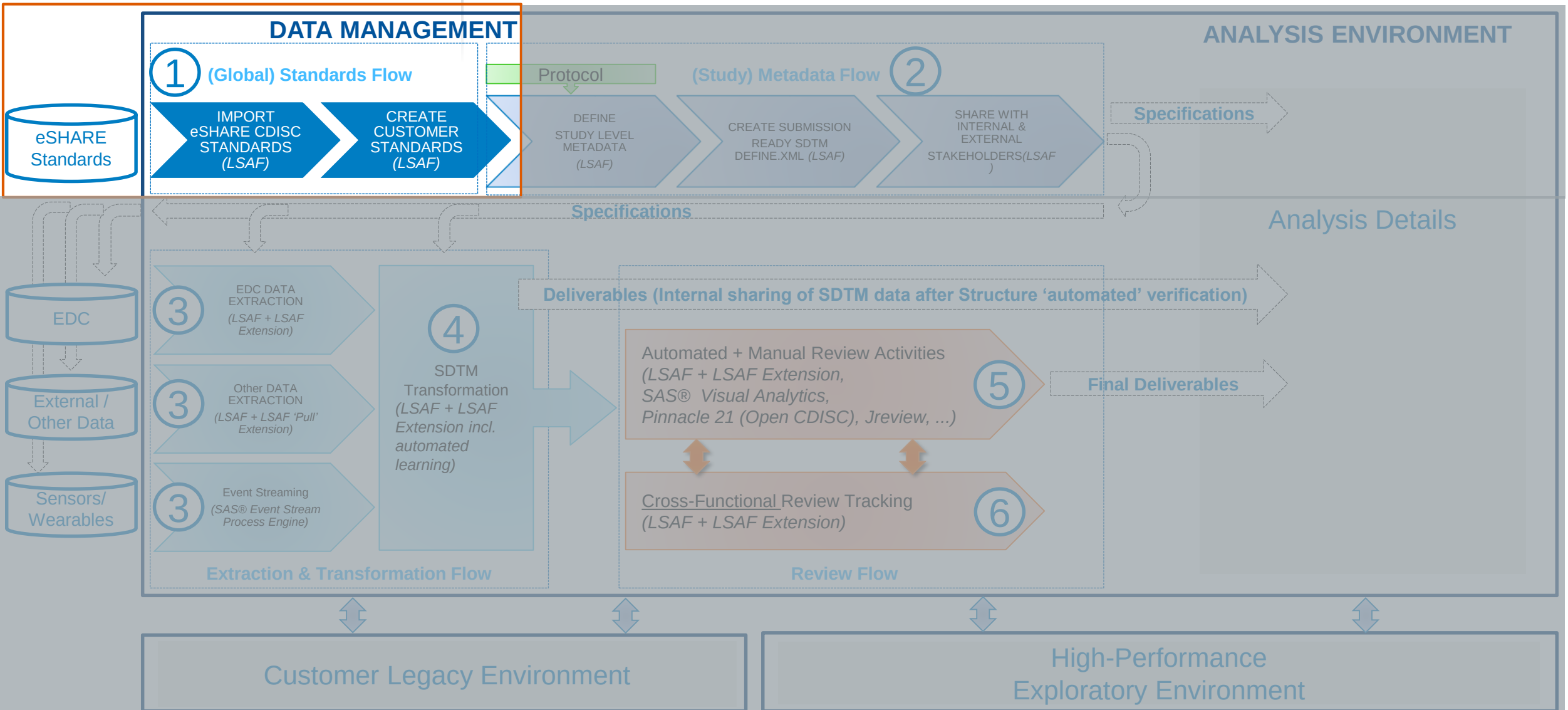
EFFECTIVE AND OPERATIONAL USE OF CDISC STANDARDS AND STUDY METADATA THROUGH SAS LIFE SCIENCE ANALYTICS FRAMEWORK

- High Level Overview End-to-End flow
- CDISC Standards and Company 'CDISC' Standards (SDTM/SEND)
- Study Metadata
 - Define Study Level Metadata → Submission Ready Define.XML → Internal & External collaboration
- Data Extraction
 - Automated extraction from eCRF (EDC systems) and ancillary data to SDTM/SEND 'like' data (directly) in Repository
- SDTM transformation
 - SDTM Mapping through automated learning and code generation
- Repository Metadata through (Extended) Attributes

PHUSE SDE CAMBRIDGE

END-TO-END SINGLE DATA MANAGEMENT & ANALYSIS ENVIRONMENT





- Made available by SAS within Life Science analytics Framework for all customers
- Future Standards: using Life Science Analytics Framework API and stable eSHARE API (*pilot(s) ongoing*)

6 data standards

Type	Name	Source	Source Version	Release Date
	CDISC SDTM Controlled Terminology, 2015-06-26	NCI Thesaurus	2015-06-26	2015-06-26T00:00:00
	CDISC SDTM Controlled Terminology, 2015-12-18	NCI Thesaurus	2015-12-18	2015-12-18T00:00:00
	CDISC SDTM V3.1.2	CDISC-SDTM	3.1.2	
	CDISC SDTM V3.1.3	CDISC-SDTM	3.1.3	
	CDISC SDTM V3.2	CDISC-SDTM	3.2	
	CDISC SEND V3.0	CDISC-SEND	3.0	

- Details / Domains / Studies / Properties info

CDISC SDTM V3.1.3 (Read Only)

Details

Tabulation Standard Details

Name: CDISC SDTM V3.1.3

Source: CDISC-SDTM

Built in: Yes

Source version: 3.1.3

Description: Study Data Tabulation Model, Final Version 1.3 (and Implementation Guide: Human Clinical Trials, Final Version 3.1.3), July 16, 2012

CDISC SDTM V3.1.3 (Read Only)

Domains

Identifier	Name	Reference Comment
AE	Adverse Events	The Adverse Events dataset includes clinical data describing "any untoward medical occurrence in
CE	Clinical Events	The intent of the domain model is to capture clinical events of interest that would not be classified
CM	Concomitant Medications	CRF data that captures the Concomitant and Prior Medications/Therapies used by the subject. Exa
CO	Comments	The Comments special-purpose domain provides a solution for submitting free-text comments rela
DA	Drug Accountability	Drug Accountability is for data regarding the accountability of study drug, such as information on r
DM	Demographics	This domain captures subject demographics, with one record for each subject used in the study.
DS	Disposition	The Disposition dataset provides an accounting for all subjects who entered the study and may inc
DV	Protocol Deviations	The DV domain is an Events model for collected protocol deviations and not for derived protocol c
EG	ECG Test Results	CRF data that captures interval measurements and summary information from an ECG. This domain



CM Domain

Domain **Columns**

Identifier: CM

Name: Concomitant Medications

Classification: Interventions

Keys: STUDYID USUBJID CMTRT CMSTDTC

Purpose: Tabulation

Structure: One record per recorded medication occurrence or constant-dosing interval per subject

Archive filename: ../transport/cm:CM Domain

Archive title: Concomitant M

Reference comment: CRF data that c

Columns

#	Name	Label	Length	Type	Key
1	STUDYID	Study Identifier	40	char	✓
2	DOMAIN	Domain Abbreviation	8	char	
3	USUBJID	Unique Subject Identifier	40	char	✓
4	CMSEQ	Sequence Number	8	num	
5	CMGRPID	Group ID	40	char	
6	CMSPID	Sponsor-Defined Identifier	40	char	
7	CMTRT	Reported Name of Drug, Med, or Therapy	200	char	✓
8	CMMODIFY	Modified Reported Name	200	char	

Close

- ⏪ |
 CDISC SDTM V3.1.3 (Read Only)

