

How to Build and Manage CDISC Data and Create Analytical Reports with SAS

SAS[®] Clinical Standards Toolkit
SAS[®] Clinical Data Integration
JMP[®] Clinical

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Coordinateur Secteur Service et Industries

SAS – Aix en Provence

Agenda

- How to Built and Manage your Clinical Data ?
 - SAS® Clinical Standards Toolkit
 - SAS® Clinical Data Integration
- How to Create Analytical Reports from your CDISC data ?
 - JMP® Clinical



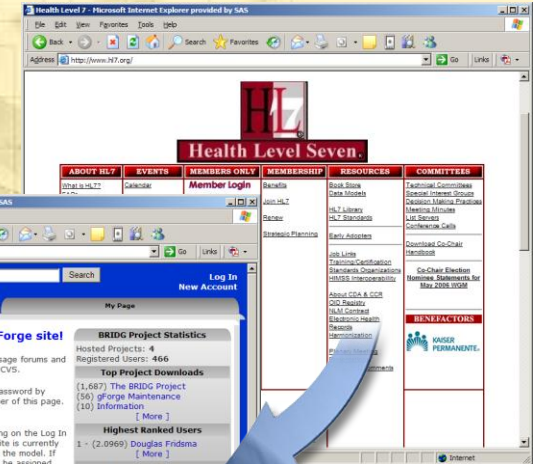
State of Standards

■ CDISC

- ODM
- SDTM
- ADaM
- CRT-DDS (define.xml)
- Etc.

■ Other initiatives

- Protocol Representation
- BRIDG
- Etc.



Introduction to...

