

## Sas Ba

## 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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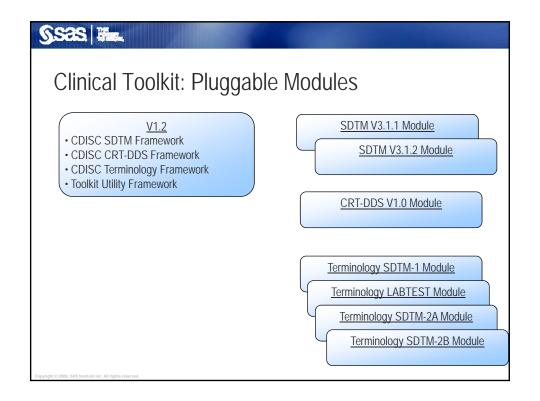
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## Clinical Standards Toolkit

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

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#### SSS B Clinical Toolkit: Framework V1.2 **Example Methods** CDISC SDTM Framework %sdtm\_validate(...); • CDISC CRT-DDS Framework %sdtm\_report\_validationResults(); CDISC Terminology Framework %sdtm\_create\_cterms(...); Toolkit Utility Framework %sdtm\_create\_domainType(...); %sdtm\_create\_domains(...); %crtdds\_validate(...); %crtdds\_report\_validationResults(...); %crtdds\_create\_cterms(...); %crtdds\_write(...); %crtdds\_read(...); %cterms\_create\_package(...);

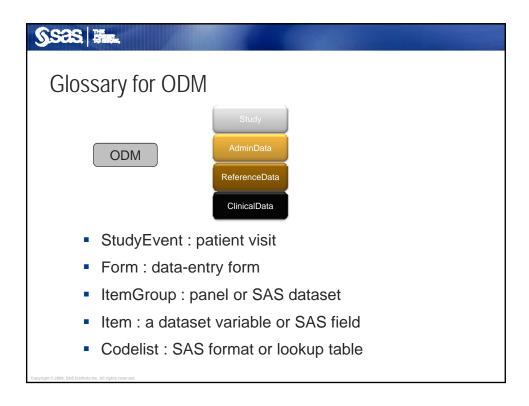


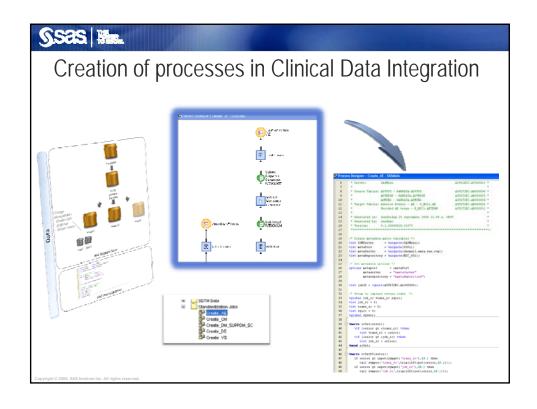
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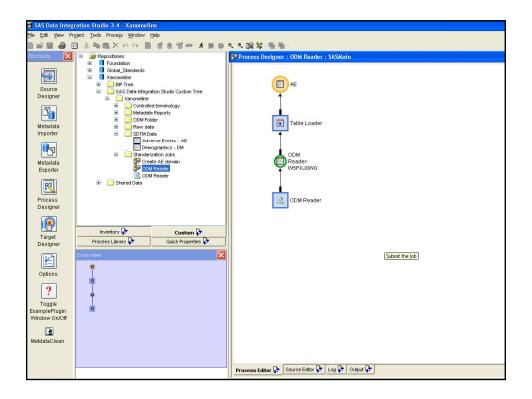
# Clinical Data Integration functionalities

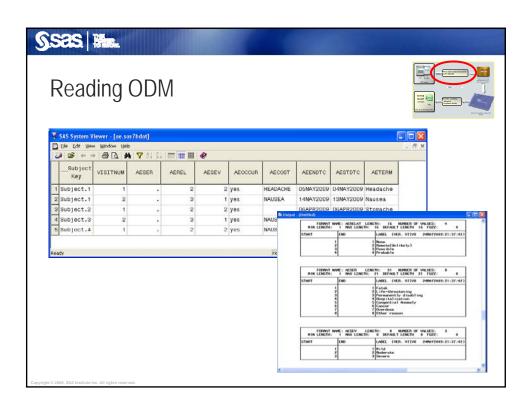
- SAS code-based solution
- Robust generation of processes that transform and integrate data
- Extensive process library to process data
- Included SDTM 3.1.1 IG data model
- Extensible with user-written SAS code transformations

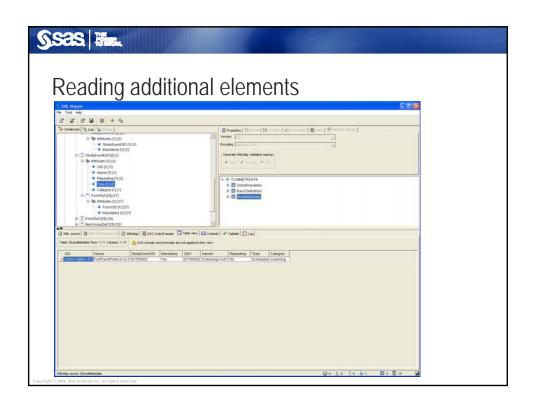
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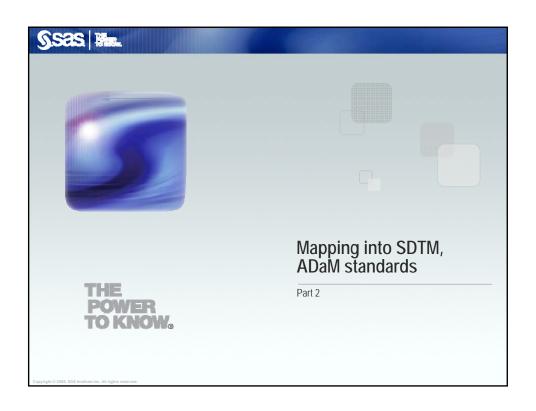