Details Domains Studies Properties	Studies Total studies: 1 Studies not displayed: 0 <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>Name</th> <th>Description</th> <th>Path</th> <th>State</th> </tr> </thead> <tbody> <tr> <td>L - XXX-0001</td> <td>Default Study Description</td> <td>/SAS/L - XXX (Compound)/XXX-001 (Trial Code)</td> <td>Development</td> </tr> </tbody> </table>	Name	Description	Path	State	L - XXX-0001	Default Study Description	/SAS/L - XXX (Compound)/XXX-001 (Trial Code)	Development
Name	Description	Path	State						
L - XXX-0001	Default Study Description	/SAS/L - XXX (Compound)/XXX-001 (Trial Code)	Development						

- Within same Data Standards Module

SAS® Life Science Analytics Framework - Data Stan...

pharma X

1 data standard

Type	Name	Source	Source Version	Release Date
	Pharma X Global SDTM 3.1.2	CDISC-SDTM	3.1.2	

Import Select

Pharma X Global SDTM 3.1.2 (Read Only)

Details	Domains	Studies	Properties
SUPPCM	Supplemental Qualifiers for CM		
SUPPDA	Supplemental Qualifiers for DA		
SUPPDM	Supplemental Qualifiers for DM		
SUPPDS	Supplemental Qualifiers for DS		
SUPPDV	Supplemental Qualifiers for DV		
SUPPEG	Supplemental Qualifiers for EG		
SUPPEX	Supplemental Qualifiers for EX		
SUPPIE	Supplemental Qualifiers for IE		
SUPPLB	Supplemental Qualifiers for LB		

- How ?
 - Step 1: By Selecting the CDISC Standard (or other 'Customer' Standard) and Exporting into Repository
 - 2 SAS tables will be generated/available for making required updates: *"Reference_Columns"* and *"Reference_Tables"*

6 data standards

☐	Type	Name	Source	Source Version
☐		CDISC SDTM Controlled Terminology, 2015-06-26	NCI Thesaurus	2015-06-26
☐		CDISC SDTM Controlled Terminology, 2015-12-18	NCI Thesaurus	2015-12-18
☒		CDISC SDTM V3.1.2	CDISC-SDTM	3.1.2

Export Tabulation Standard

Output folder:

☐ Overwrite existing files

Versioning

Check in comment:

☒ Enable versioning

Version to be applied to all output files:

☒ Enable versioning

Version to be applied to all output files:

☒ Major

☐ Minor

☐ Custom

1.0



Dashboard Repository Workspace

/SAS/Files/GlobalLibrary/Company/reference_columns_pharmax312.sas7bdat

Name	Size
ct-sdtm-nclevs-odm-2015-06-26.xml	4.9 MB
reference_columns_pharmax312.sas7bdat	2.5 MB
reference_tables_pharmax312.sas7bdat	256 KB

- Step 2: Import 'updated' SAS tables as new/updated "Customer" Standard
i.e. Global → TA/Indication → Study Standard.

The screenshot shows the SAS Studio interface with the 'Import Tabulation Standard' dialog box open. The dialog box contains the following information:

- Name:** Pharma X Global SDTM 3.1.2
- Description:** (empty field)
- Tables data set:** /SAS/Files/GlobalLibrary/Company/reference_tables_pharmac312.sas7bdat
- Columns data set:** /SAS/Files/GlobalLibrary/Company/reference_columns_pharmac312.sas7bdat

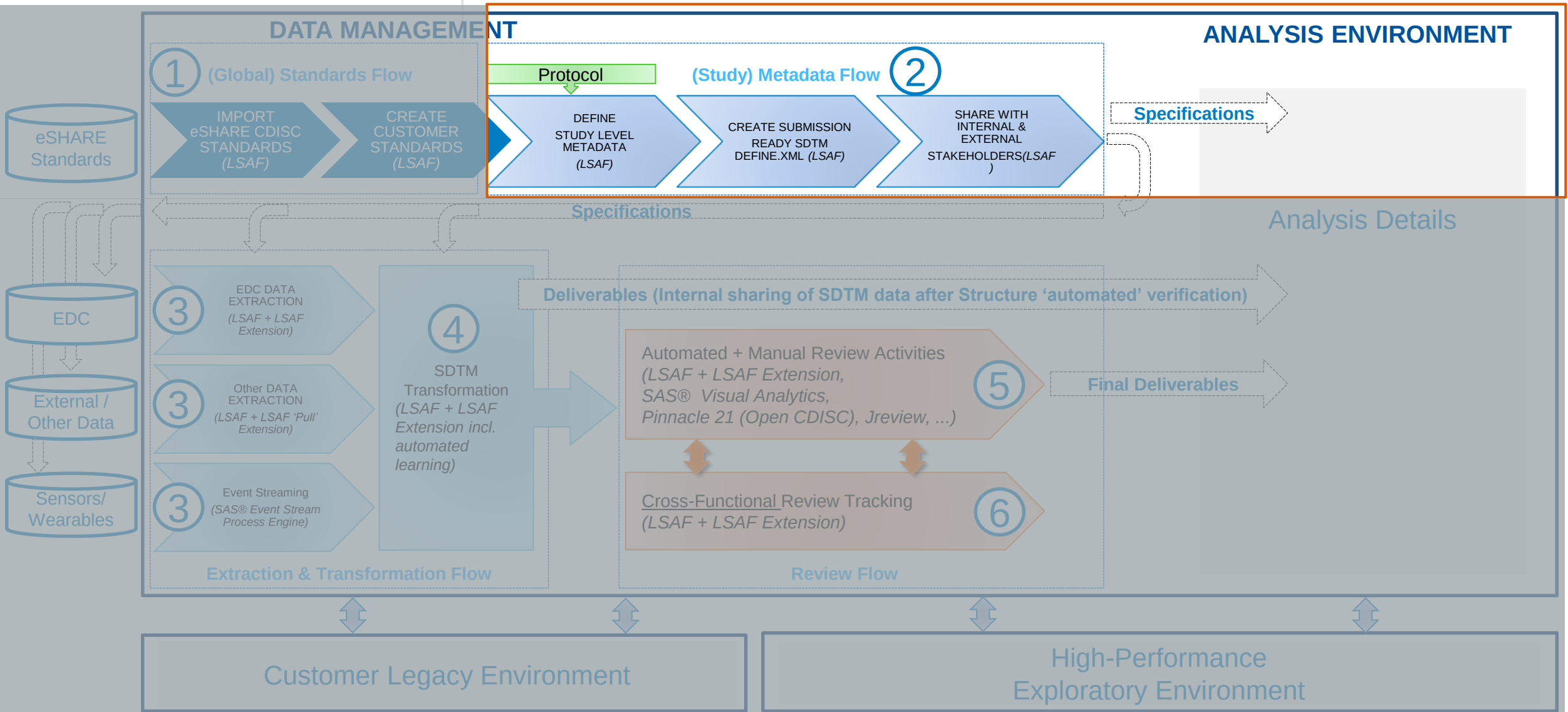
The 'Import' button is highlighted in blue.



The 'Action Status (Details)' window shows the following table:

Name	Library/Company	Description
mms_pharmac312.sas7bdat	y	as part of the upgrade from the previous release.
reference_columns_pharmac312.sas7bdat	/SAS/Files/GlobalLibrary/Company	One or more XMLCODELIST values has been reset to a non-null value referencing an External Codelist.
Pharma X Global SDTM 3.1.2_2		Tabulation standard import complete.

The 'Action Status' is indicated as 'complete' with a green checkmark.