SAS Clinical Standards Toolkit

SAS Clinical Standards Toolkit

Set of macros designed to supersede Proc CDISC

Free to existing SAS customers

Built into Clinical Data Integration

SAS Clinical Standards 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(...);
```

SAS Clinical Standards 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

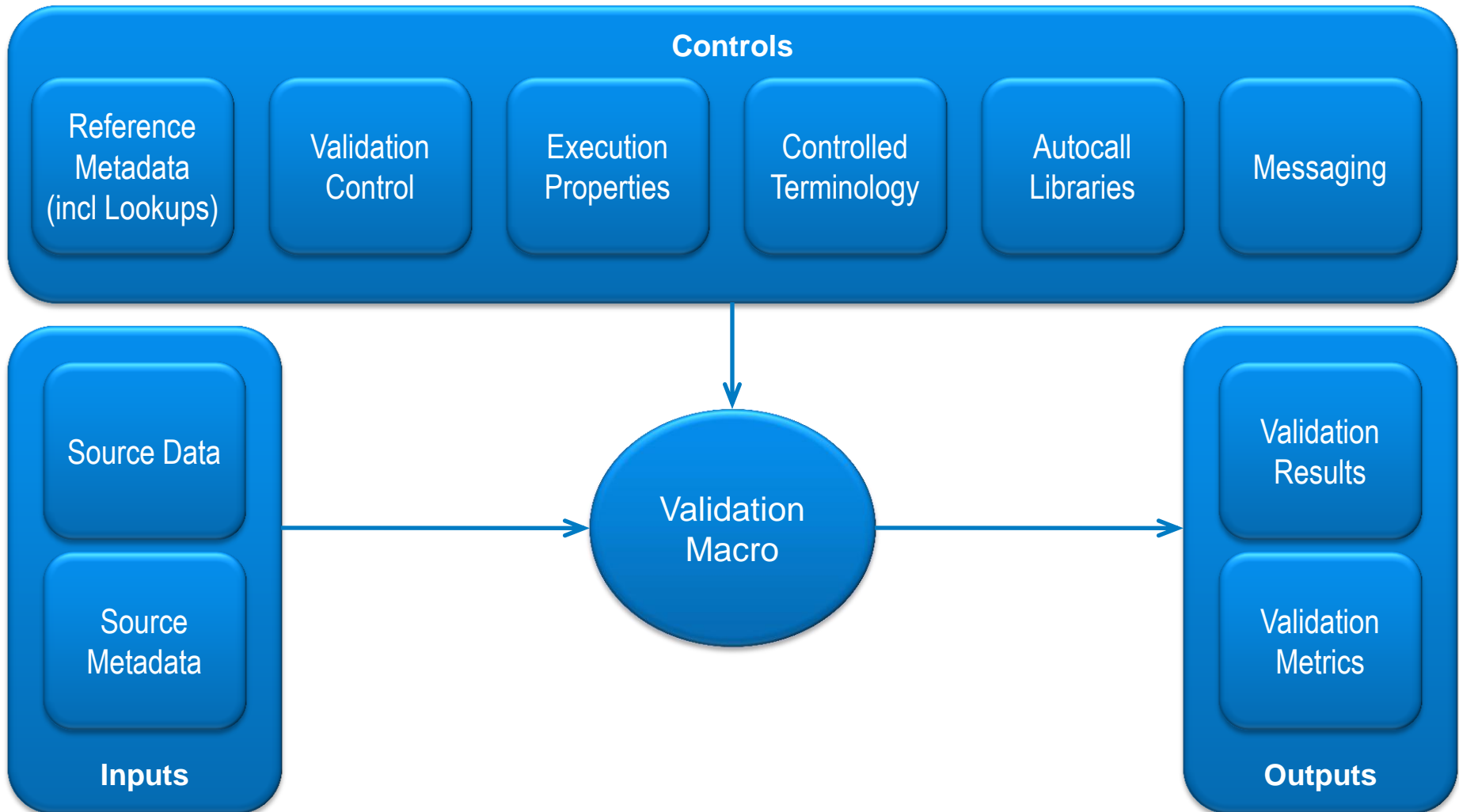
Terminology LABTEST Module

Terminology SDTM-2A Module

Terminology SDTM-2B Module

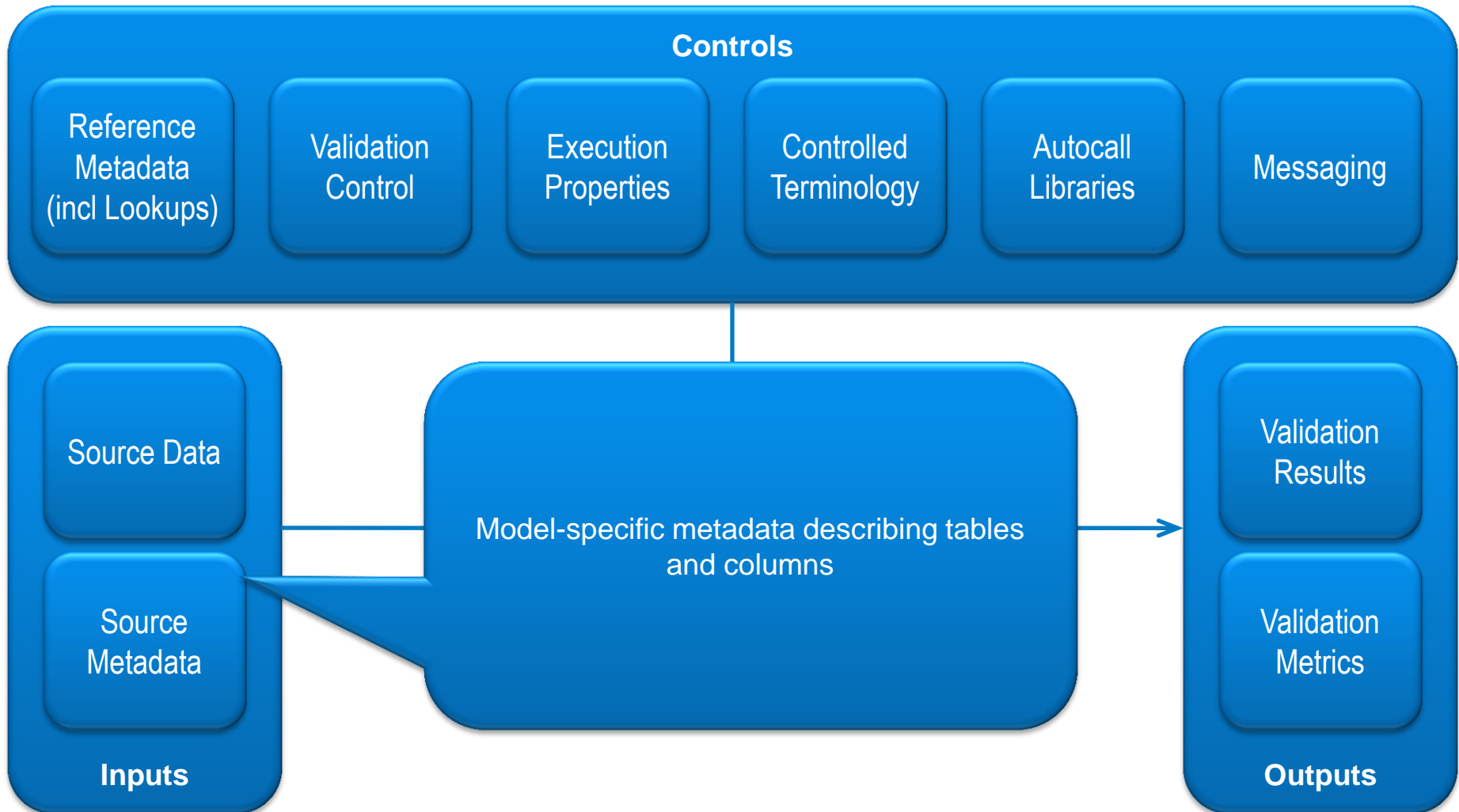
SAS Clinical Standards Toolkit

CDISC SDTM Validation



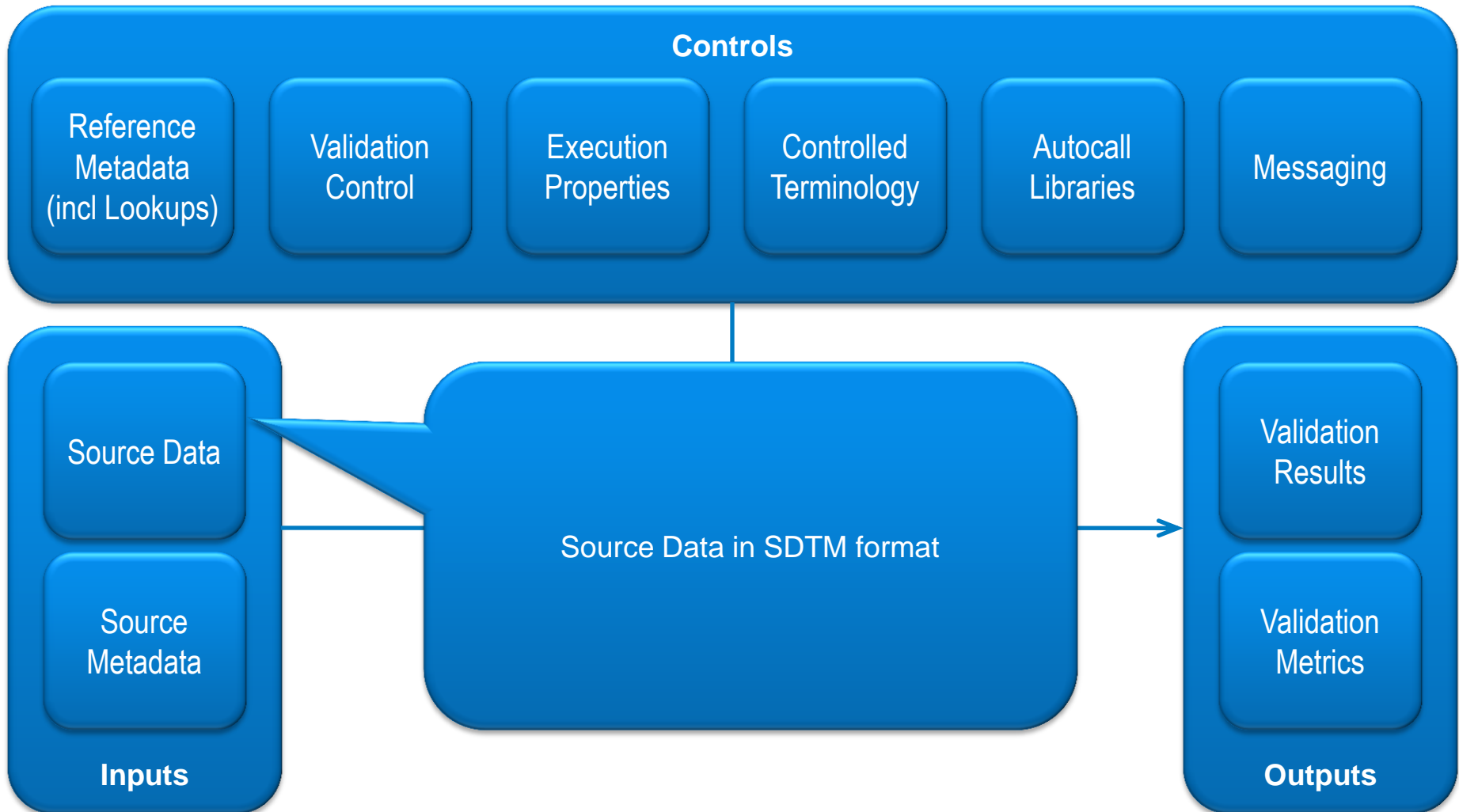
SAS Clinical Standards Toolkit

CDISC SDTM Validation



