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From Standards Management to Final Analysis: Workflow-driven Automation in Primary Research

Daniel Christen



SAS Life Sciences Support

SDD / CST / CDI



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Clinical Standards Toolkit
(CST)

SAS
Life Science
Analytics Frame-
Work (LSAF)

Clinical Data Integration
(CDI)

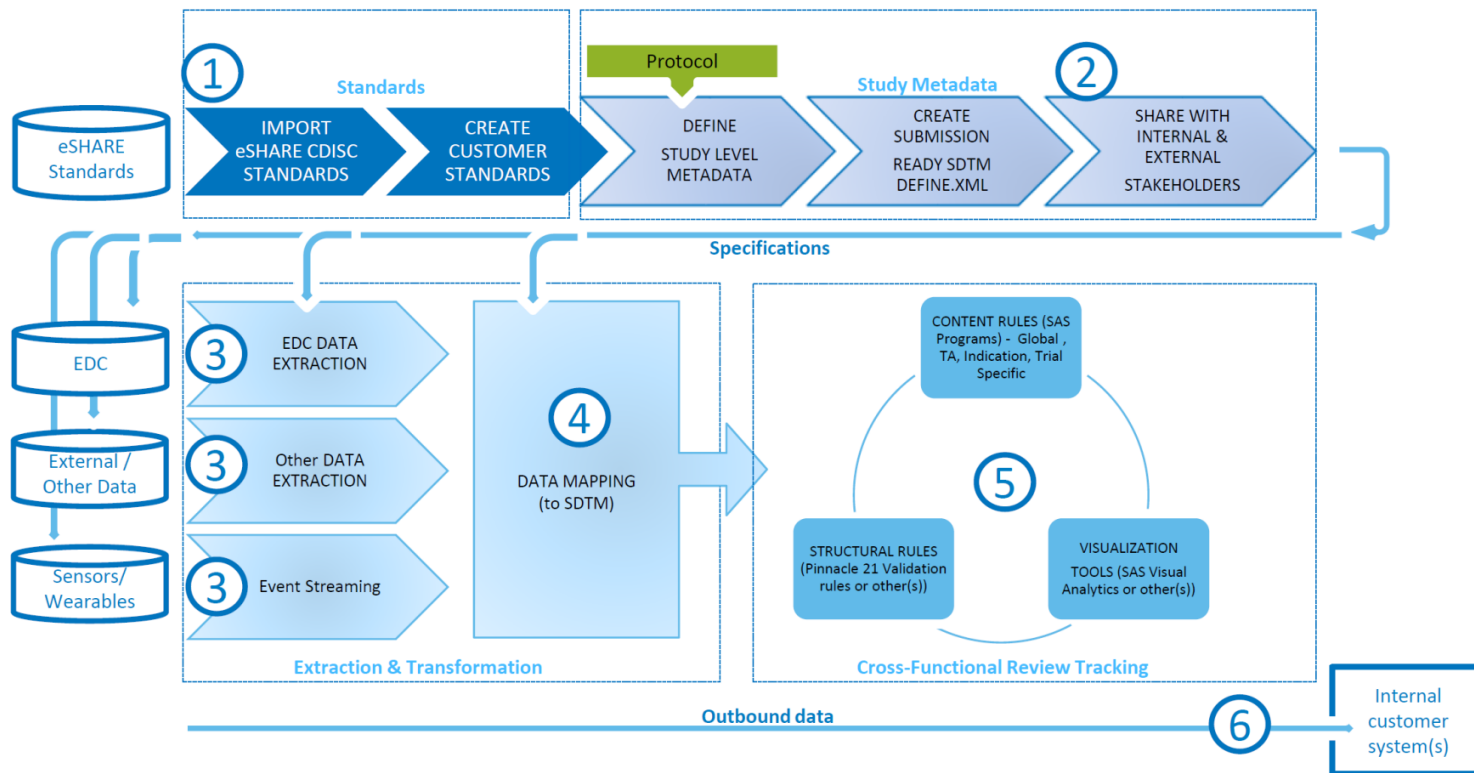


End-To-End Workflow In SAS LSAF

From EDC To SDTM

End To End Processing In LSAF

STANDARDS MANAGEMENT – STUDY METADATA – DATA PROCESSING – REVIEW





SAS Life Science Analytics Framework (LSAF)