- Details / Tabulation Standards using “Study” Tabulation Standard example
- Study-specific metadata entered in **reference_columns** for AE, such as origin, algorithms, and codelists further customized from the parent standard, and comments.

SAS® Life Science Analytics Framework - Studies

CLC Test Study 2

Details

Tabulation Standards

Domains

Code List Packages

External Code Lists

Study Details

Name: * CLC Test Study 2

Description: * Testing CLC Features, Take 2

Tabulation model: * CDISC-SDTM

Path: * /SAS/Melissa CLC Project2

CLC Test Study 2

Details

Tabulation Standards

Domains

Tabulation Standards

☐	Name	Source	Source Version
☐	CABC123D4567E1 Study SDTM 3.1.2	CDISC-SDTM	3.1.2

- Select the domain(s) desired and their target location. You will only be able to navigate within the analysis/project's Files folder that was selected for the Study. You can enable versioning and/or select to overwrite existing files.

→ Result: zero-observation datasets have been created for each one in repository.

Note: Import / Export feature is for Dataset.XML files (out of scope for this presentation)

Name	Size	Modified By	Date Modified	Signed	Repository Version	Word
ae.sas7bdat	128 KB	Melissa	May 06, 2016 07:00 P...		1.0	
cm.sas7bdat	128 KB	Melissa	May 06, 2016 07:00 P...		1.0	
da.sas7bdat	128 KB	Melissa	May 06, 2016 07:00 P...		1.0	
dm.sas7bdat	128 KB	Melissa	May 06, 2016 07:00 P...		1.0	
ds.sas7bdat	128 KB	Melissa	May 06, 2016 07:00 P...		1.0	
eg.sas7bdat	128 KB	Melissa	May 06, 2016 07:00 P...		1.0	
ex.sas7bdat	128 KB	Melissa	May 06, 2016 07:00 P...		1.0	
ie.sas7bdat	128 KB	Melissa	May 06, 2016 07:00 P...		1.0	
lb.sas7bdat	128 KB	Melissa	May 06, 2016 07:00 P...		1.0	
mh.sas7bdat	128 KB	Melissa	May 06, 2016 07:00 P...		1.0	
pe.sas7bdat	128 KB	Melissa	May 06, 2016 07:00 P...		1.0	
qs.cgs.sas7bdat	128 KB	Melissa	May 06, 2016 07:00 P...		1.0	
qscs.sas7bdat	128 KB	Melissa	May 06, 2016 07:00 P...		1.0	
qsmm.sas7bdat	128 KB	Melissa	May 06, 2016 07:00 P...		1.0	
relrec.sas7bdat	128 KB	Melissa	May 06, 2016 07:00 P...		1.0	
sc.sas7bdat	128 KB	Melissa	May 06, 2016 07:00 P...		1.0	
se.sas7bdat	128 KB	Melissa	May 06, 2016 07:00 P...		1.0	
suppae.sas7bdat	128 KB	Melissa	May 06, 2016 07:00 P...		1.0	
suppcm.sas7bdat	128 KB	Melissa	May 06, 2016 07:00 P...		1.0	

New Domain

CABC123D4567E1 Study SDTM 3.1.2

Domains: *

☐	Identifier	Name	Reference Comment
☐	AE	Adverse Events	
☐	CM	Concomitant Medications	
☐	DA	Drug Accountability	
☐	DM	Demographics	See Reviewer's Guide, Section 2.1 Demographics
☐	DS	Disposition	

Selected: NONE

Output folder: *

Browse to a repository folder

Browse

☐ Overwrite existing files

Versioning

Check in comment:

☐ Enable versioning

Version to be applied to all output files:

- ☒ Major
- ☐ Minor
- ☐ Custom

1.0

Submit

Cancel

CLC Test Study 2

Details

Tabulation Standards

Domains

Code List Packages

External Code Lists

Value Level Metadata

Supporting Documents

Protocol

Domains

☐	Identifier	Name	Folder	Standard
☐	AE	Adverse Events	/SAS/Melissa CLC Project2/Files/SDTM/data	CABC123D4567E1 Study SDTM 3.1.2
☐	CM	Concomitant Medications	/SAS/Melissa CLC Project2/Files/SDTM/data	CABC123D4567E1 Study SDTM 3.1.2
☐	DA	Drug Accountability	/SAS/Melissa CLC Project2/Files/SDTM/data	CABC123D4567E1 Study SDTM 3.1.2
☐	DM	Demographics	/SAS/Melissa CLC Project2/Files/SDTM/data	CABC123D4567E1 Study SDTM 3.1.2
☐	DS	Disposition	/SAS/Melissa CLC Project2/Files/SDTM/data	CABC123D4567E1 Study SDTM 3.1.2
☐	EG	ECG Test Results	/SAS/Melissa CLC Project2/Files/SDTM/data	CABC123D4567E1 Study SDTM 3.1.2
☐	EX	Exposure	/SAS/Melissa CLC Project2/Files/SDTM/data	CABC123D4567E1 Study SDTM 3.1.2
☐	IE	Inclusion/Exclusion Criteria Not Met	/SAS/Melissa CLC Project2/Files/SDTM/data	CABC123D4567E1 Study SDTM 3.1.2
☐	LB	Laboratory Tests Results	/SAS/Melissa CLC Project2/Files/SDTM/data	CABC123D4567E1 Study SDTM 3.1.2
☐	MH	Medical History	/SAS/Melissa CLC Project2/Files/SDTM/data	CABC123D4567E1 Study SDTM 3.1.2

- Making use of **Multiple** Terminology Packages:

Controlled Terminology that has already been made available by SAS in the Standards Module may be selected for the study. Many (other) Code Lists may be added by the customer.

After you Save the study, the **View Resulting Code Lists** button will be active.

- The define.xml file will ONLY pick up and display the codelists that are actually used by a variable in the study.

CLC Test Study 2

Code List Packages

Name	Source	Source Version	Release Date
☐ Study CABC123D4567E1 Terminology Codelists	NCI Thesaurus	2016-05-07	2015-09-25T00:00:00
☐ CDISC SDTM Controlled Terminology, 2015-12-18	NCI Thesaurus	2015-12-18	2015-12-18T00:00:00

Code lists in packages higher in the list will take precedence over those lower in the list. You must save the study before you can view the resulting code lists for this study.

View Resulting Code Lists for Study

ACN

Properties Items

ACN (7)

Search by coded ...

Coded Value	Decoded Value	Definition	Preferred Term	Synonyms	NCI Code
DOSE INCREASED		An indication that a medication schedu...	Dose Increased		C49503
DOSE NOT CHANGED		An indication that a medication schedu...	Dose Not Changed		C49504
DOSE REDUCED		An indication that a medication schedu...	Dose Reduced		C49505
DRUG INTERRUPTED		An indication that a medication schedu...	Drug Interrupted		C49501
DRUG WITHDRAWN		An indication that a medication schedu...	Drug Withdrawn		C49502
NOT APPLICABLE		Determination of a value is not relevan...	Not Applicable	NA; Not Applicable	C48660
UNKNOWN		Not known, not observed, not recorde...	Unknown	U; Unknown	C17998

- External Code Lists (2 Options):
 - **Import** assumes you have a dataset in the required structure already populated that you would like to use (import).
 - **Create Template** will create either a “zero-observation” dataset with the required structure, or if you select “*Populate with default entries*” - screenshot below - it will add the most commonly used external codelists (data dictionaries).

This is however NOT submission-ready. There are placeholders that must be either modified or deleted, and the default entries should be reviewed for accuracy for the particular study and modified as needed.