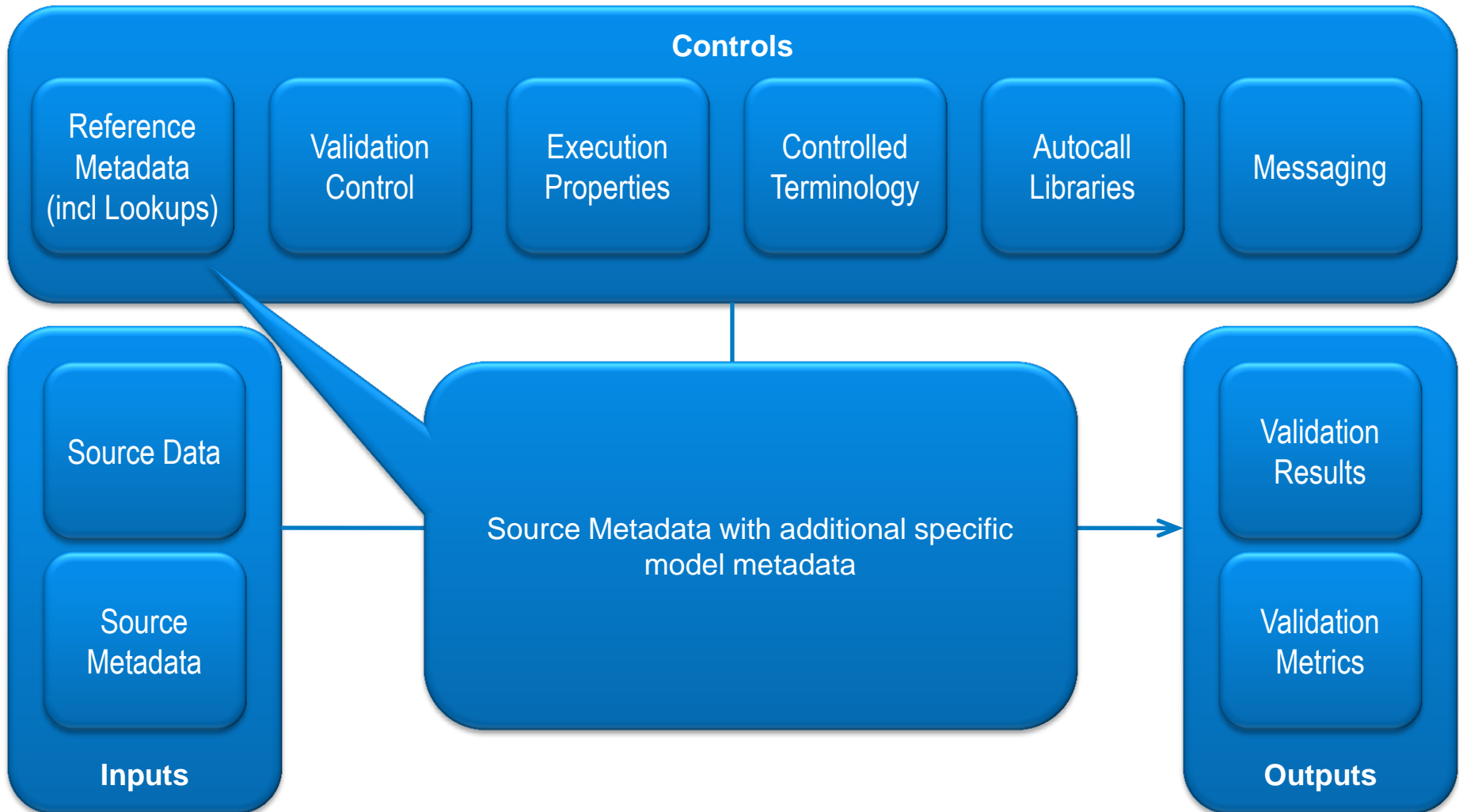
SAS Clinical Standards Toolkit

CDISC SDTM Validation



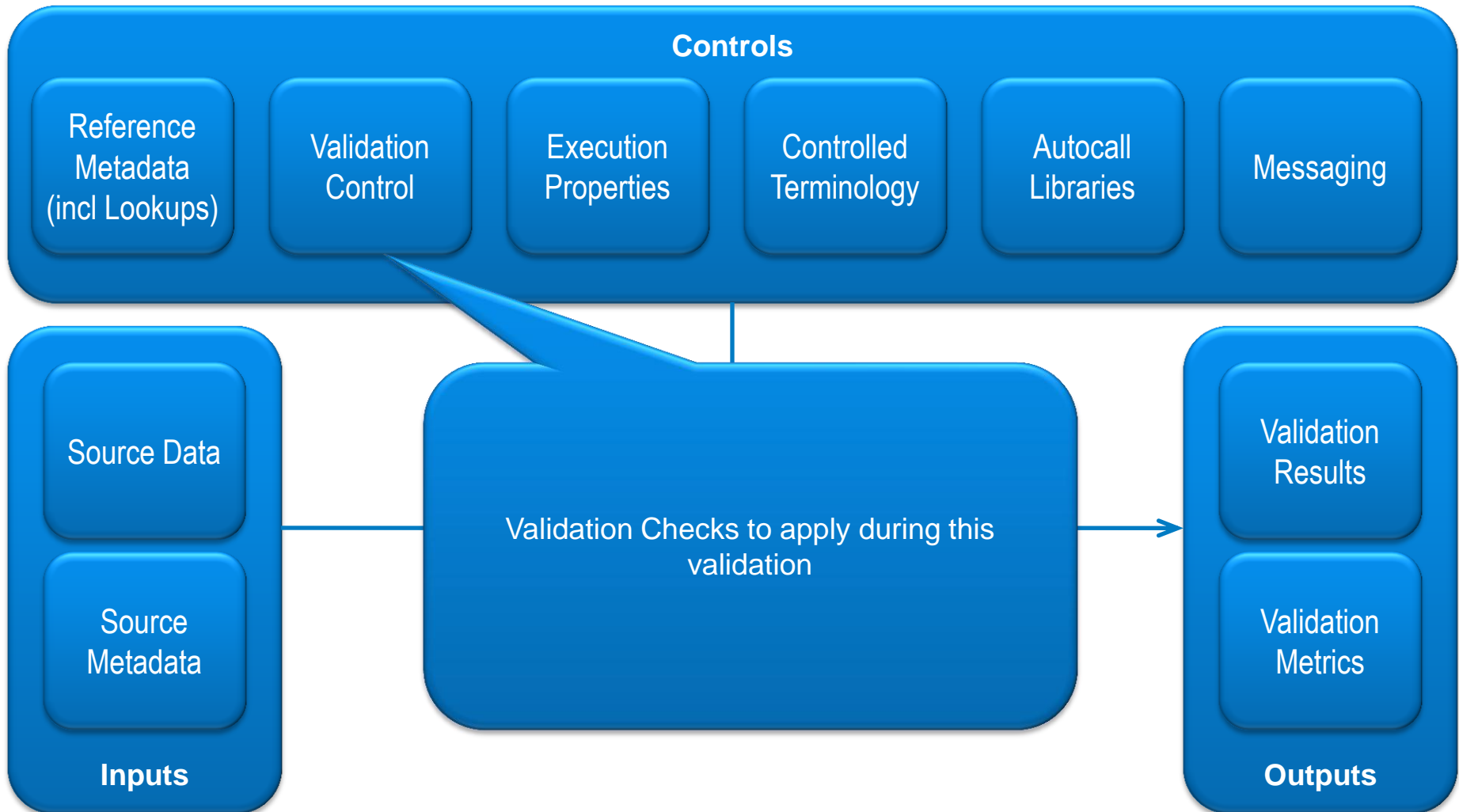
SAS Clinical Standards Toolkit

CDISC SDTM Validation



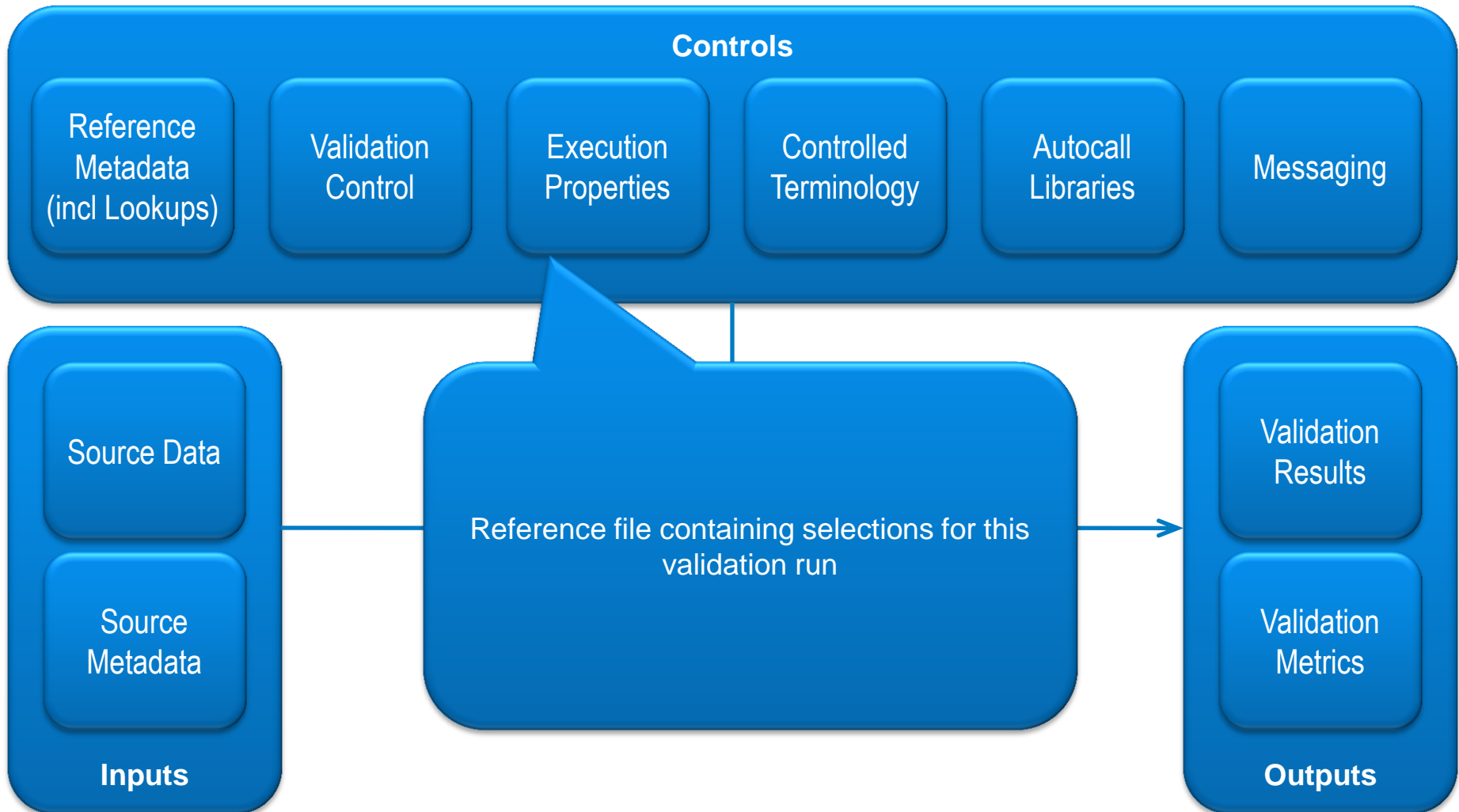
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CDISC SDTM Validation



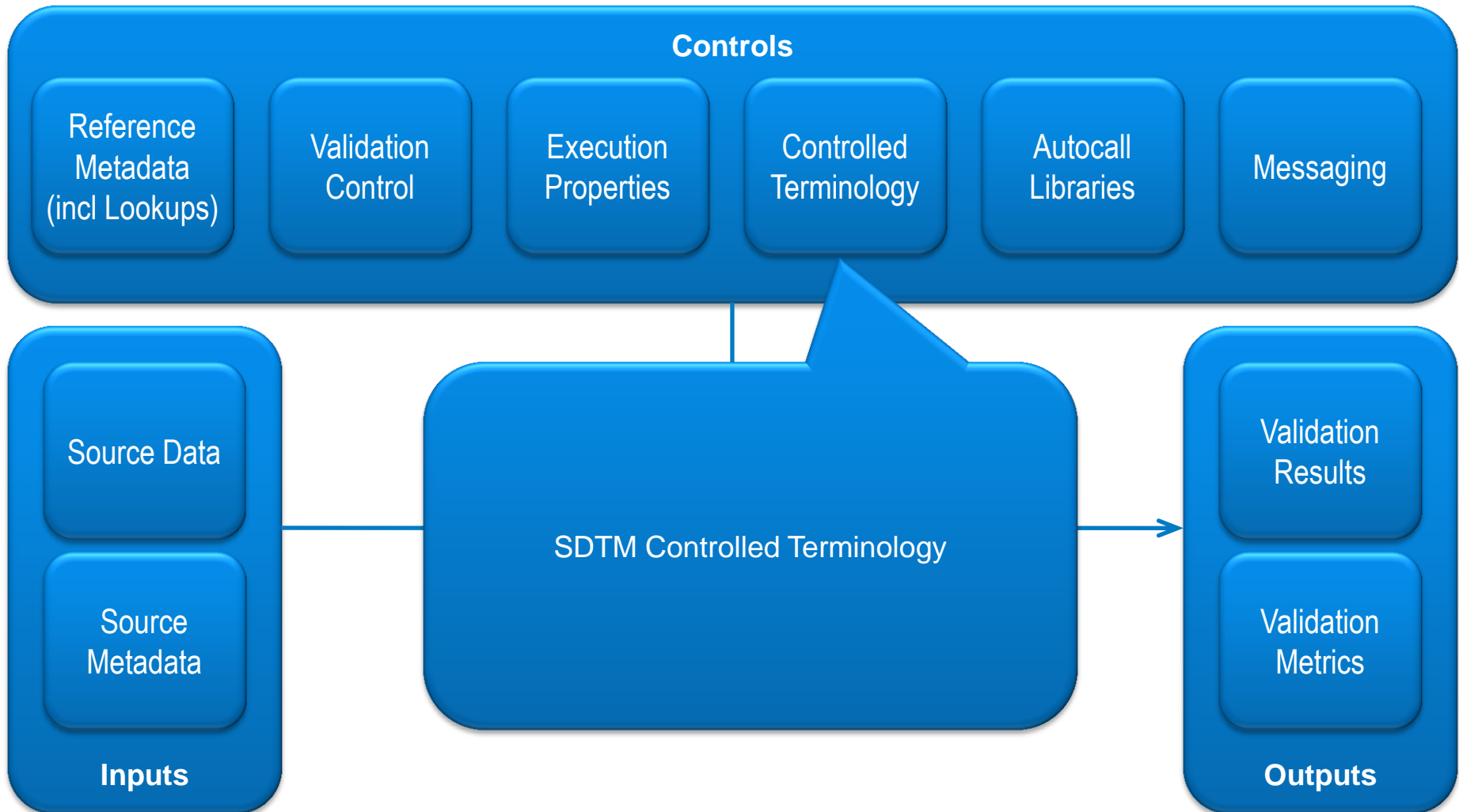