Quick Introduction

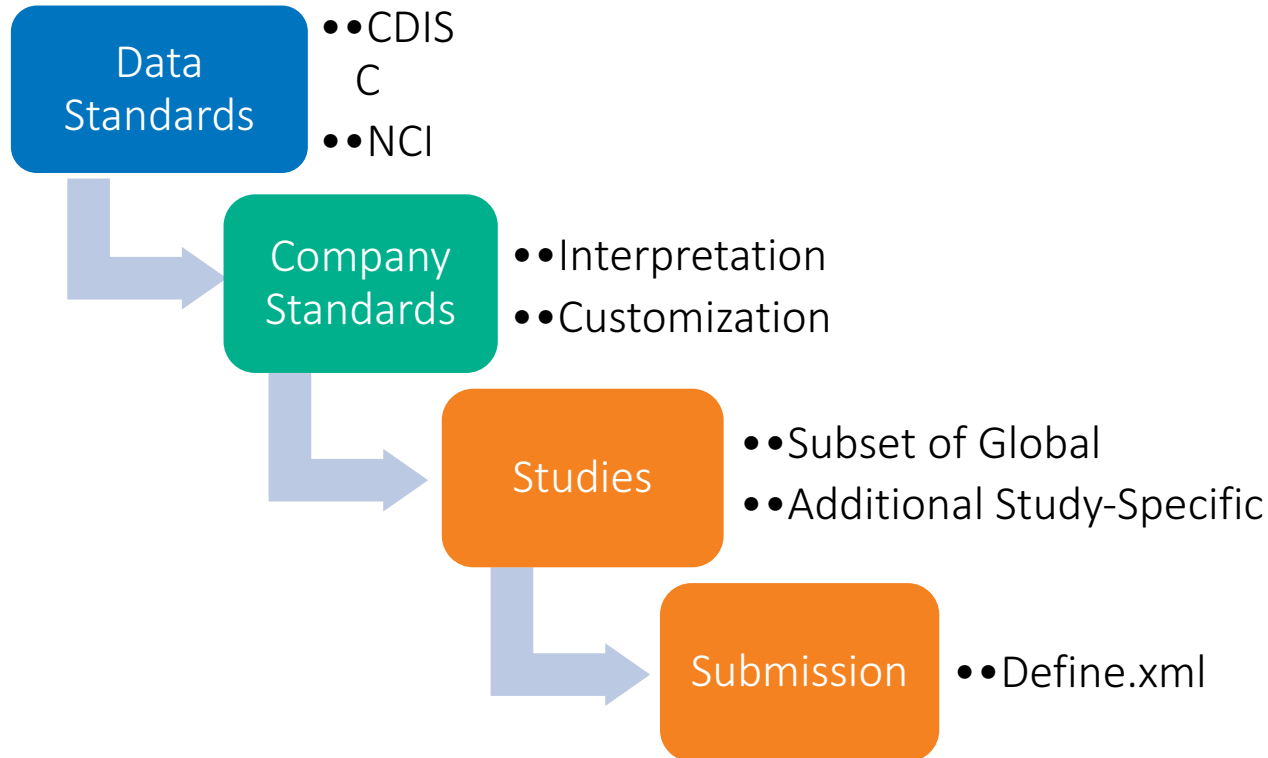
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Clinical Metadata

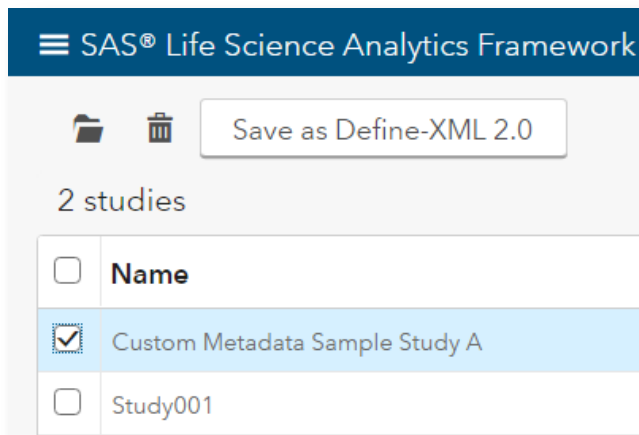
Metadata Driven Process

Clinical Metadata



SAS Life Science Analytics Framework 4.7.1

- Catalog Data Standards and Controlled Terminology
- Store Study Metadata
- Create Zero-Observation Datasets for Domains
- Read and Create Dataset-xml Files
- Create Define.xml File