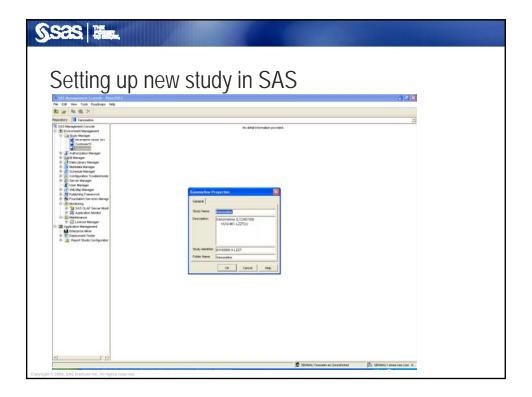




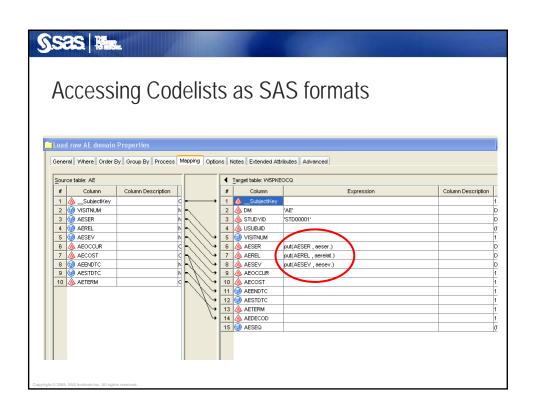


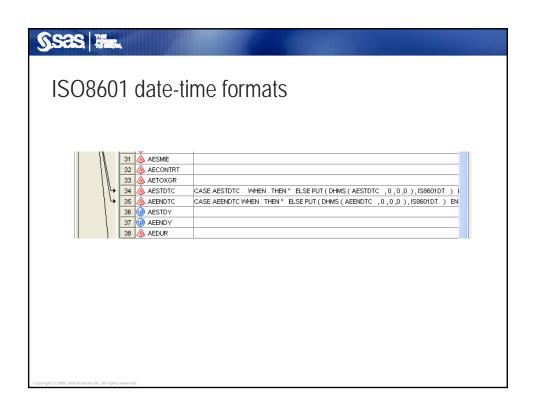


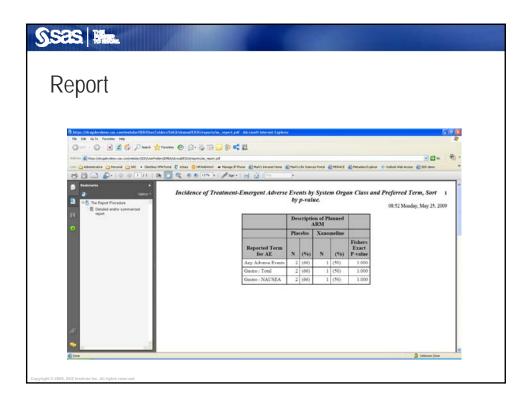


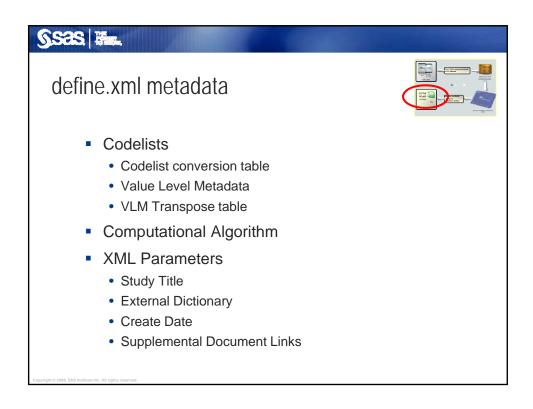


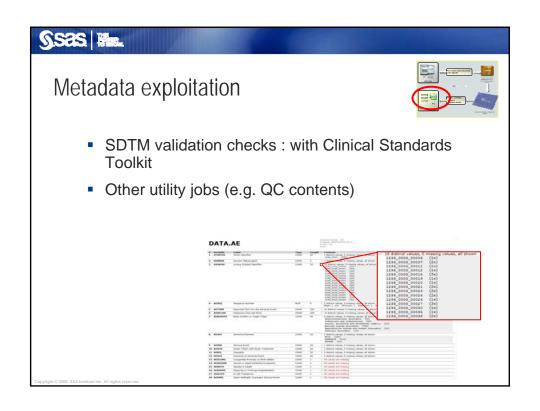


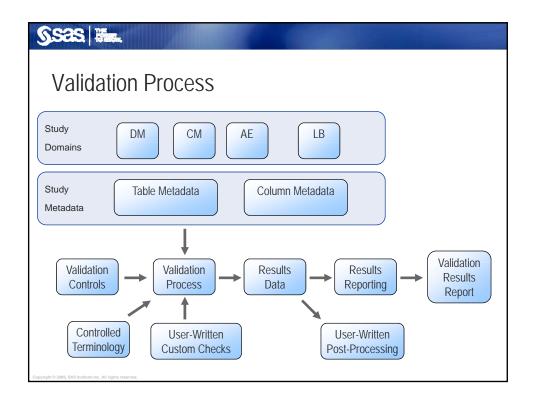












#### SSS Bas

# 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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