



**THE
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CDISC end-to-end in SAS

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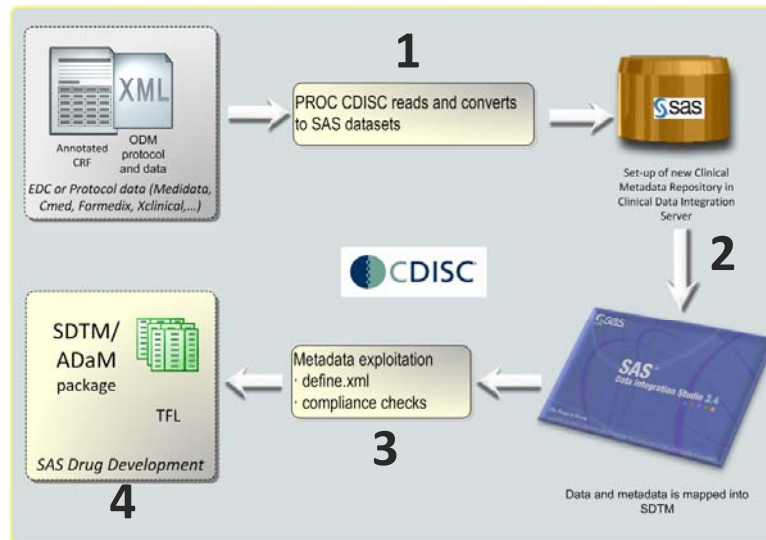
**THE
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Importing ODM into SAS

Part 1

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Steps in demonstration



Short intro to SAS and CDISC

- PROC CDISC
- Clinical Standards Toolkit

PROC CDISC

- Input CDISC ODM XML files to SAS data set(s)
- Output SAS data set content to CDISC ODM XML
- Validates CDISC SDTM content against model

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Clinical Standards Toolkit

- Set of macros designed to supersede Proc CDISC
- Free to existing SAS customers
- Built into Clinical Data Integration

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Clinical Toolkit: Framework

V1.2

- CDISC SDTM Framework
- CDISC CRT-DDS Framework
- CDISC Terminology Framework
- Toolkit Utility Framework

Example Methods

```
%sdm_validate(...);
%sdm_report_validationResults();
%sdm_create_terms(...);
%sdm_create_domainType(...);
%sdm_create_domains(...);

%crtdds_validate(...);
%crtdds_report_validationResults(...);
%crtdds_create_terms(...);
%crtdds_write(...);
%crtdds_read(...);

%cterm_create_package(...);
```

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Clinical Toolkit: Pluggable Modules

V1.2

- CDISC SDTM Framework
- CDISC CRT-DDS Framework
- CDISC Terminology Framework
- Toolkit Utility Framework

SDTM V3.1.1 Module

SDTM V3.1.2 Module

CRT-DDS V1.0 Module

Terminology SDTM-1 Module

Terminology LABTEST Module

Terminology SDTM-2A Module

Terminology SDTM-2B Module

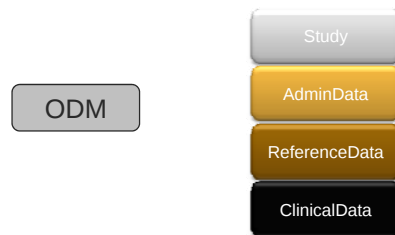
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Clinical Data Integration functionalities

- SAS code-based solution
- Robust generation of processes that transform and integrate data
- Extensive process library to process data
- Included SDTM 3.1.1 IG data model
- Extensible with user-written SAS code transformations