Supported Standards

SAS Life Science Analytics Framework 4.7.1

- Data Standards
 - SDTM (3.1.2, 3.1.3, 3.2 included)
 - SEND (3.0 included)
- Controlled Terminology
 - SDTM
 - SEND
 - Custom*
- Define.xml
 - Export V2
- Dataset-xml
 - Import
 - Export



Demo

Data Standards View

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Data Standards

- Data Standards
 - SAS Dataset
 - Table metadata
 - Column metadata
- Controlled Terminology
 - SAS Dataset
 - odm.xml

SAS Datasets

- Data Standards
 - reference_tables.sas7bdat
 - reference_columns.sas7bdat
- Controlled Terminology
 - codelistpackage.sas7bdat
- Need a new standard? Export an existing one, edit files, import as new standard.

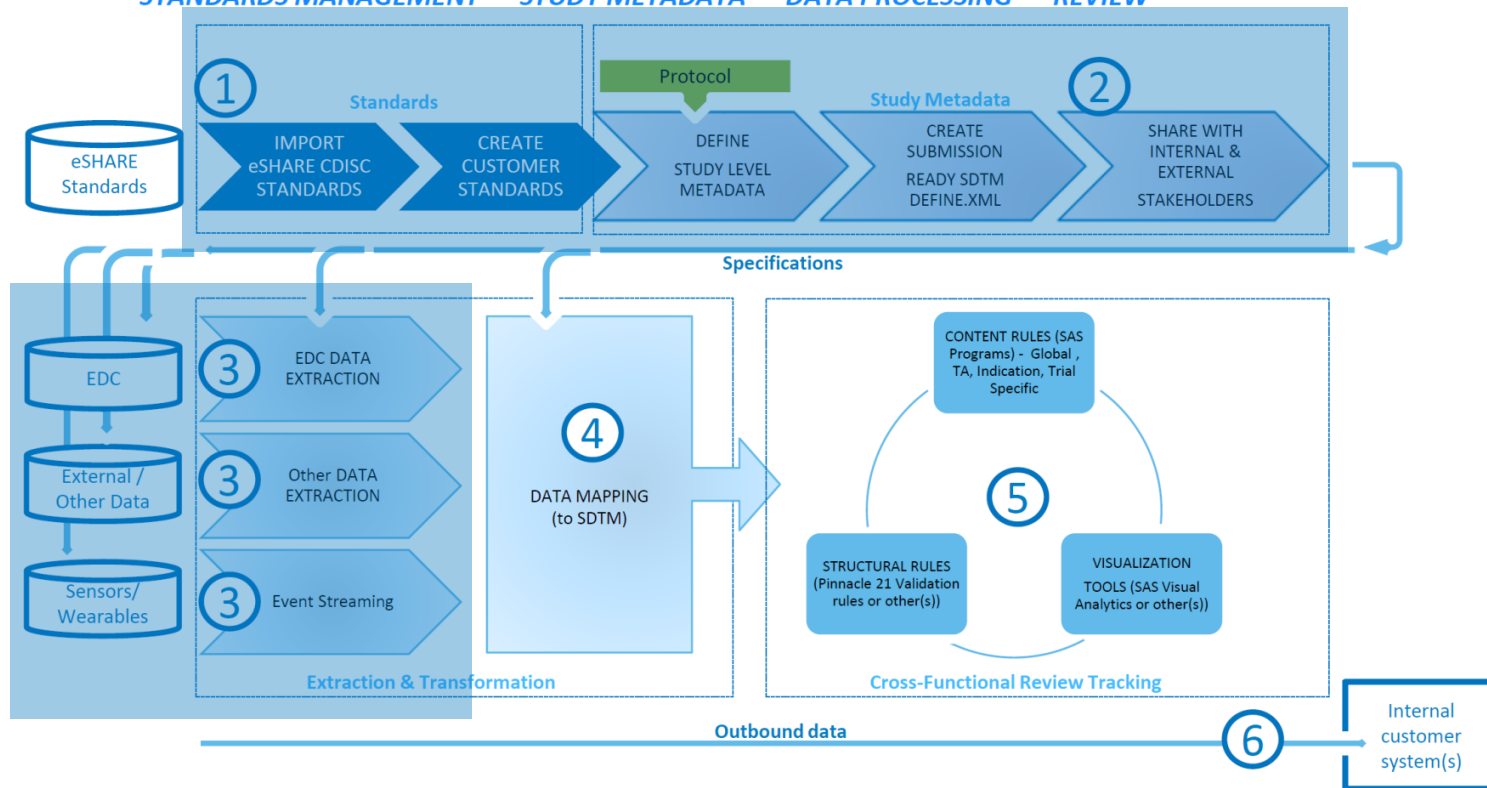


Demo

Define.xml file at the push of a button!

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STANDARDS MANAGEMENT – STUDY METADATA – DATA PROCESSING – REVIEW





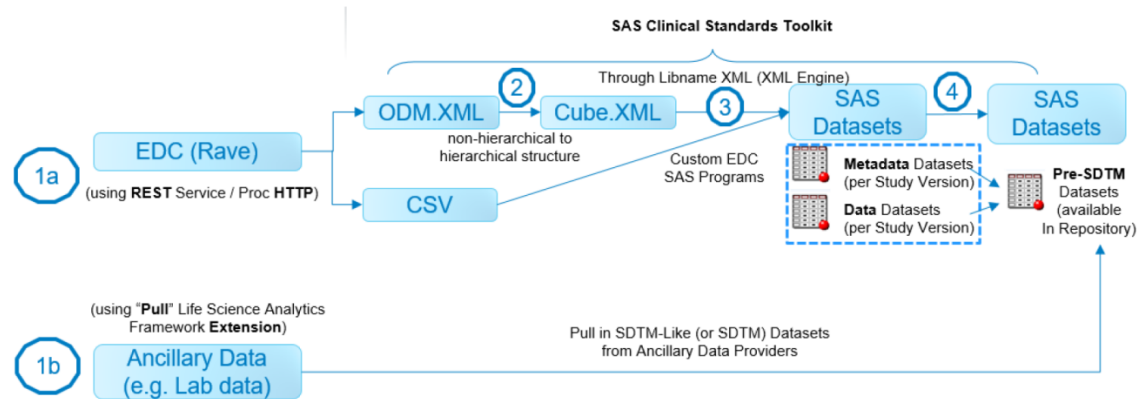
Data Extraction And Data Mapping

Transferring Data From Multiple Source Systems

Automation through integration and extension modules

3. AUTOMATED DATA EXTRACTION INTO LSAF REPOSITORY

- eCRF (EDC systems) – both Rave and Inform
- Ancillary data
- Wearables/Sensor data



Note: Similar process available for Inform (Oracle) - using **SOAP** Service / Proc **SOAP**.

