CDISC end-to-end in SAS

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May 27th 2009

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Importing ODM into SAS

Part 1

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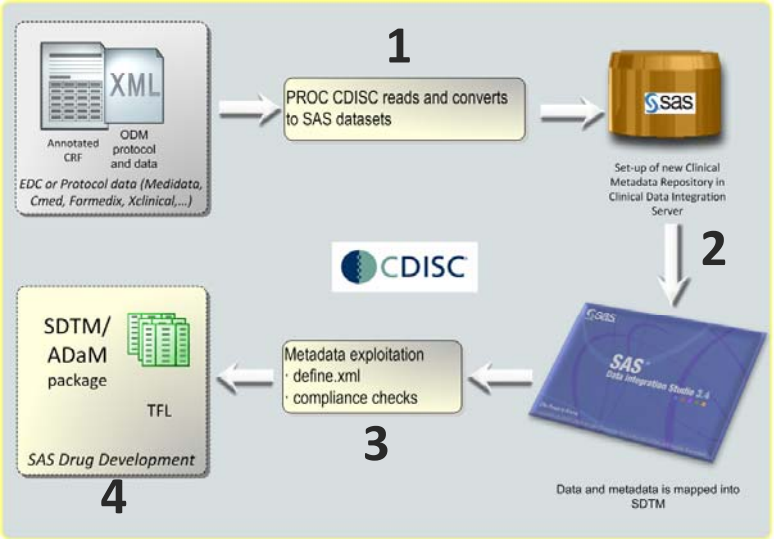
Steps in demonstration



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Short intro to SAS and CDISC