SAS Clinical Standards Toolkit

CDISC SDTM Validation



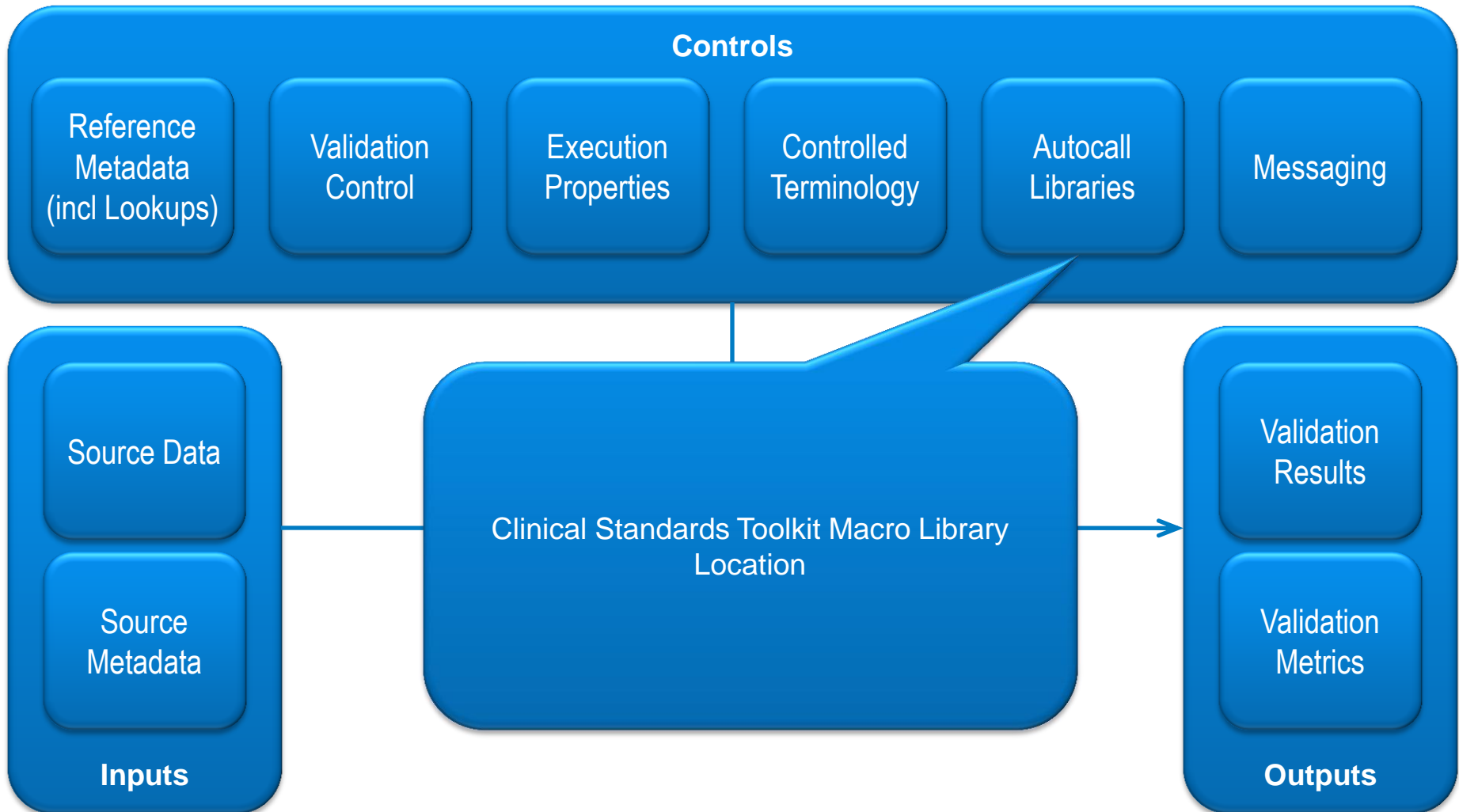
SAS Clinical Standards Toolkit

CDISC SDTM Validation



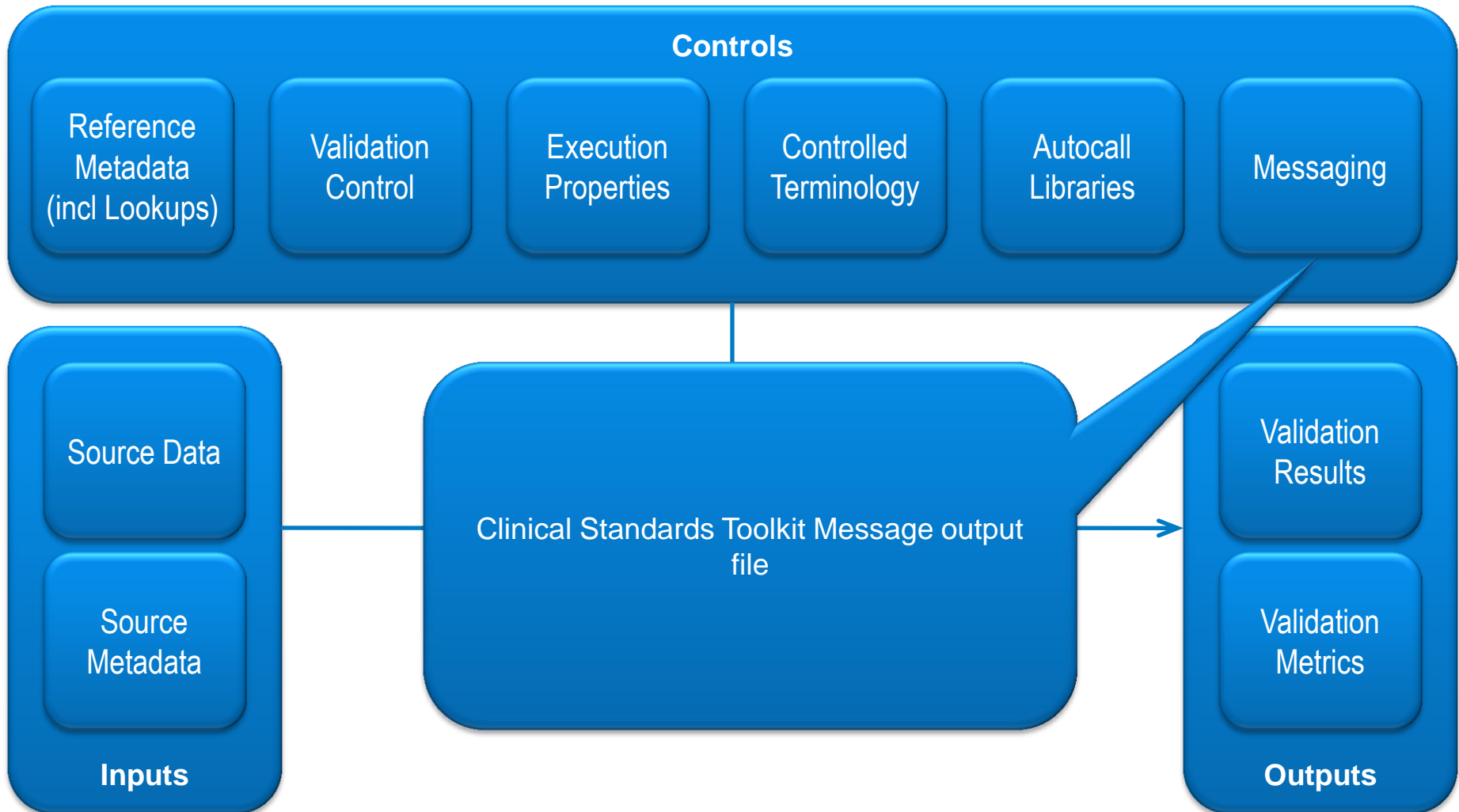
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CDISC SDTM Validation

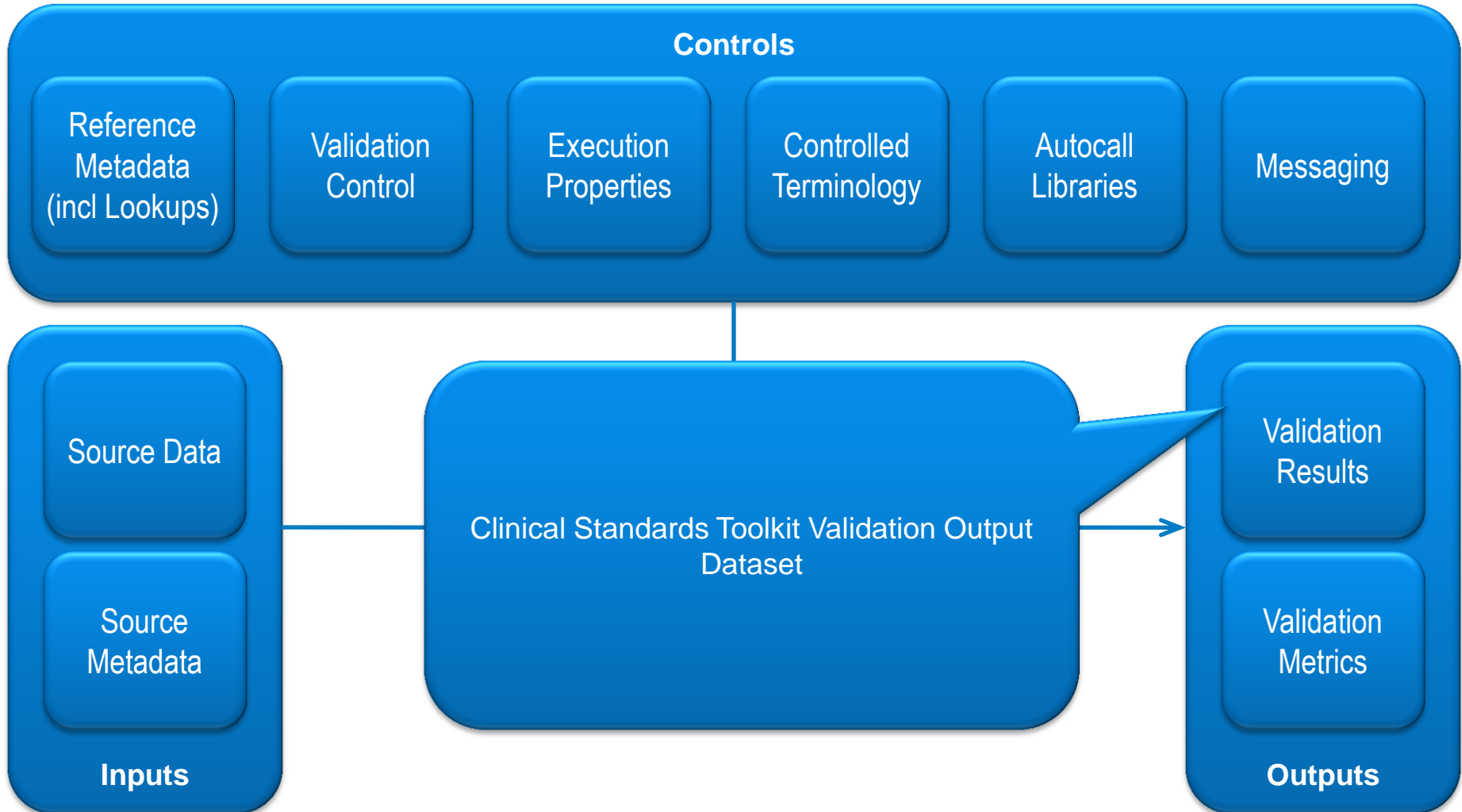


SAS Clinical Standards Toolkit