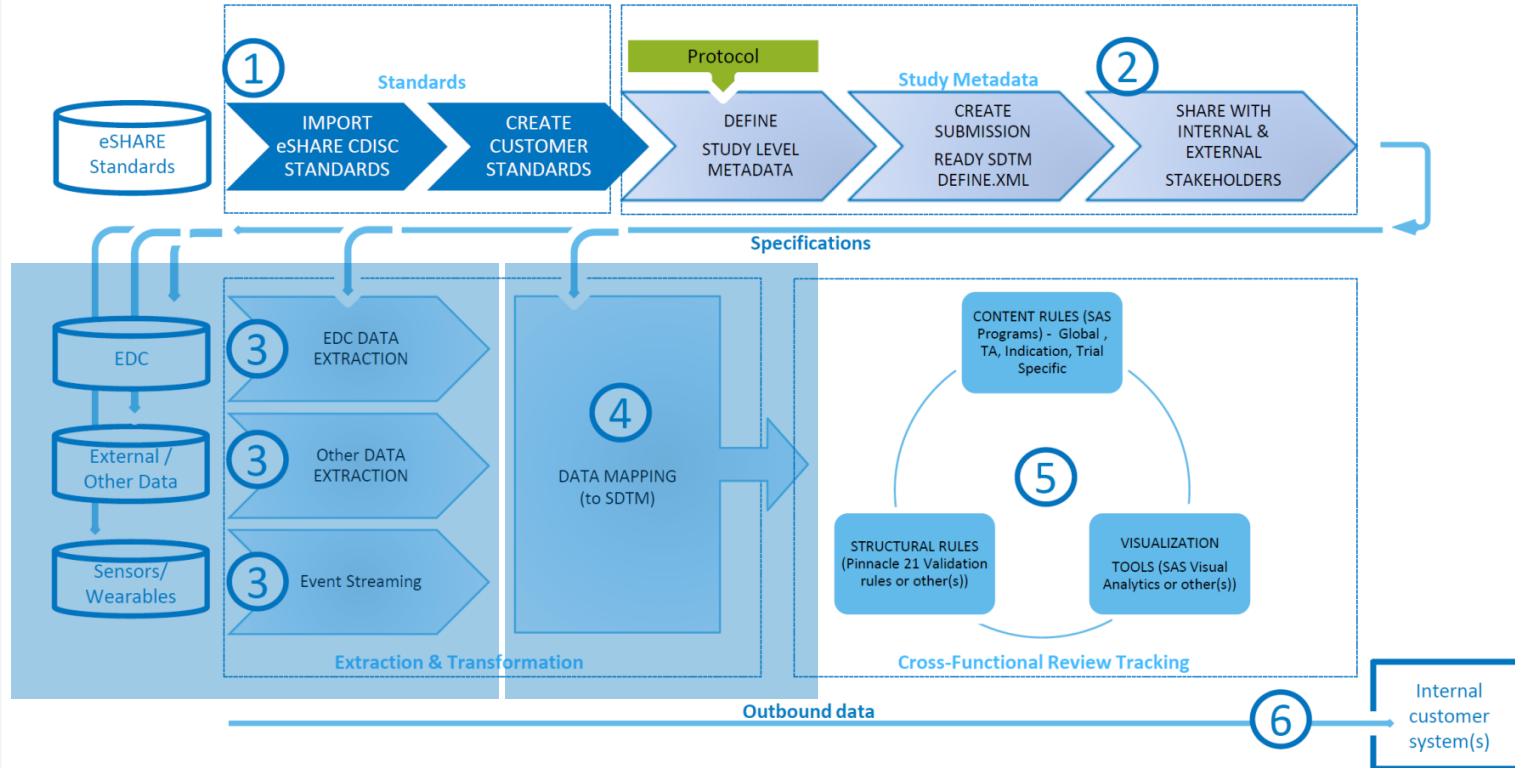


Demo

Accessing Raw Data From Multiple Data Sources

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STANDARDS MANAGEMENT – STUDY METADATA – DATA PROCESSING – REVIEW



Data Transfers, Data Transformations, Reporting

- Data Repository
- Code Repository



Demo

Transferring Data

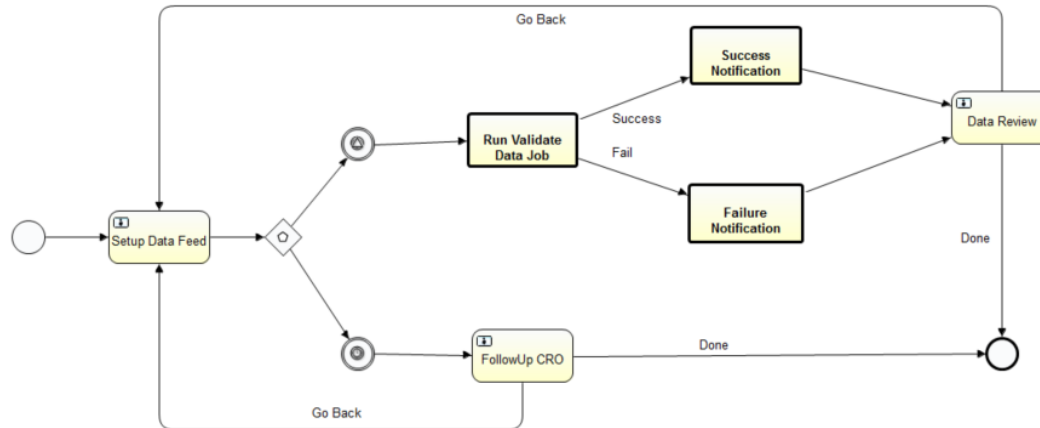
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Bringing It All Together