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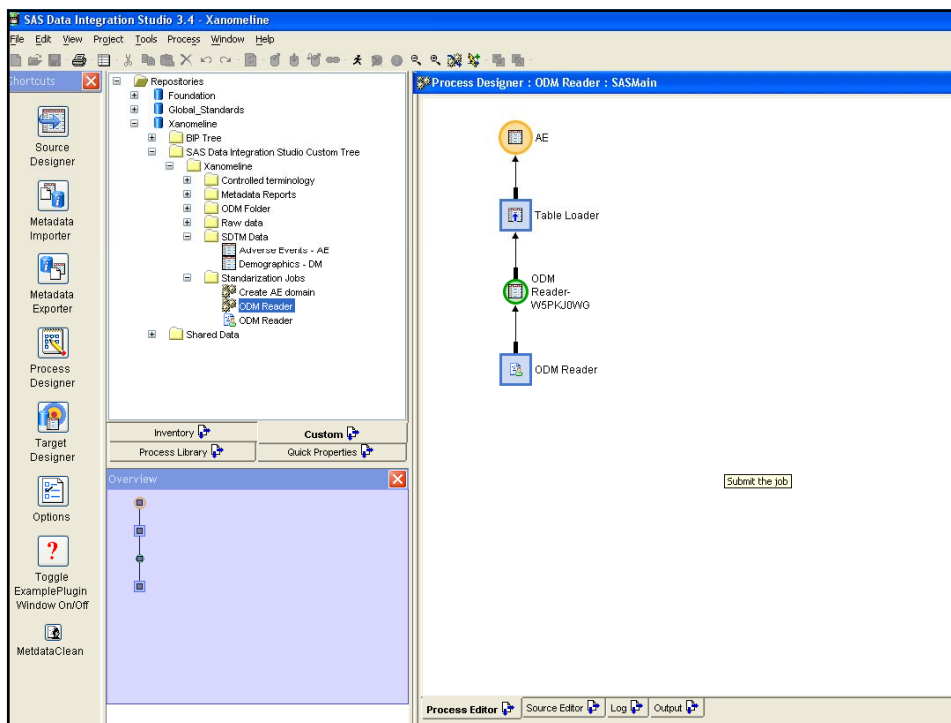
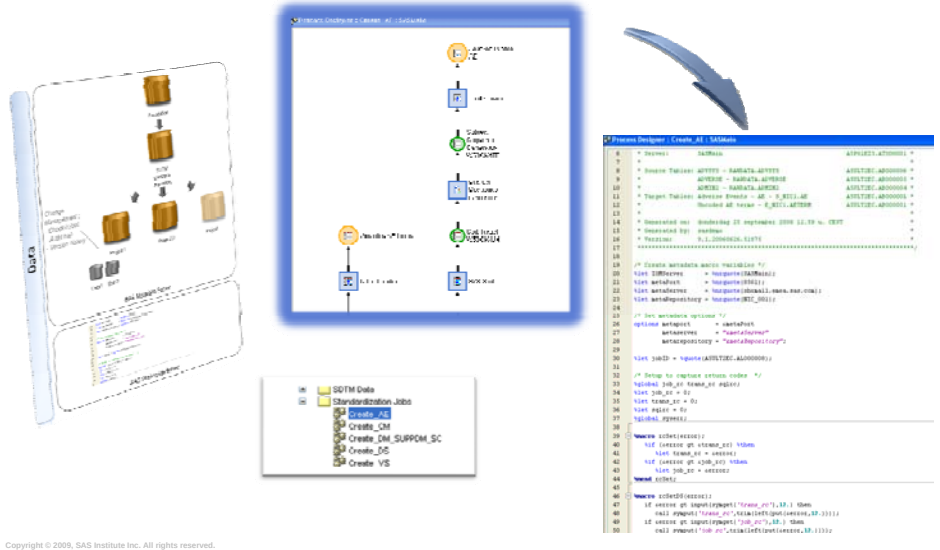
Glossary for ODM



- StudyEvent : patient visit
- Form : data-entry form
- ItemGroup : panel or SAS dataset
- Item : a dataset variable or SAS field
- Codelist : SAS format or lookup table

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Creation of processes in Clinical Data Integration





SAS System Viewer - [ae_sas7bdat]

_Subject Key	VISITNUM	AESER	AEREL	AESEV	AECCUR	AEOGT	AENDTC	AESTDTC	AETERM
1 Subject.1	1	.	2	2	yes	HEADACHE	05MAY2009	04MAY2009	Headache
2 Subject.1	2	.	3	1	yes	NAUSEA	14MAY2009	13MAY2009	Nausea
3 Subject.2	1	.	2	2	yes	NAUSEA	06APR2009	06APR2009	Stomach
4 Subject.3	2	.	3	1	yes	NAUSEA			
5 Subject.4	1	.	2	2	yes	NAUSEA			

Output

EVENT NAME	AERELAT	LENGTH	NUMBER OF MIN LENGTH	1 MAX LENGTH	16 DEFINITE LENGTH	17
1	HEADACHE	10	10	10	10	10
2	NAUSEA	10	10	10	10	10
3	NAUSEA	10	10	10	10	10
4	NAUSEA	10	10	10	10	10

Ready

FORMATT NAME: AHEAD LENGTH: 15 NUMBER OF UNLIS: 4			
MIN LENGTH: 1 MAX LENGTH: 15		DEFAULT LENGTH: 15 FUGZ: 0	
START	END	LABEL: UWER. VTJWE 24M02009.31.37.42	
1	2	None	
2	3	Functional(ly)	
3	4	Passible	
4	5	Probable	