- PROC CDISC
- Clinical Standards Toolkit

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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

```
%sdtm_validate(…);
%sdtm_report_validationResults();
%sdtm_create_cterms(…);
%sdtm_create_domainType(…);
%sdtm_create_domains(…);

%crtdds_validate(…);
%crtdds_report_validationResults(…);
%crtdds_create_cterms(…);
%crtdds_write(…);
%crtdds_read(…);

%cterms_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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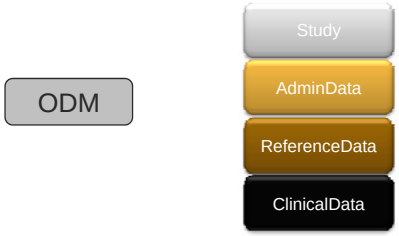
Glossary for ODM



- 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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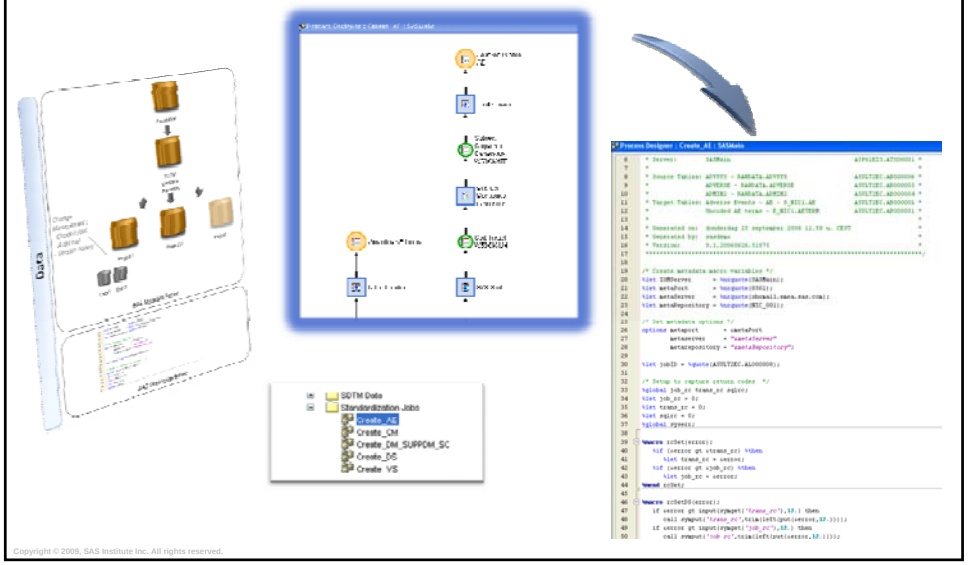
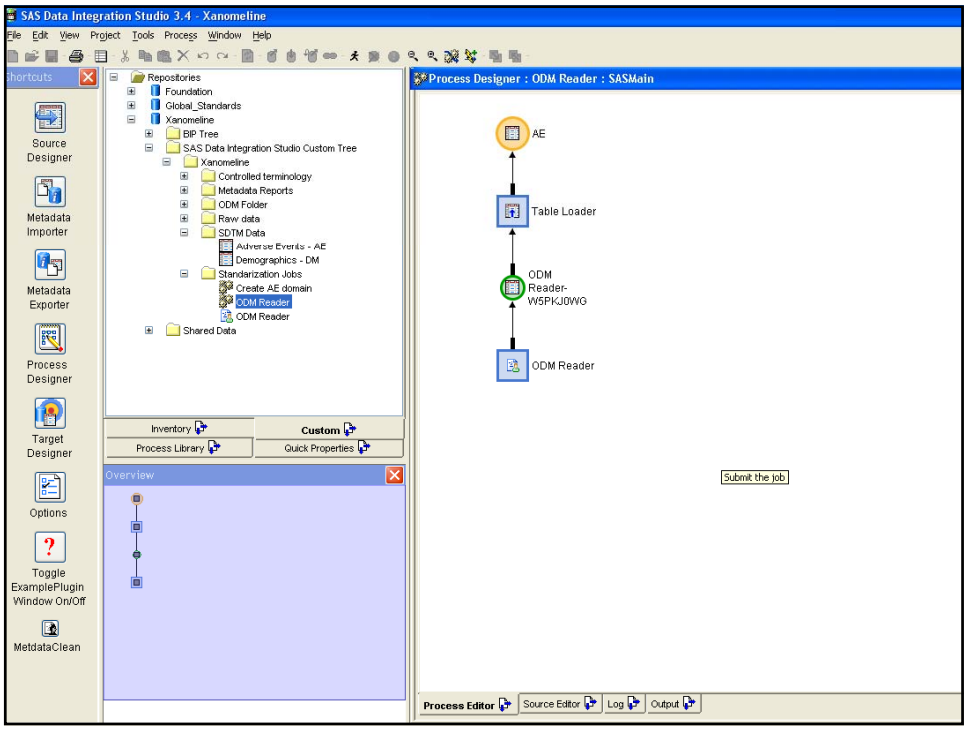
Creation of processes in Clinical Data Integration





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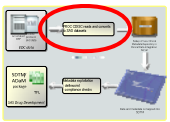
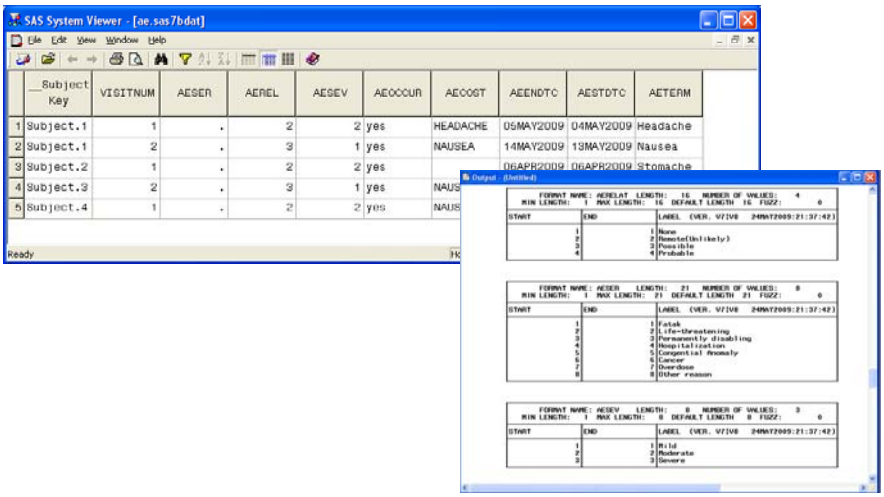
Reading ODM