Obs	dictionary_name	dictionary_versi...	dictionary_rele...	codelist_name	codelist_dataty...	codelist_definition	localref	href
1	To-be-specified	To-be-specified		Health Encounter Name	text			
2	MedDRA	18.1	2015-09	MedDRA Body System or Organ Class Code	integer	MedDRA is an international me...		http://www.med...
3	MedDRA	18.1	2015-09	MedDRA Body System or Organ Class Term	text	MedDRA is an international me...		http://www.med...
4	MedDRA	18.1	2015-09	MedDRA Body System or Organ Class Term for ...	text	MedDRA is an international me...		http://www.med...
5	MedDRA	18.1	2015-09	MedDRA Body System or Organ Class Term for ...	text	MedDRA is an international me...		http://www.med...
6	MedDRA	18.1	2015-09	MedDRA High Level Code	integer	MedDRA is an international me...		http://www.med...
7	MedDRA	18.1	2015-09	MedDRA High Level Group Code	integer	MedDRA is an international me...		http://www.med...
8	MedDRA	18.1	2015-09	MedDRA High Level Group Term	text	MedDRA is an international me...		http://www.med...
9	MedDRA	18.1	2015-09	MedDRA High Level Term	text	MedDRA is an international me...		http://www.med...
10	MedDRA	18.1	2015-09	MedDRA Lowest Level Code	integer	MedDRA is an international me...		http://www.med...
11	MedDRA	18.1	2015-09	MedDRA Lowest Level Term	text	MedDRA is an international me...		http://www.med...
12	MedDRA	18.1	2015-09	MedDRA Preferred Term	text	MedDRA is an international me...		http://www.med...
13	MedDRA	18.1	2015-09	MedDRA Preferred Term Code	integer	MedDRA is an international me...		http://www.med...
14	MedDRA	18.1	2015-09	MedDRA Preferred Term for Clinical Event	text	MedDRA is an international me...		http://www.med...
15	MedDRA	18.1	2015-09	MedDRA Preferred Term for Medical History	text	MedDRA is an international me...		http://www.med...
16	To-be-specified	To-be-specified		Procedure Name	text			
17	LOINC	2.5.2	2015-06-29	Unique LOINC Lab Test or Result Code	text	Logical Observation, Identifiers...		
18	LOINC	2.5.2	2015-06-29	Unique LOINC Microbiology Specimen Test or R...	text	Logical Observation, Identifiers...		
19	LOINC	2.5.2	2015-06-29	Unique LOINC Microbiology Susceptibility Test o...	text	Logical Observation, Identifiers...		
20	WHODRUG	WHO DDE 1 M...	2016-03-01	WHODRUG Medication Class Code	text	WHO DDE contains codes for id...		
21	WHODRUG	WHO DDE 1 M...	2016-03-01	WHODRUG Medication Class Name	text	WHO DDE contains codes for id...		
22	WHODRUG	WHO DDE 1 M...	2016-03-01	WHODRUG Medication or Substance Name	text	WHO DDE contains codes for id...		

- Import Template:

If a template is used, once it is populated, you will need to **Import** it into the study. Creating a template does NOT automatically associate the template dataset with the study. The screen shot below shows the external codelists in the Study after they've been imported.

External Code Lists							
Name	Data Type	Definition	Dictionary Name	Dictionary Version	Dictionary Release Date	Local Dictionary Reference	External Dictionary HREF
Country Codes - ISO 3166	text	The purpose of ISO 3166 is to define international...	ISO3166	Current		ISO3166	http://www.iso.org/iso/country_codes
MedDRA Body System or Organ Classification	text	MedDRA is an international medical terminology d...	MedDRA	18.1	2015-09	AEDICT_F	http://www.meddra.org
WHODRUG Medication Class Code	text	WHO DDE contains codes for identifying drug na...	WHODRUG	WHO DDE 1 March 2016	2016-03-01	DRUGDICT_F	

- Same principle for Value Level Metadata & Supporting Documents

Details

Tabulation Standards

Domains

Code List Packages

External Code Lists

Value Level Metadata

Supporting Documents

Protocol

Value Level Metadata

Import

Export

Create Template

Clear All

Table	Column	Where Clause	Type	Length	Controlled Terms	Origin	Algorithm	
EG	EGORRES	EGTESTCD EQ "INTP"	char	8		CRF		
EG	EGORRES	EGTESTCD EQ "PRMEAN"	num	3		CRF		
EG	EGORRES	EGTESTCD EQ "QRSUR"	num	3		CRF		
EG	EGORRES	EGTESTCD EQ "QTMEAN"	num	3		CRF		
EG	EGORRES	EGTESTCD EQ "VRMEAN"	num	2		CRF		
EG	EGSTRESC	EGTESTCD EQ "QTCB"	num	5		Derived	QTcB = QT interval / square root of ...	
EG	EGSTRESC	EGTESTCD EQ "QTCF"	num	5		Derived	QTcF = QT interval / cubic root of (6...	
IE	IEORRES	IETESTCD EQ "EXCL01"						
IE	IEORRES	IETESTCD EQ "EXCL02"						
IE	IEORRES	IETESTCD EQ "EXCL03"						

CLC Test Study 2

Details

Tabulation Standards

Domains

Code List Packages

External Code Lists

Value Level Metadata

Supporting Documents

Protocol

Properties

Supporting Documents

Import

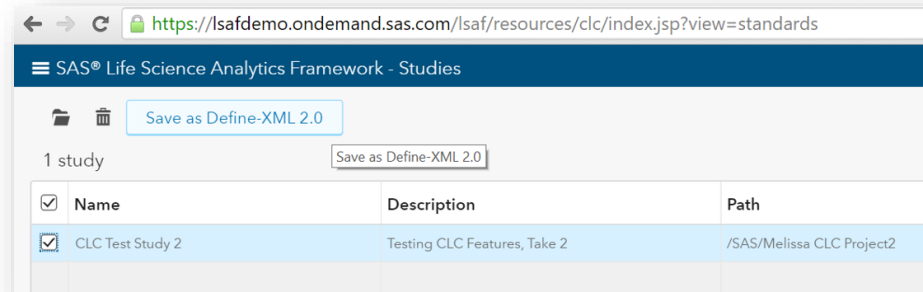
Export

Create Template

Clear All

Table	Column	Where Clause	Document Type	Title	HREF	Page Reference Type	Page Reference	
CM	CMTRT		CRF	Annotated Case Report Fo...	blankcrf.pdf	PhysicalRef	9 22	
DA	DADTC		CRF	Annotated Case Report Fo...	blankcrf.pdf	PhysicalRef	19	
DA	DAORRES	DATESTCD EQ "DISP...	CRF	Annotated Case Report Fo...	blankcrf.pdf	PhysicalRef	19	
DA	DAORRES		CRF	Annotated Case Report Fo...	blankcrf.pdf	PhysicalRef	19	
DA	DAORRES	DATESTCD EQ "RETA...	CRF	Annotated Case Report Fo...	blankcrf.pdf	PhysicalRef	19	
DA	DAORRESU		CRF	Annotated Case Report Fo...	blankcrf.pdf	PhysicalRef	19	
DA	DATEST		CRF	Annotated Case Report Fo...	blankcrf.pdf	PhysicalRef	19	
DM			COMMENT	Reviewers Guide	reviewersguide...	NamedDestination	section2.1	
DM	AGE		METHOD	Complex Algorithms	complexalgorit...	NamedDestination	DM	
DM	ARMCD		COMMENT	Reviewers Guide	reviewersguide...			

- Select your study, and then click the **Save as Define-XML** button. Select the **standard** (if more than one was associated with the study) and domains to include.
- Specify the **output repository** location for the define to be stored + options to overwrite existing, choose encoding, add the stylesheet (always recommended) and set versioning.