FORMATT NAME: AHEAD LENGTH: 21 NUMBER OF UNLIS: 8			
MIN LENGTH: 1 MAX LENGTH: 21		DEFAULT LENGTH: 21 FUGZ: 0	
START	END	LABEL: UWER. VTJWE 24M02009.31.37.42	
1	2	Patak	
2	3	For transiting	
3	4	Permanently dishing	
4	5	Preliminary	
5	6	Consequential anomaly	
6	7	Lower	
7	8	Overdue	
8	9	Other reason	

FORMATT NAME: AHEAD LENGTH: 8 NUMBER OF UNLIS: 3			
MIN LENGTH: 1 MAX LENGTH: 8		DEFAULT LENGTH: 8 FUGZ: 0	
START	END	LABEL: UWER. VTJWE 24M02009.31.37.42	
1	2	Prid	
2	3	Severe	

Reading additional elements

The screenshot displays the SAS XMLMap application. The left pane shows the XML schema tree for 'StudyMilestone'. The right pane shows the 'Properties' for the selected 'StudyEventOID' element, including 'Version' (1) and 'Encoding' (UTF-8). The bottom pane shows a table with data for the 'StudyMilestone' row, including columns for 'OID', 'Name', 'StudyEventOID', 'Mandatory', 'OID1', 'Name1', 'Repeating', 'Type', and 'Category'.

OID	Name	StudyEventOID	Mandatory	OID1	Name1	Repeating	Type	Category
STUDYMILESTONE1	PostTreatmentFollow-up 2.0.EVT00002	Yes	EVT00002	Screening Visit 2_R0	Scheduled screening			







Mapping into SDTM, ADaM standards

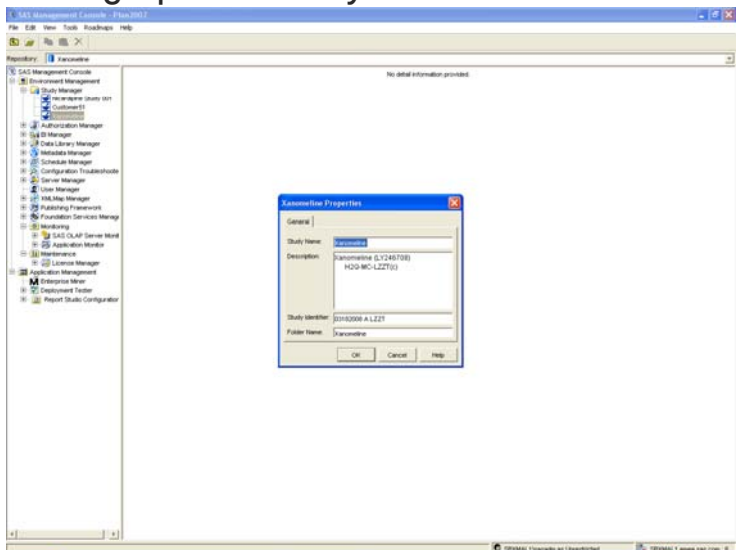
Part 2



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Setting up new study in SAS



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Accessing Codelists as SAS formats

Load raw AE domain Properties

General Where Order By Group By Process Mapping Options Notes Extended Attributes Advanced

Source table: AE

#	Column	Column Description
1	SubjectKey	
2	VISITNUM	
3	AESER	
4	AEREL	
5	AESEV	
6	AEOCCUR	
7	AECOST	
8	AEENDTC	
9	AESTDTC	
10	AETERM	

Target table: WSPKEOCQ

#	Column	Expression	Column Description
1	SubjectKey		
2	DM	'AE'	
3	STUDID	'STD00001'	
4	USUBID		
5	VISITNUM		
6	AESER	put(AESER, aeser.)	
7	AEREL	put(AEREL, aerele.)	
8	AESEV	put(AESEV, aesev.)	
9	AEOCCUR		
10	AECOST		
11	AEENDTC		
12	AESTDTC		
13	AETERM		
14	AEDECOD		
15	AESQ		

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ISO8601 date-time formats

31	AESMIE	
32	AECONTRT	
33	AETOXGR	
34	AESTDTC	CASE AESTDTC WHEN , THEN " ELSE PUT (DHMS (AESTDTC , 0 , 0 , 0) , IS8601DT.)
35	AEENDTC	CASE AEENDTC WHEN , THEN " ELSE PUT (DHMS (AEENDTC , 0 , 0 , 0) , IS8601DT.) EN
36	AESTDY	
37	AEENDY	
38	AEDUR	

Report

https://dragondemo.usc.com/webdev/DORA?url=file:///E:/A/HKansu/ESG/Report/tse_report.pdf

Address bar shows the URL.