	Subject Key	VISITNUM	AESER	AEREL	AESEV	AEOCCUR	AECOGT	AEENDTC	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		06APR2009	06APR2009	Stomache
4	Subject.3	2	.	3	1	yes	NAUS			
5	Subject.4	1	.	2	2	yes	NAUS			

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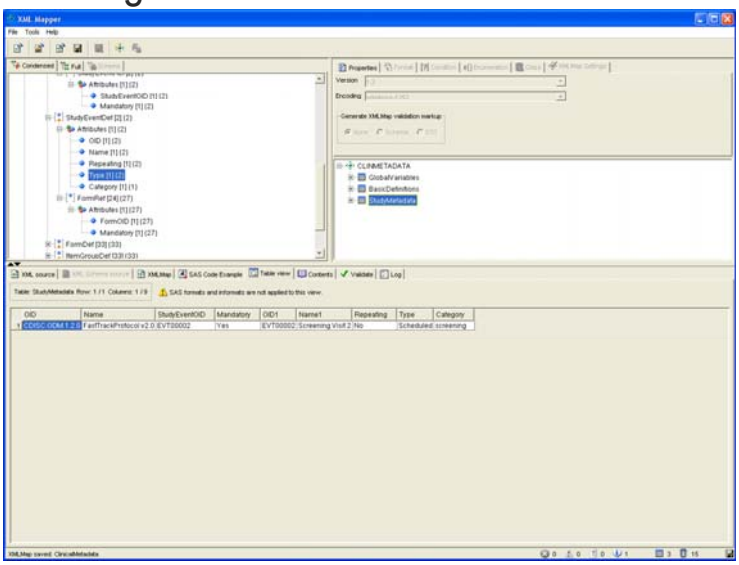
Reading additional elements



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Mapping into SDTM, ADaM standards

Part 2

THE POWER TO KNOW.

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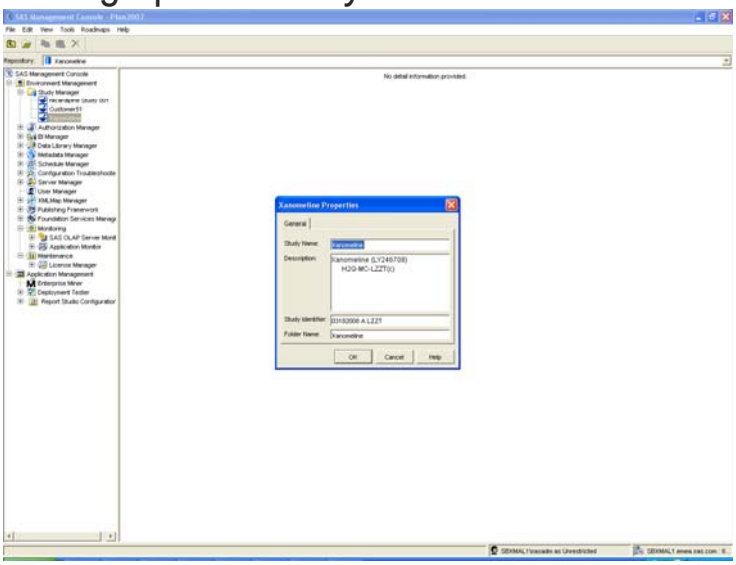
Setting up new study in SAS



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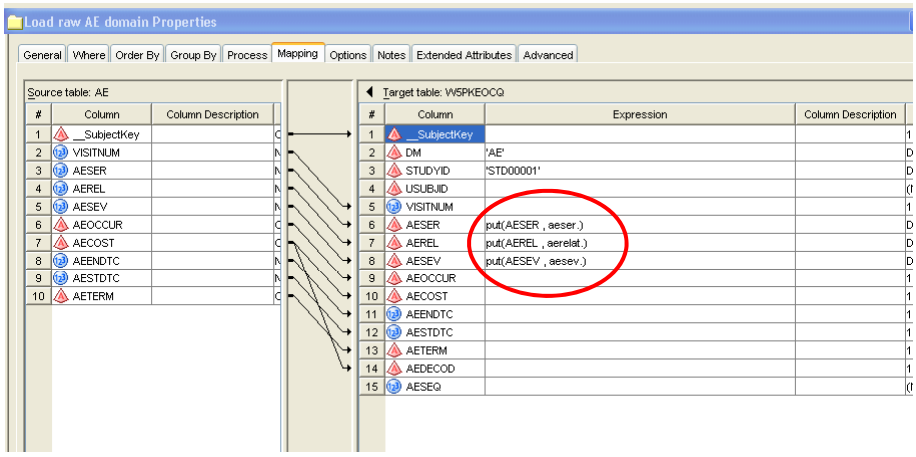
Accessing Codelists as SAS formats



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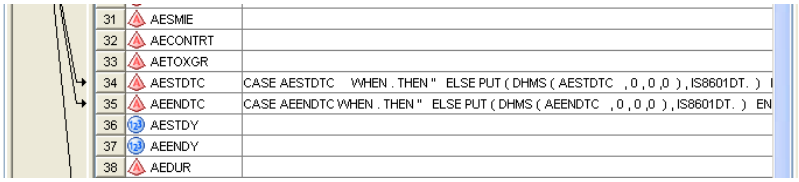
ISO8601 date-time formats



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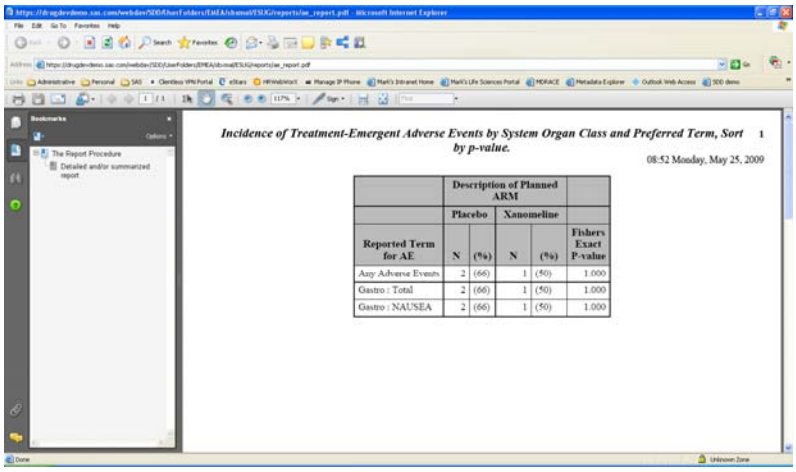
Report