Save Study as Define-XML 2.0

Standard: *
CABC123D4567E1 Study SDTM 3.1.2

Domains: *

☒	Identifier	Name	Folder	Standard
☒	AE	Adverse Events	/SAS/Melissa CLC Project2/Files/SDTM/data	CABC123D4567E1 Study SDTM 3...
☒	CM	Concomitant Medications	/SAS/Melissa CLC Project2/Files/SDTM/data	CABC123D4567E1 Study SDTM 3...
☒	DA	Drug Accountability	/SAS/Melissa CLC Project2/Files/SDTM/data	CABC123D4567E1 Study SDTM 3...
☒	DM	Demographics	/SAS/Melissa CLC Project2/Files/SDTM/data	CABC123D4567E1 Study SDTM 3...
☒	DS	Disposition	/SAS/Melissa CLC Project2/Files/SDTM/data	CABC123D4567E1 Study SDTM 3...

Selected: AE, CM, DA, DM, DS, EG, EX, IE, LB, MH, PE, QSCG, QSCS, QSM, RELREC, SC, SE, SUPPAE, SUPPCM, SUPPDM, SUPPEG, SUPPEX, SUPPLB, SUPPOSCG, SUPPOSCS, SUPPOSM, SUPPV, SV, TA, TE, TI, TS, TV, VS

Define-XML output folder: *
Browse to a repository folder

☐ Overwrite existing files

File encoding: * UTF-8

☐ Add style sheet for HTML display

Versioning

Check in comment:

☐ Enable versioning

Version to be applied to all output files:
☒ Major
☐ Minor
☐ Custom

1.0

- Once it completes, your define.xml file and the stylesheet will appear in the location you specified in the Repository.

SDTM-IG 3.1.2
Annotated Case Report Form
Complex Algorithms
Reviewers Guide
► Tabulation Datasets
► Value Level Metadata
► Controlled Terminology
► Computational Algorithms
► Comments

Date of document generation: 2016-05-09T00:04:18+00:00
Stylesheet version: 2014-09-03

Tabulation Datasets for Study CLC Test Study 2 (SDTM-IG 3.1.2)

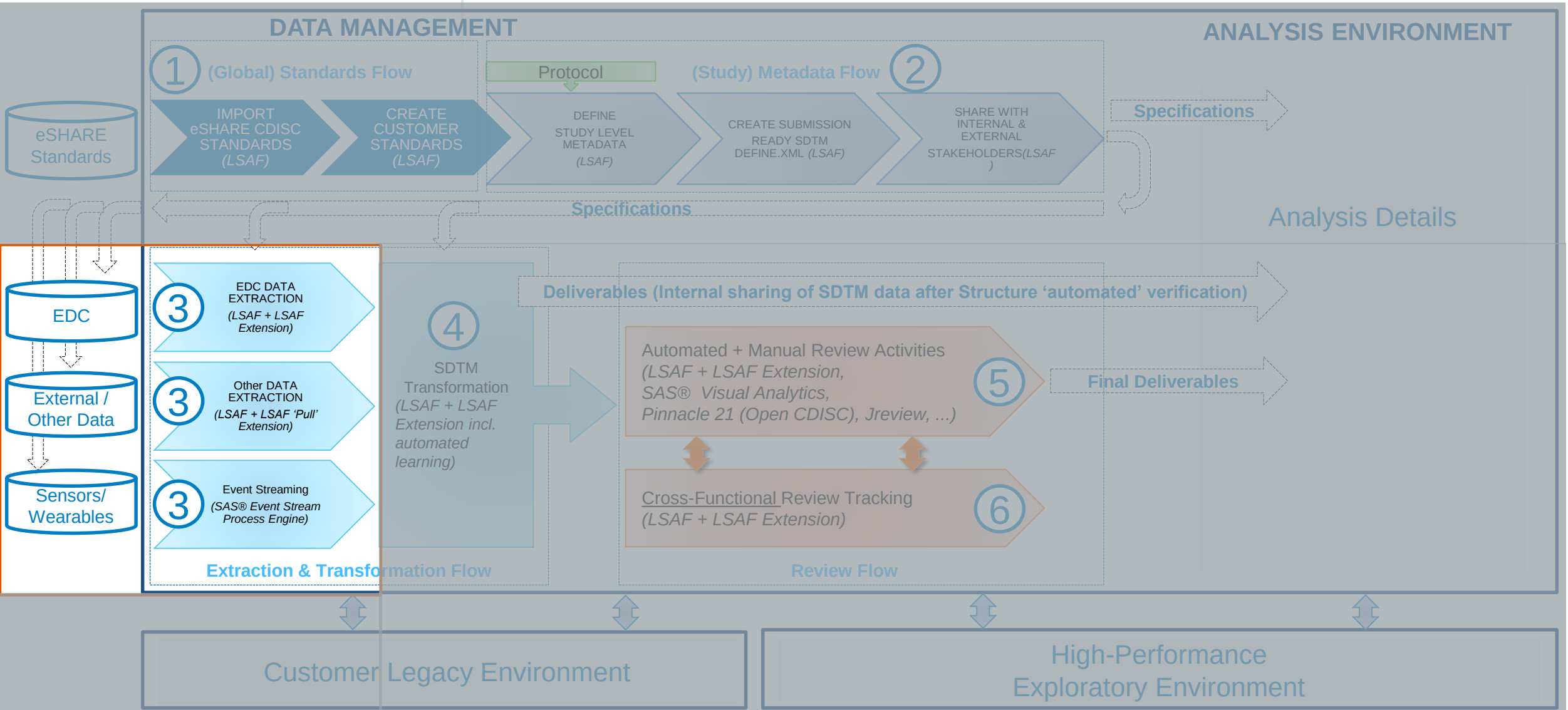
Dataset	Description	Class	Structure	Purpose	Keys	Location	Documentation
AE	Adverse Events	EVENTS	One record per adverse event per subject	Tabulation	STUDYID, USUBJID, AEDECOD, AESTDTC	ae.xpt	
CM	Concomitant Medications	INTERVENTIONS	One record per recorded medication occurrence or constant-dosing interval per subject	Tabulation	STUDYID, USUBJID, CMSTDTC, CMENDTC, CMCAT, CMTRT, CMDOSTXT, CMDOSU, CMINDC, CMDOSFRQ	cm.xpt	
DA	Drug Accountability	FIND					
DM	Demographics	SPEC PURP					
DS	Disposition	EVEN					

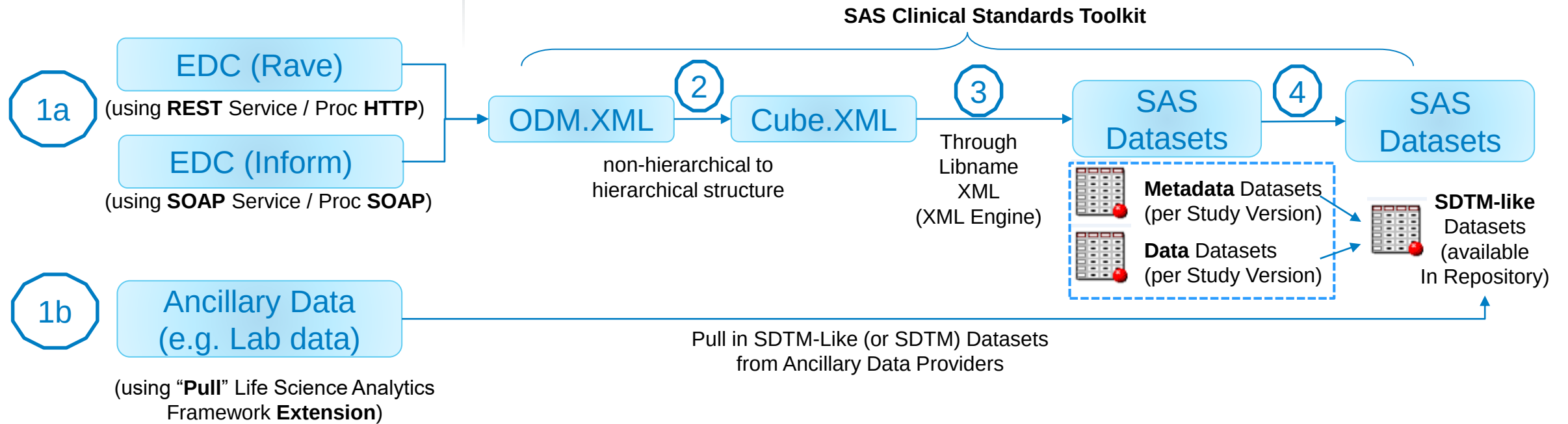
Adverse Events (AE) [Location: [ae.xpt](#)]