Workflows

- Data Feed Workflow

- Data feed setup (UserTask)
- Event Gateway
 - Signal Event - When new Data file is available, validate it (via Job Task)
 - If PASS, Review it (via User Task)
 - If FAIL, notify CRO (via Notification Task)
 - Timer Event – No data came in time, Ping CRO (via User Task)



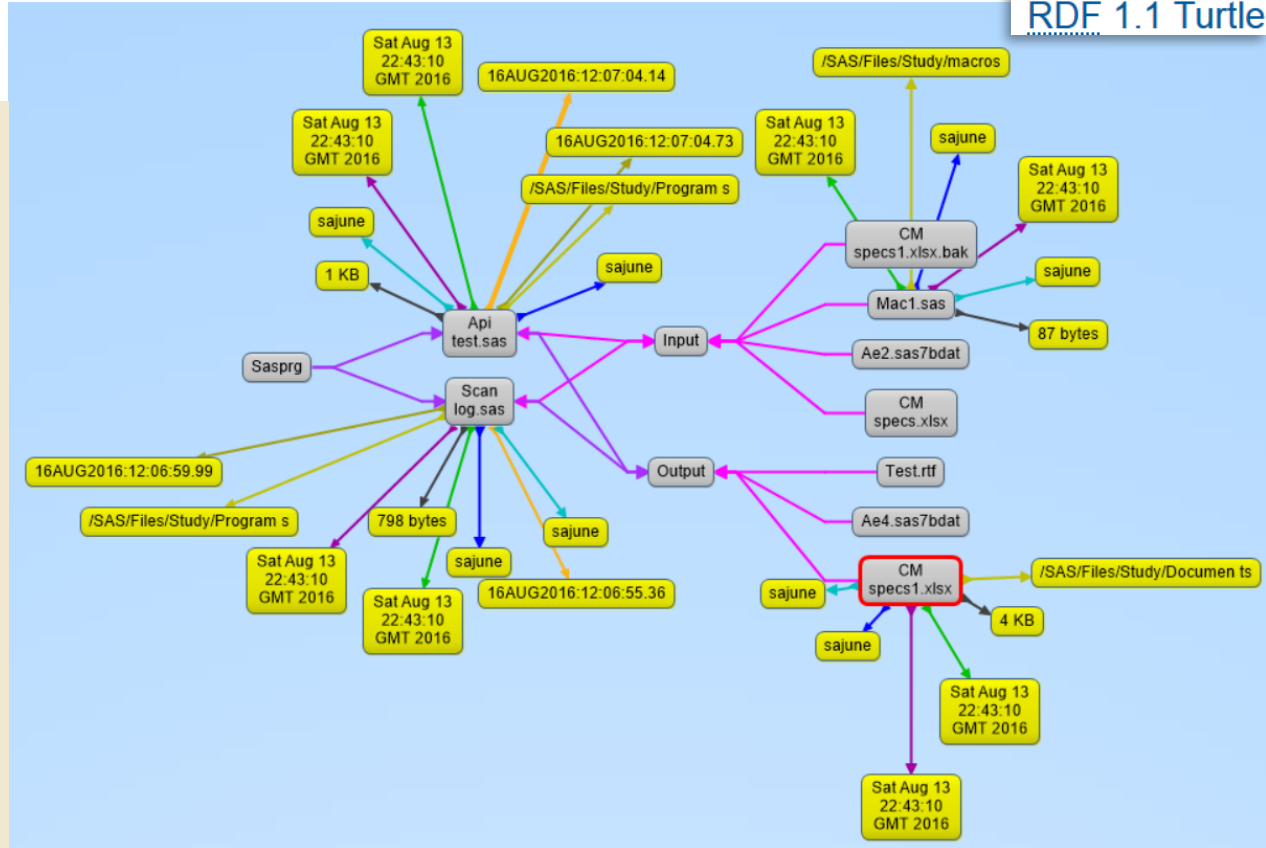
RDF (Resource Description Framework)

Impact Analysis



Graphical impact analysis

W3C[®]
RDF 1.1 Turtle





Special Thanks To

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