Incidence of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term, Sort by p-value. 1

08:52 Monday, May 25, 2009

	Description of Planned ARM				
	Placebo		Xanomeline		
Reported Term for AE	N	(%)	N	(%)	Fishers Exact P-value
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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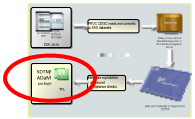
define.xml metadata



- 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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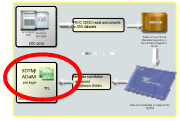
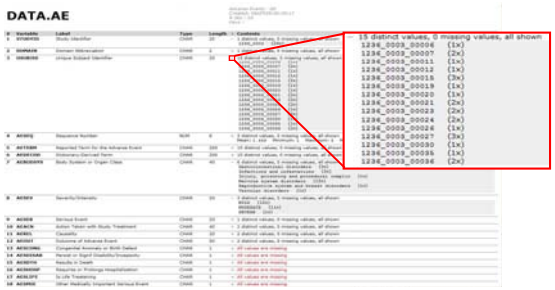
Metadata exploitation



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



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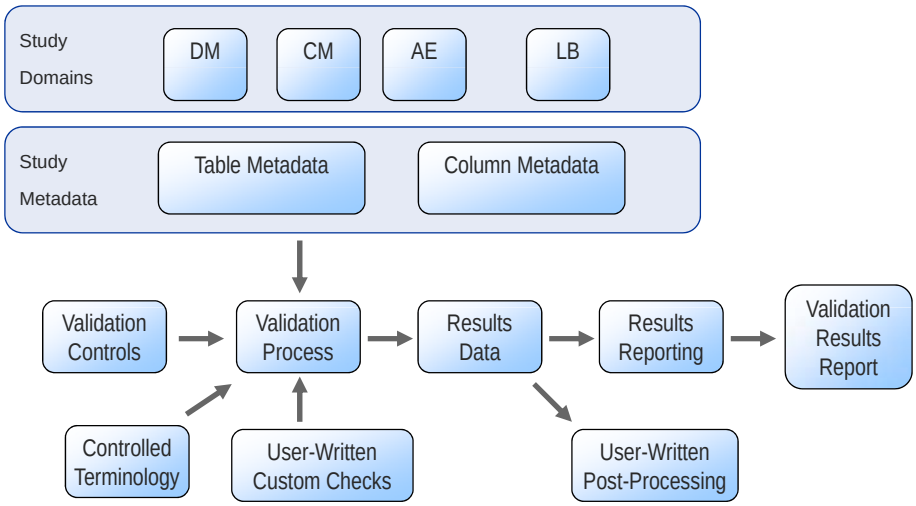
Validation Process



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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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THE POWER TO KNOW.

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