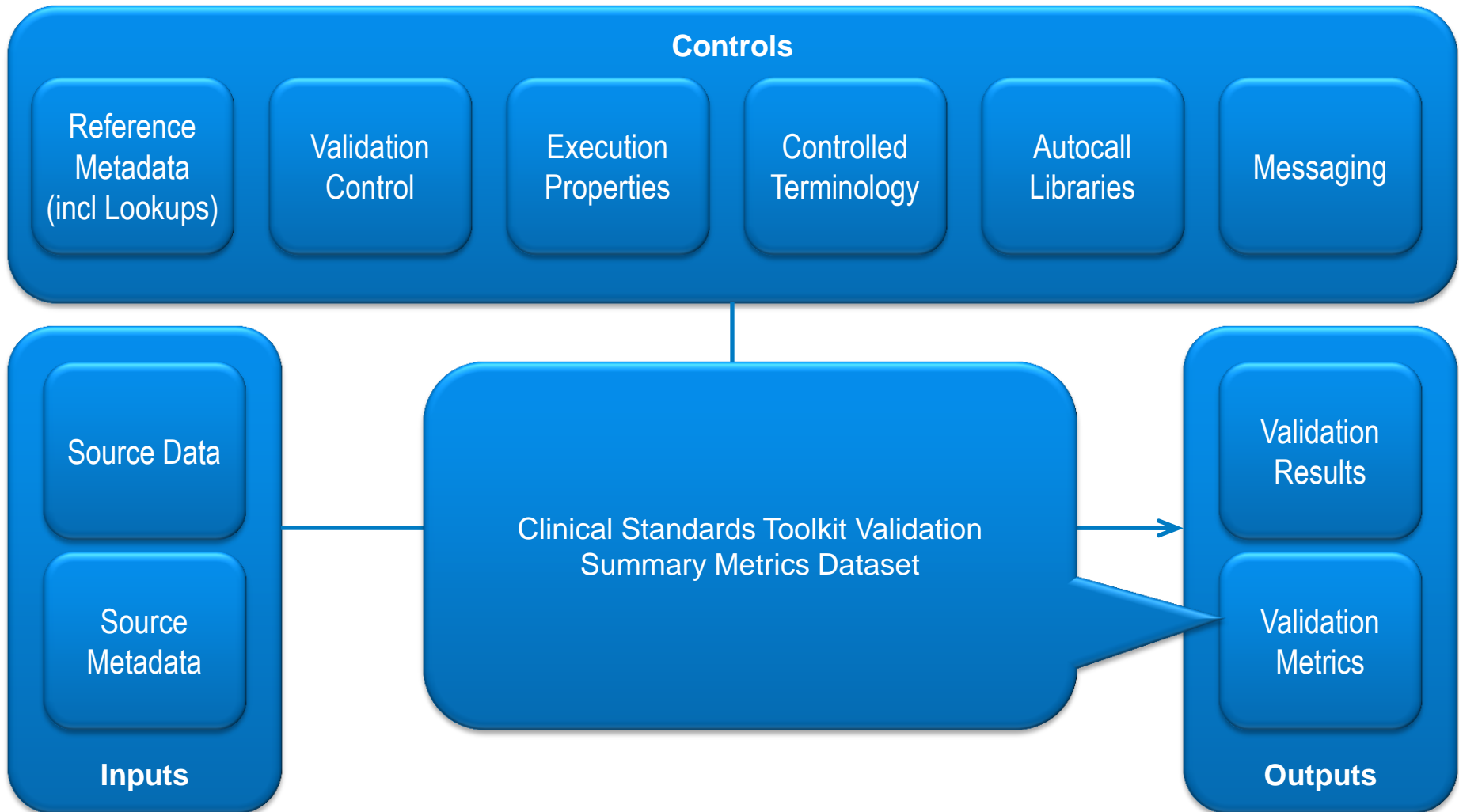
CDISC SDTM Validation



SAS Clinical Standards Toolkit CDISC SDTM Validation

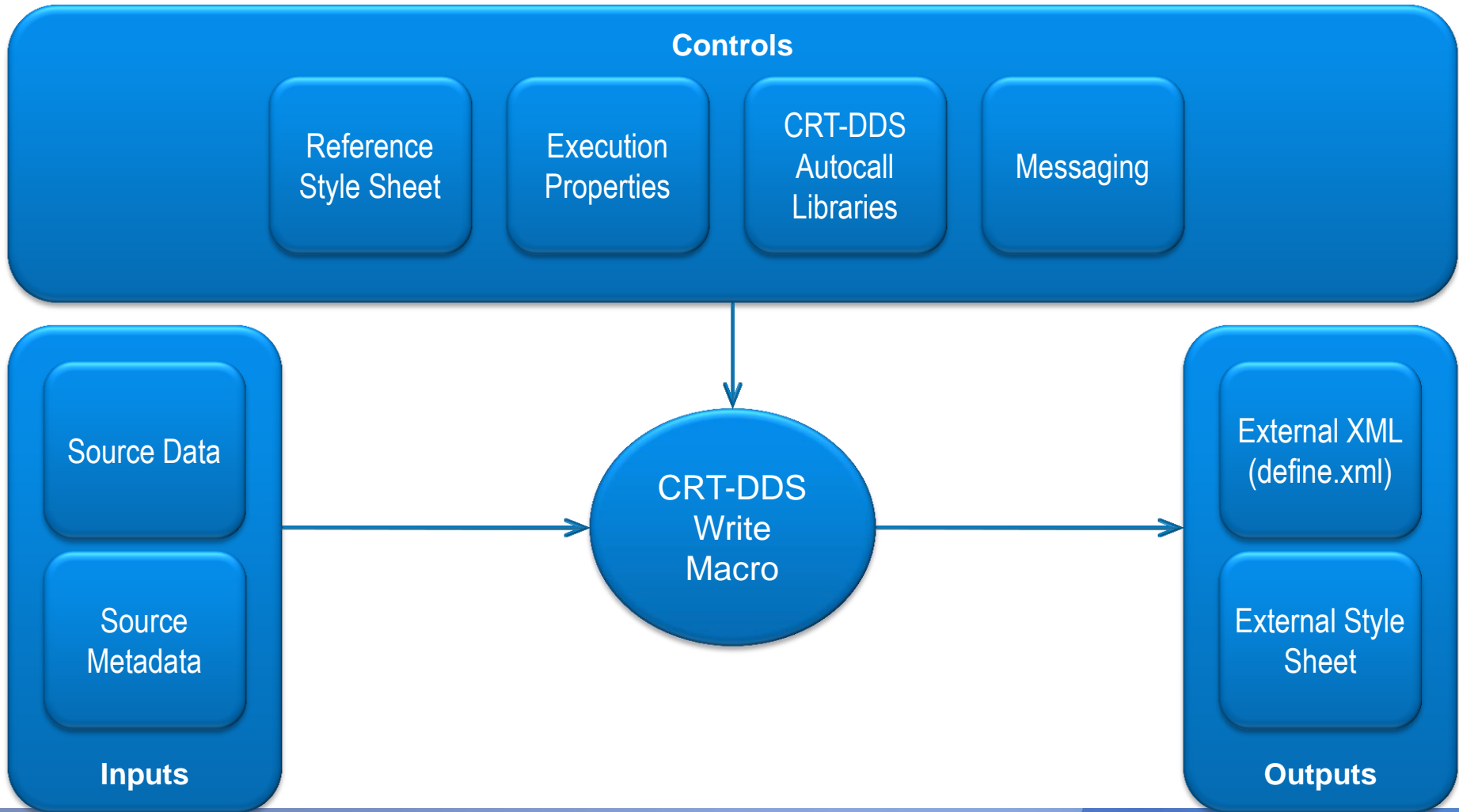


SAS Clinical Standards Toolkit CDISC SDTM Validation



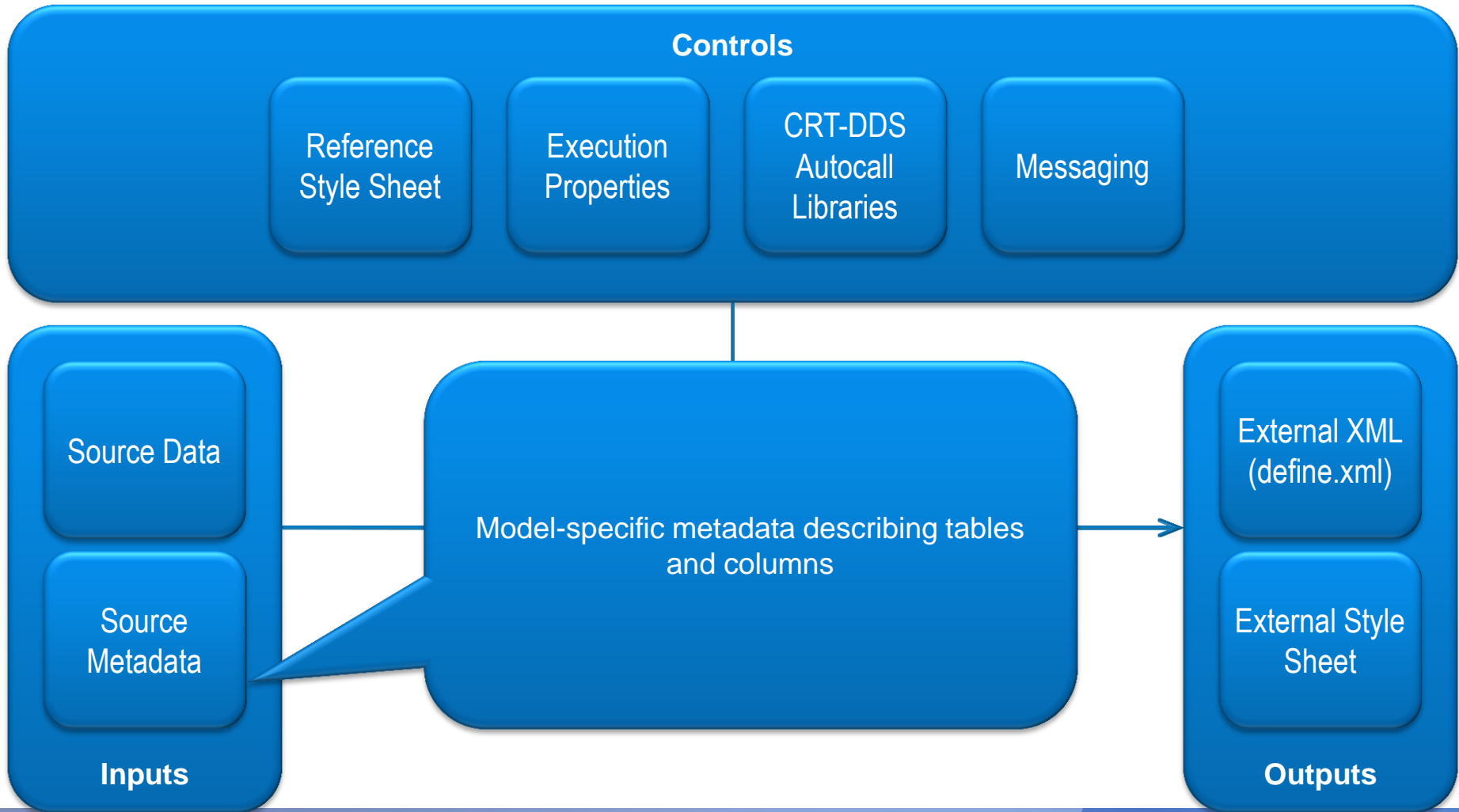
SAS Clinical Standards Toolkit

Define.xml (CDISC CRT-DDS) Creation