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
STUDYID	Study Identifier	1	text	7		Protocol	
DOMAIN	Domain Abbreviation		text	2	["AE"] <AEDOM>	Assigned	
USUBJID	Unique Subject Identifier	2	text	14		Derived	Concatenation of STUDYID and SUBJID
AESEQ	Sequence Number		integer	1		Derived	Sequential number identifying records within each USUBJID in the domain.
AESPID	Sponsor-Defined Identifier		text	4		CRF Page 21	
AESTDTC	Reported Start Date/Time		text	25		CRF	

Reviewers Guide
► Tabulation Datasets
► Value Level Metadata
► Controlled Terminology
► Computational Algorithms
► Comments

- Use Repository to share with Internal & External Stakeholders:
 - For **Review**
 - For **Specifications**: e.g. Stats-Programming; DM-CRO; ...
- Make use of Workflow Engine and Notifications (email or within Life Science Analytics Framework)





(example) ODM XML 1.3.0 – Data

```
<?xml version="1.0" encoding="UTF-8"?>
<ODM xmlns="http://www.cdisc.org/ns/odm/v1.3" xmlns:xlink="http://www.w3.org/1999/xhtml" xmlns:cdm="http://www.cdisc.org/ns/odm/v1.3" CreationDateTime="2016-05-11T02:16:17.836-0000" FileID="f0b94841-182f-44de-ad8c-d4102ab6f414" FileType="Transactional">
  <ClinicalData MetaDataVersionOID="298" StudyOID="SAS_CDI">
    <SubjectData SubjectKey="011-003">
      <SiteRef LocationOID="3001"/>
      <StudyEventData StudyEventOID="SUBJECT">
        <FormData FormRepeatKey="1" FormOID="AE">
          <ItemGroupData TransactionType="Insert" ItemGroupRepeatKey="11" ItemGroupOID="AE_LOG_LINE">
            <ItemData Value="POLYURIA" ItemOID="AE.AETERM"/>
            <ItemData ItemOID="AE.AEOCCUR" IsNull="Yes"/>
            <ItemData ItemOID="AE.AEOCCUR_STD" IsNull="Yes"/>
            <ItemData ItemOID="AE.AEOCCUR.DECODE" IsNull="Yes"/>
            <ItemData Value="YESNO" ItemOID="AE.AEOCCUR.CODELIST"/>
            <ItemData Value="2007-11-09" ItemOID="AE.AESTDAT"/>
            <ItemData Value="09 NOV 2007" ItemOID="AE.AESTDAT.RAW"/>
            <ItemData Value="2007-11-09" ItemOID="AE.AEENDAT"/>
            <ItemData Value="09 NOV 2007" ItemOID="AE.AEENDAT.RAW"/>
            <ItemData ItemOID="AE.AEONGO" IsNull="Yes"/>
            <ItemData ItemOID="AE.AEONGO.RAW" IsNull="Yes"/>
            <ItemData Value="Severe" ItemOID="AE.AESEV"/>
            <ItemData Value="SEVERE" ItemOID="AE.AESEV_STD"/>
            <ItemData Value="Severe" ItemOID="AE.AESEV.DECODE"/>
            <ItemData Value="AESEVERITY" ItemOID="AE.AESEV.CODELIST"/>
            <ItemData ItemOID="AE.AETOXGR" IsNull="Yes"/>
            <ItemData ItemOID="AE.AETOXGR_STD" IsNull="Yes"/>
            <ItemData ItemOID="AE.AETOXGR.DECODE" IsNull="Yes"/>
            <ItemData Value="CTC OXICITY GRADE" ItemOID="AE.AETOXGR.CODELIST"/>
            <ItemData Value="Yes" ItemOID="AE.AESER"/>
            <ItemData Value="Y" ItemOID="AE.AESER_STD"/>
            <ItemData Value="Yes" ItemOID="AE.AESER.DECODE"/>
            <ItemData Value="YESNO" ItemOID="AE.AESER.CODELIST"/>
            <ItemData ItemOID="AE.AESDTH" IsNull="Yes"/>
            <ItemData ItemOID="AE.AESDTH.RAW" IsNull="Yes"/>
            <ItemData ItemOID="AE.AESLIFE" IsNull="Yes"/>
            <ItemData ItemOID="AE.AESLIFE.RAW" IsNull="Yes"/>
            <ItemData ItemOID="AE.AESHOSP" IsNull="Yes"/>
            <ItemData ItemOID="AE.AESHOSP.RAW" IsNull="Yes"/>
            <ItemData ItemOID="AE.AESSISAB" IsNull="Yes"/>
            <ItemData ItemOID="AE.AESSISAB.RAW" IsNull="Yes"/>
            <ItemData ItemOID="AE.AESCONG" IsNull="Yes"/>
            <ItemData ItemOID="AE.AESCONG.RAW" IsNull="Yes"/>
            <ItemData ItemOID="AE.AESMIE" IsNull="Yes"/>
            <ItemData ItemOID="AE.AESMIE.RAW" IsNull="Yes"/>
            <ItemData Value="Not Related" ItemOID="AE.AEREL"/>
            <ItemData Value="NOT RELATED" ItemOID="AE.AEREL_STD"/>
            <ItemData Value="Not Related" ItemOID="AE.AEREL.DECODE"/>
            <ItemData Value="RELATIONSHIP" ItemOID="AE.AEREL.CODELIST"/>
            <ItemData ItemOID="AE.AEACN" IsNull="Yes"/>
            <ItemData ItemOID="AE.AEACN_STD" IsNull="Yes"/>
            <ItemData ItemOID="AE.AEACN.DECODE" IsNull="Yes"/>
            <ItemData Value="AE ACTION TAKEN" ItemOID="AE.AEACN.CODELIST"/>
            <ItemData ItemOID="AE.AEACNOTH" IsNull="Yes"/>
            <ItemData ItemOID="AE.AEOUT" IsNull="Yes"/>
            <ItemData ItemOID="AE.AEOUT_STD" IsNull="Yes"/>
            <ItemData ItemOID="AE.AEOUT.DECODE" IsNull="Yes"/>
            <ItemData Value="OUTCOME" ItemOID="AE.AEOUT.CODELIST"/>
            <ItemData ItemOID="AE.AEDIS" IsNull="Yes"/>
            <ItemData ItemOID="AE.AEDIS_STD" IsNull="Yes"/>
            <ItemData ItemOID="AE.AEDIS.DECODE" IsNull="Yes"/>
            <ItemData Value="YESNO" ItemOID="AE.AEDIS.CODELIST"/>
          </ItemGroupData>
        </FormData>
      </StudyEventData>
    </SubjectData>
  </ClinicalData>
</ODM>
```