The browser displays the title "Incidence of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term, Sort by p-value."

A sidebar on the left lists navigation options:

- Home
- The Report Procedure
- Download and/or summarized report

The main content area contains a table titled "Description of Planned ARM". The table has columns for "Placebo", "Xanomeline", and "Fishery Exact P-value". The rows represent different adverse events, sorted by p-value.

Reported Term for AE	Description of Planned ARM		Fishery Exact P-value
	Placebo	Xanomeline	
	N (%)	N (%)	
Any Adverse Events	2 (66)	1 (50)	1.000
Gastro : Total	2 (66)	1 (50)	1.000
Gastro : NAUSEA	2 (66)	1 (50)	1.000

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define.xml metadata



- **Codelists**
 - Codelist conversion table
 - Value Level Metadata
 - VLM Transpose table
- **Computational Algorithm**
- **XML Parameters**
 - Study Title
 - External Dictionary
 - Create Date
 - Supplemental Document Links

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Metadata exploitation



- SDTM validation checks : with Clinical Standards Toolkit
- Other utility jobs (e.g. QC contents)

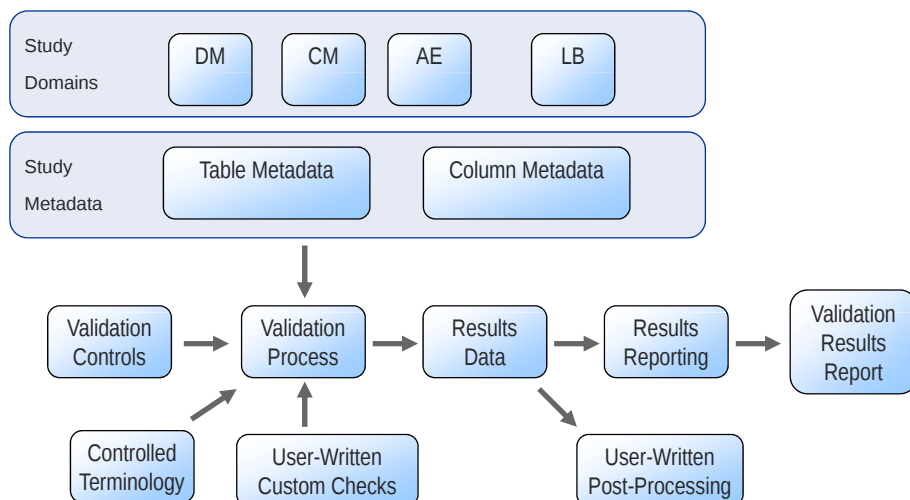
DATA.AE

Variable	Label	Type	Length	Column	Values
AE01	Adverse Event	Character	1	1	1288_0000_00000 (1x)
AE02	Adverse Event	Character	1	2	1288_0000_00007 (2x)
AE03	Adverse Event	Character	1	3	1288_0000_00010 (1x)
AE04	Adverse Event	Character	1	4	1288_0000_00012 (2x)
AE05	Adverse Event	Character	1	5	1288_0000_00015 (1x)
AE06	Adverse Event	Character	1	6	1288_0000_00018 (1x)
AE07	Adverse Event	Character	1	7	1288_0000_00020 (2x)
AE08	Adverse Event	Character	1	8	1288_0000_00022 (2x)
AE09	Adverse Event	Character	1	9	1288_0000_00024 (2x)
AE10	Adverse Event	Character	1	10	1288_0000_00026 (1x)
AE11	Adverse Event	Character	1	11	1288_0000_00028 (1x)
AE12	Adverse Event	Character	1	12	1288_0000_00030 (1x)
AE13	Adverse Event	Character	1	13	1288_0000_00032 (1x)
AE14	Adverse Event	Character	1	14	1288_0000_00034 (2x)

19 distinct values, 0 missing values, all shown

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Validation Process



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Conclusion on using this methodology

- CDISC SDTM/ADaM expertise remains crucial
- Changed our thinking about metadata
 - We have turned it from deliverables into a central component for our conversions.
 - We create it at the very beginning of the process, and start using it as a valuable process driver
 - Metadata is fun!!... once we realized its value
- SAS is ready to support end-to-end CDISC
 - Integrated with operational systems (EDC)
 - End-to-end metadata and data
 - A clinical repository for data, metadata and transformation analysis code

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