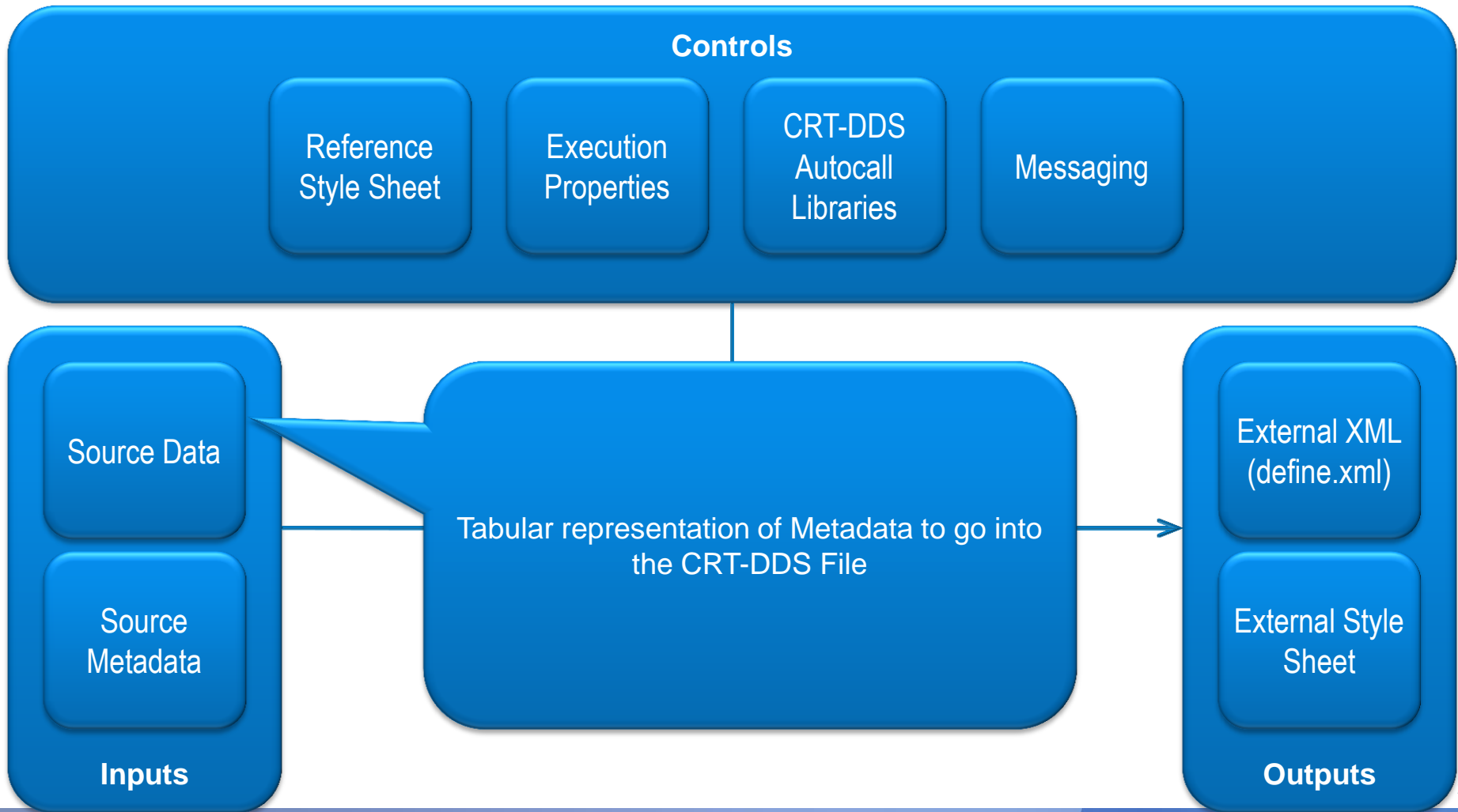
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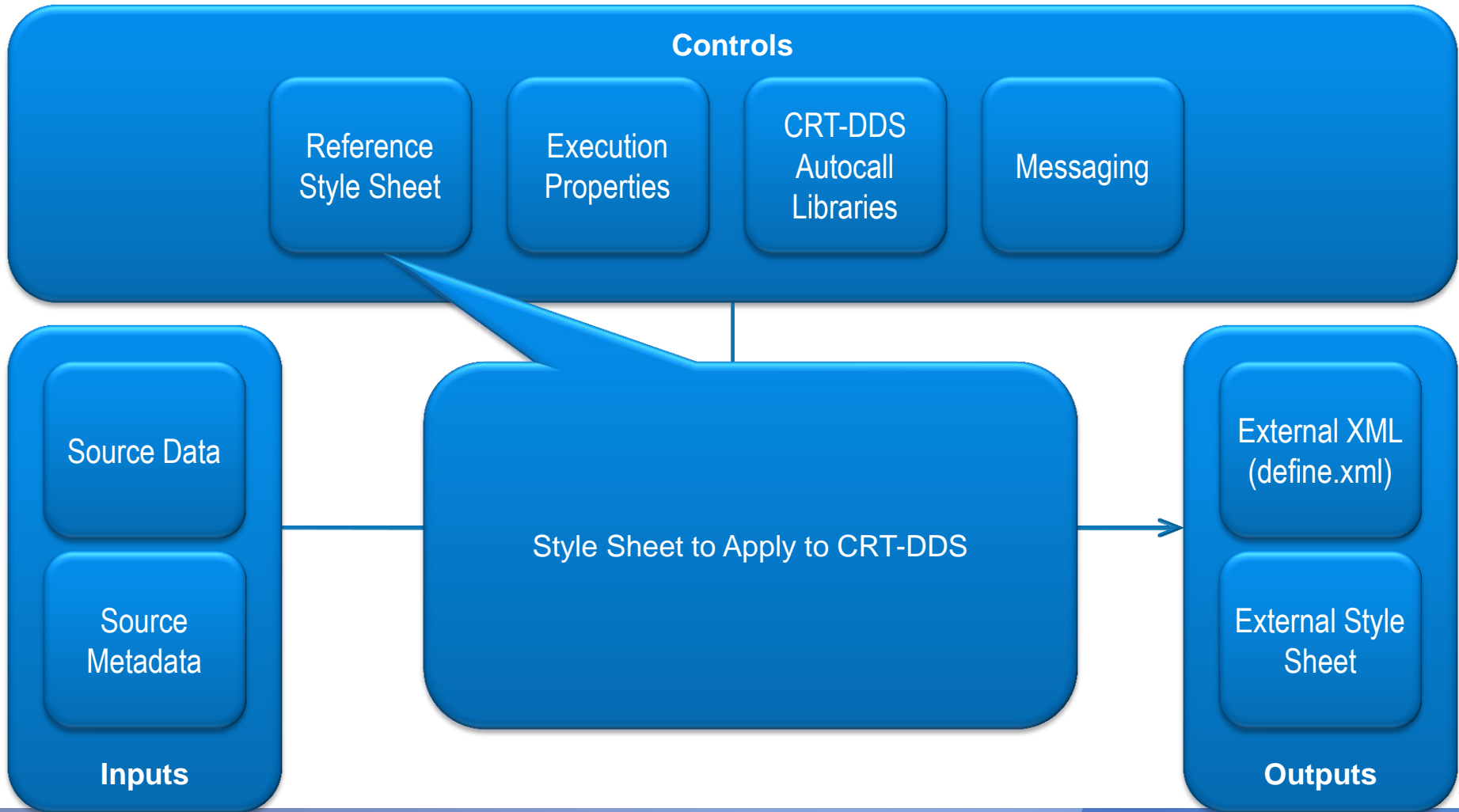
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Define.xml (CDISC CRT-DDS) Creation



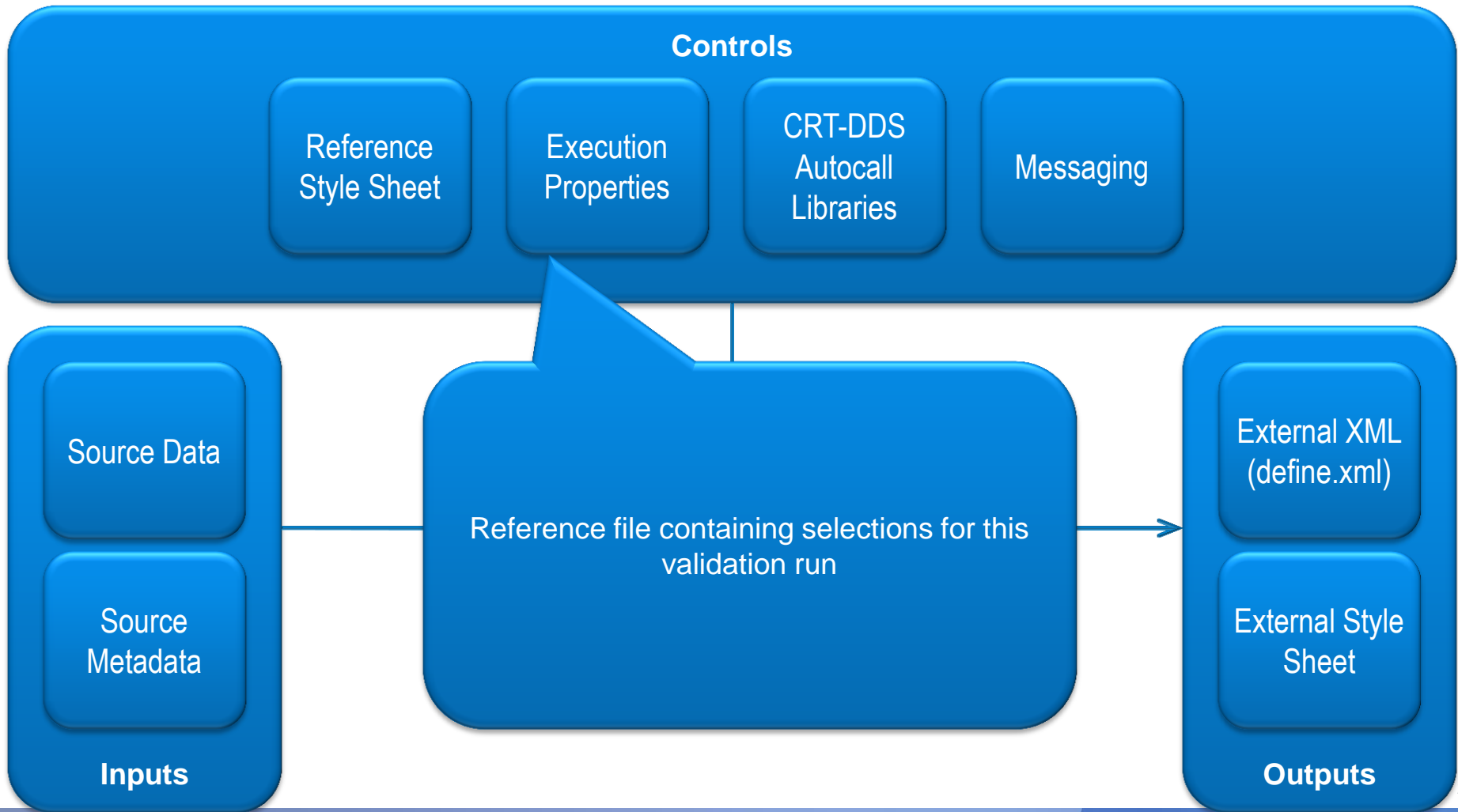
SAS Clinical Standards Toolkit

Define.xml (CDISC CRT-DDS) Creation