(Example) Cube XML – Metadata

```
<?xml version="1.0" encoding="UTF-8"?>
- <LIBRARY xmlns="http://www.phaseforward.com/InFormAdapter/ODM/2.0">
  - <ODM>
    <FileOID>d087589c-0233-49a5-941b-282b801375af</FileOID>
    <Archival/>
    <AsOfDateTime/>
    <CreationDateTime>2016-05-11T17:42:37.857-00:00</CreationDateTime>
    <Description/>
    <FileType>Snapshot</FileType>
    <Granularity>Metadata</Granularity>
    <Id/>
    <ODMVersion>1.3</ODMVersion>
    <Originator/>
    <PriorFileOID/>
    <SourceSystem/>
    <SourceSystemVersion/>
    <pf:InFormAdapterVersion xmlns:pf="http://www.phaseforward.com/InFormAdapter/ODM/Extensions/2.0"/>
    <pf:MappingVersion xmlns:pf="http://www.phaseforward.com/InFormAdapter/ODM/Extensions/2.0"/>
    <pf:HierarchicalOIDs xmlns:pf="http://www.phaseforward.com/InFormAdapter/ODM/Extensions/2.0"/>
  </ODM>
  - <Study xmlns="">
    <OID>SAS_CDI</OID>
    <StudyName>SAS_CDI</StudyName>
    <StudyDescription/>
    <ProtocolName>SAS_CDI</ProtocolName>
    <FK_ODM>d087589c-0233-49a5-941b-282b801375af</FK_ODM>
  </Study>
  - <MeasurementUnits xmlns="">
    <OID>298.VS Units BMI.kg/m2</OID>
    <Name>kg/m2</Name>
    <FK_Study>SAS_CDI</FK_Study>
  </MeasurementUnits>
  - <MeasurementUnits xmlns="">
    <OID>298.VS Units BODYFAT.%</OID>
    <Name>%</Name>
    <FK_Study>SAS_CDI</FK_Study>
  </MeasurementUnits>
  - <MeasurementUnits xmlns="">
    <OID>298.VS Units BODYFAT.ohm</OID>
    <Name>ohm</Name>
    <FK_Study>SAS_CDI</FK_Study>
  </MeasurementUnits>
  - <MeasurementUnits xmlns="">
    <OID>298.VS Units BSA.m2</OID>
    <Name>m2</Name>
    <FK_Study>SAS_CDI</FK_Study>
  </MeasurementUnits>
  - <MeasurementUnits xmlns="">
    <OID>298.VS Units DIABP.mmHg</OID>
```

(Example) Cube XML – Data

```
<?xml version="1.0" encoding="UTF-8"?>
- <LIBRARY xmlns="http://www.phaseforward.com/InFormAdapter/ODM/2.0">
  - <ODM>
    <FileOID>bc2d9422-e121-42d1-88c0-fa8f5f3d82fa</FileOID>
    <Archival/>
    <AsOfDateTime/>
    <CreationDateTime>2016-05-09T12:42:43.091-00:00</CreationDateTime>
    <Description/>
    <FileType>Transactional</FileType>
    <Granularity/>
    <Id/>
    <ODMVersion>1.3</ODMVersion>
    <Originator/>
    <PriorFileOID/>
    <SourceSystem/>
    <SourceSystemVersion/>
    <pf:InFormAdapterVersion xmlns:pf="http://www.phaseforward.com/InFormAdapter/ODM/Extensions/2.0"/>
    <pf:MappingVersion xmlns:pf="http://www.phaseforward.com/InFormAdapter/ODM/Extensions/2.0"/>
    <pf:HierarchicalOIDs xmlns:pf="http://www.phaseforward.com/InFormAdapter/ODM/Extensions/2.0"/>
  </ODM>
  - <ClinicalData>
    <OID>N65547</OID>
    <StudyOID>SAS_CDI</StudyOID>
    <MetaDataVersionOID>298</MetaDataVersionOID>
    <pf:TransactionGuid xmlns:pf="http://www.phaseforward.com/InFormAdapter/ODM/Extensions/2.0"/>
    <pf:Revision xmlns:pf="http://www.phaseforward.com/InFormAdapter/ODM/Extensions/2.0"/>
    <FK_ODM>bc2d9422-e121-42d1-88c0-fa8f5f3d82fa</FK_ODM>
  </ClinicalData>
  - <SubjectData>
    <OID>N65551</OID>
    <SubjectKey>011-003</SubjectKey>
    <State/>
    <ScreenFailReason/>
    <EnrollFailReason/>
    <EnrollOverrideReason/>
    <DropoutReason/>
    <SVReady/>
    <Frozen/>
    <Locked/>
    <LocationOID>3001</LocationOID>
    <TransactionType/>
    <pf:GUID xmlns:pf="http://www.phaseforward.com/InFormAdapter/ODM/Extensions/2.0"/>
    <Audit_UserOID/>
    <Audit_LocationOID/>
    <Audit_DateTimeStamp/>
    <Audit_ReasonForChange/>
    <FK_ClinicalData>N65547</FK_ClinicalData>
  </SubjectData>
```

SAS Datasets – Metadata

- itemquestionexternal.sas7bdat
- itemquestiontranslatedtext.sas7bdat
- itemrangechecks.sas7bdat
- itemrangecheckvalues.sas7bdat
- itemrcformaleexpression.sas7bdat
- itemrole.sas7bdat
- keyset.sas7bdat
- location.sas7bdat
- locationversion.sas7bdat
- measurementunits.sas7bdat
- metadataversion.sas7bdat
- methoddefformaleexpression.sas7bdat
- methoddefs.sas7bdat
- methoddeftranslatedtext.sas7bdat
- mutranslatedtext.sas7bdat
- odm.sas7bdat
- odmfmtcat_de.sas7bcat
- odmfmtcat_en.sas7bcat
- odmfmtcat_ja.sas7bcat
- odmfmtcat_zh.sas7bcat
- presentation.sas7bdat
- protocoleventrefs.sas7bdat

- admindata.sas7bdat
- annotation.sas7bdat
- annotationflag.sas7bdat
- association.sas7bdat
- auditrecord.sas7bdat
- clinicaldata.sas7bdat
- clitemdecodetranslatedtext.sas7bdat
- codelistitems.sas7bdat
- codelists.sas7bdat
- conditiondefformaleexpression.sas7bdat
- conditiondefs.sas7bdat
- conditiondeftranslatedtext.sas7bdat
- enumerateditems.sas7bdat
- externalcodelists.sas7bdat
- formdata.sas7bdat
- formdefarchlayouts.sas7bdat
- formdefitemgrouprefs.sas7bdat
- formdefs.sas7bdat
- formdeftranslatedtext.sas7bdat
- imputationmethods.sas7bdat
- itemaliases.sas7bdat
- itemdata.sas7bdat
- itemdefs.sas7bdat
- itemdeftranslatedtext.sas7bdat

SAS Datasets – Data

Address

Library ITEMDATA

Freeze Hide Show... Format Filter... Font... Find

Table View

	OID	ItemOID	TransactionType	TransactionOrder	Value	IsNull	ItemData Type	FK_ItemGroupData
1	N65569	AE.AETERM		1	POLYURIA			N65564
2	N65573	AE.AEOCCUR		2		Yes		N65564
3	N65577	AE.AEOCCUR_S...		3		Yes		N65564
4	N65581	AE.AEOCCUR.D...		4		Yes		N65564
5	N65585	AE.AEOCCUR.C...		5	YESNO			N65564
6	N65589	AE.AESTDAT		6	2007-11-09			N65564
7	N65593	AE.AESTDAT.R...		7	09 NOV 2007			N65564
8	N65597	AE.AEENDAT		8	2007-11-09			N65564
9	N65601	AE.AEENDAT.R...		9	09 NOV 2007			N65564
10	N65605	AE.AEONGO		10		Yes		N65564
11	N65609	AE.AEONGO.RAW		11		Yes		N65564
12	N65613	AE.AESEV		12	Severe			N65564
13	N65617	AE.AESEV_STD		13	SEVERE			N65564
14	N65621	AE.AESEV.DEC...		14	Severe			N65564
15	N65625	AE.AESEV.COD...		15	AESEVERITY			N65564
16	N65629	AE.AETOXGR		16		Yes		N65564
17	N65633	AE.AETOXGR_S...		17		Yes		N65564

Rows 1-312 of 312 Filter: Off Sort: none

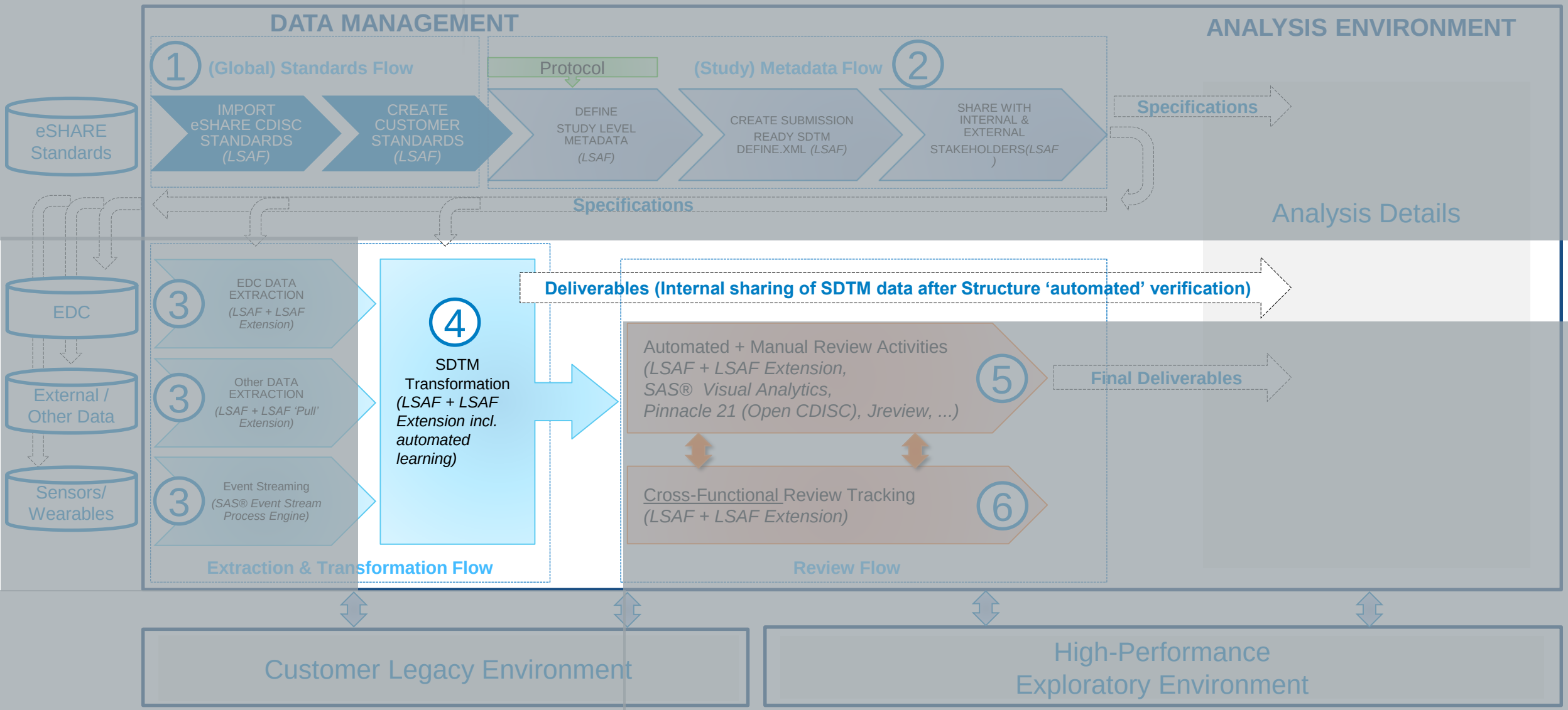
SAS Datasets – SDTM ‘like’

Library AE

Freeze Hide Show... Format Filter... Font... Find

Table View

	__StudyOID	__MetaDataVersion	__SubjectKey	__StudyEventOID	__StudyEventRepe	__FormOID	__FormRepeatKey	__ItemGroupOID	__ItemGroupRepe	__TransactionType	__LocationOID	__UserOID	__STUDYVERSION	AETERM	AEOCCUR	AEOX
1	SAS_CDI	298	011-003	SUBJECT		AE	1	AE_LOG_LINE	11	Insert				POLYURIA		
2	SAS_CDI	298	011-005	SUBJECT		AE	1	AE_LOG_LINE	11	Insert				INCREASED LIV...		
3	SAS_CDI	298	011-005	SUBJECT		AE	1	AE_LOG_LINE	15	Insert				PULMONARY E...		
4	SAS_CDI	298	011-005	SUBJECT		AE	1	AE_LOG_LINE	16	Insert				RENAL INSUFFI...		
5	SAS_CDI	298	081-001	SUBJECT		AE	1	AE_LOG_LINE	6	Insert				INTERMITTENT...		
6	SAS_CDI	298	401-001	SUBJECT		AE	1	AE_LOG_LINE	3	Insert				VASOSPASM		



Goal

- Mapping kick-offs each time data (sas datasets / sdTM-'like') are being refreshed in Repository
 - SDTM Mapping 'Rule' to be setup per trial to trigger 'mapping' automation
 - Same as 'Adaptive Design' rules e.g. 30 patients, 60 patients, ...

- Mapping through Automated Learning
 - as more Standards are being used greater % re-usability over time
 - less manual interaction for new trials / setup to be done → Review required especially at start

- Code generation (based on 'pseudo code' entry via UI)
 - Already done within SAS Clinical Data Integration Studio → Re-using capabilities for Life Science Analytics Extension

The screenshot displays the SAS Repository web interface. The top navigation bar includes 'Studies and Data Standards' and 'Interactive Sessions'. The main menu has 'View', 'Tools', 'Administration', and 'Help'. The breadcrumb trail shows the path: /SAS/CABC123D/CABC123D4567E1.

The left sidebar shows a tree view of the repository structure, with 'CABC123D456...' selected. The main area displays a table of repository objects with columns: Name, Size, Modified By, Date Modified, Signed, Repository Version, and Workspace Status.

The 'Manage Extended Attributes' dialog box is open, showing a list of attributes on the left and a table of attribute values on the right. The 'File' attribute is selected, and its value is 'Additional customer extended attribute'. The 'Type' dropdown is set to 'Character'.

The 'Properties' panel on the right shows the details for the selected object, including Name, Description, State, Created by, Lead, Date created, Modified by, Date modified, Properties modified by, Properties date modified, and Copy to workspace.

A blue double-headed arrow indicates the relationship between the 'Additional customer extended attribute' in the 'Manage Extended Attributes' dialog and the 'Description' field in the 'Properties' panel.

The bottom status bar shows 'Action Status' and 'User: Stijn Rogiers'.

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Twitter: @stijnrogiers



"Harris, when I said 'any questions' I was using only a figure of speech."