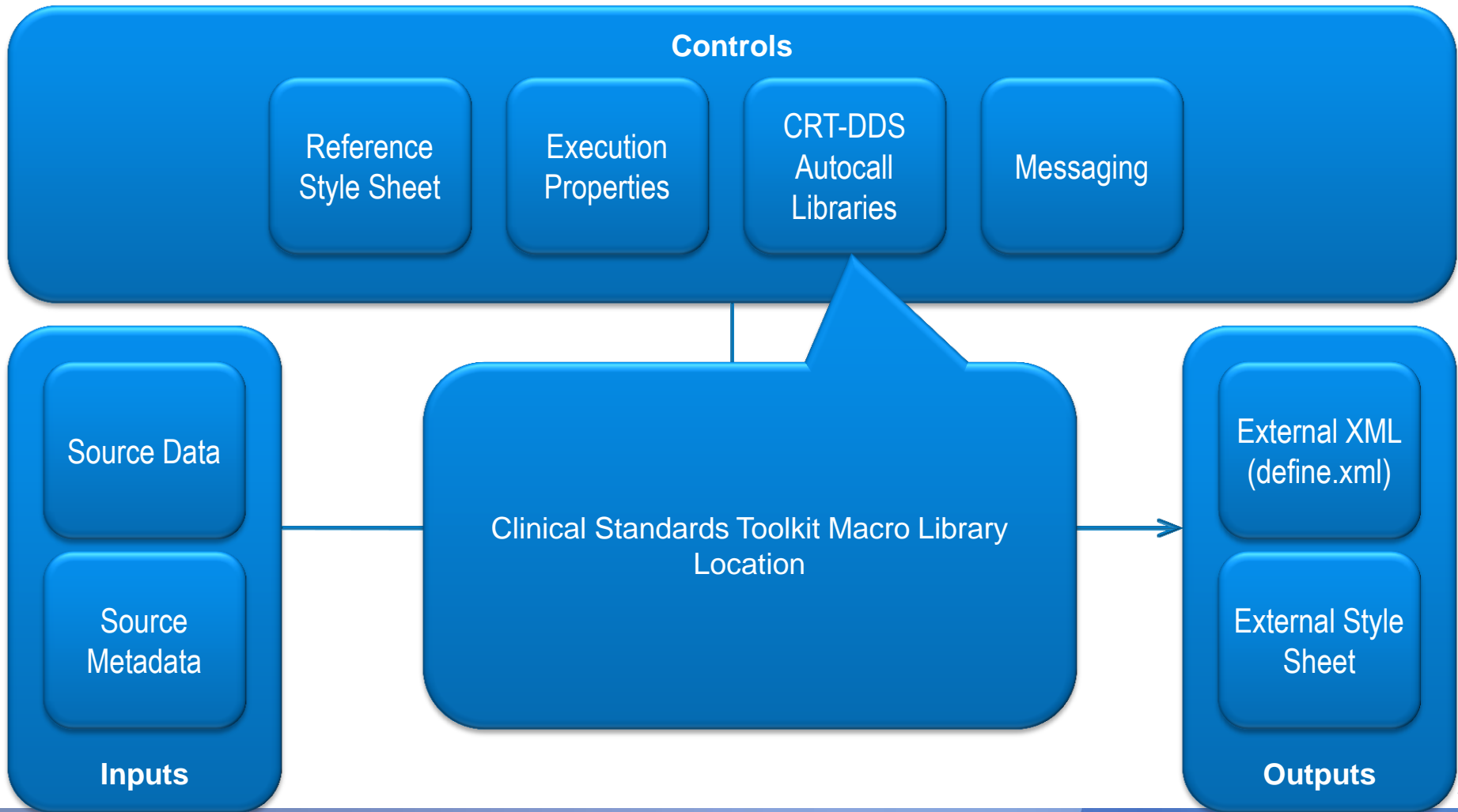


SAS Clinical Standards Toolkit

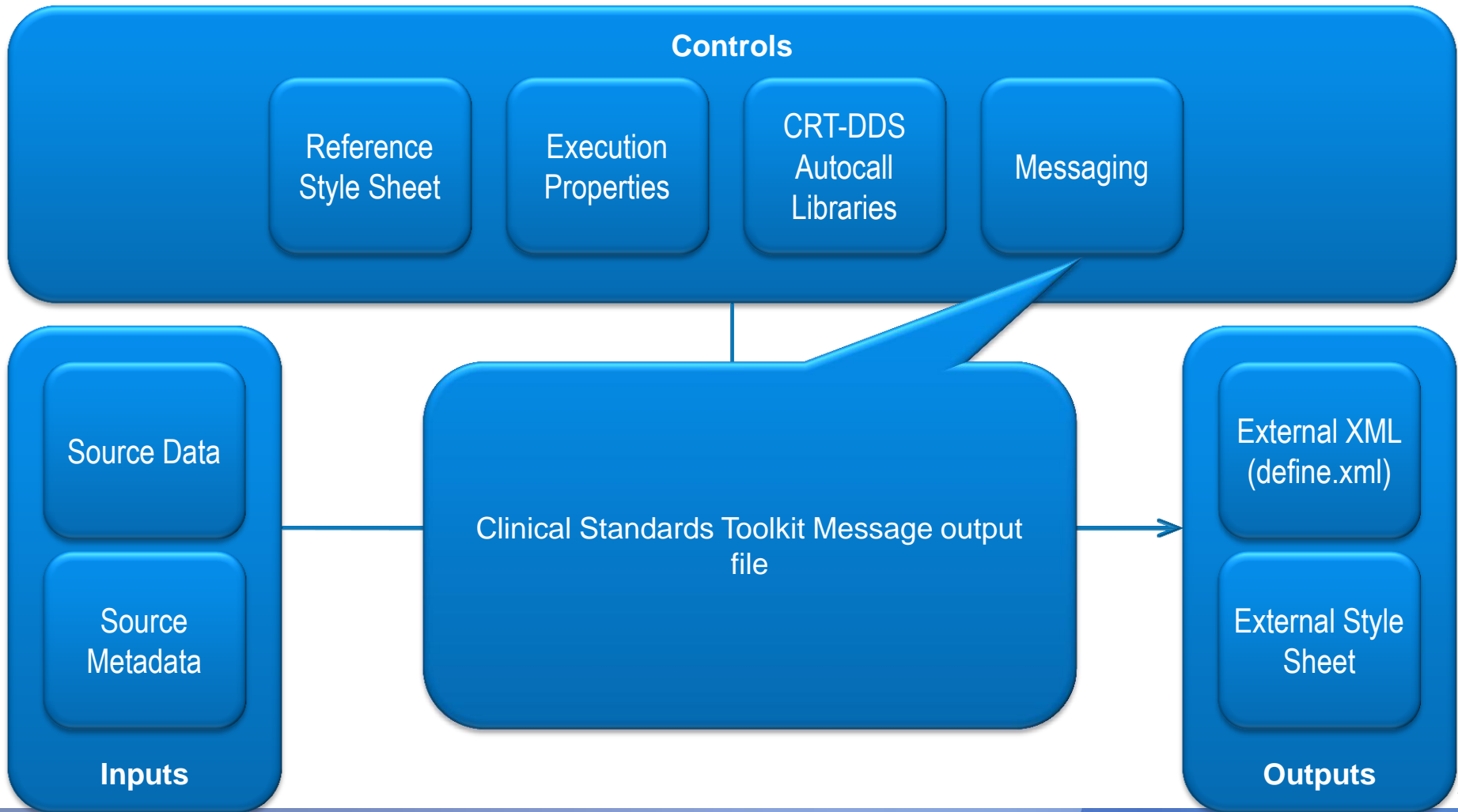
Define.xml (CDISC CRT-DDS) Creation



SAS Clinical Standards Toolkit Define.xml (CDISC CRT-DDS) Creation

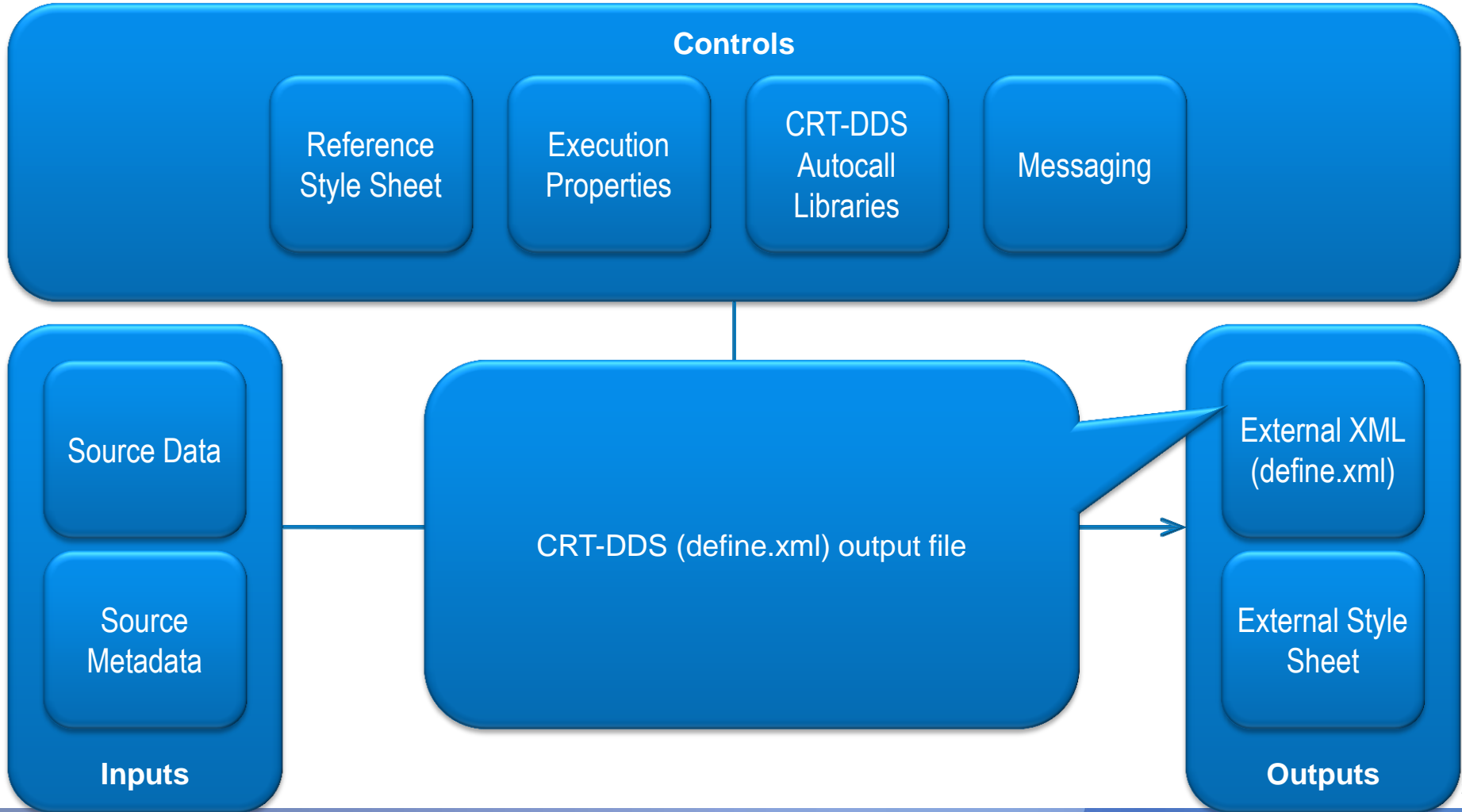


SAS Clinical Standards Toolkit Define.xml (CDISC CRT-DDS) Creation



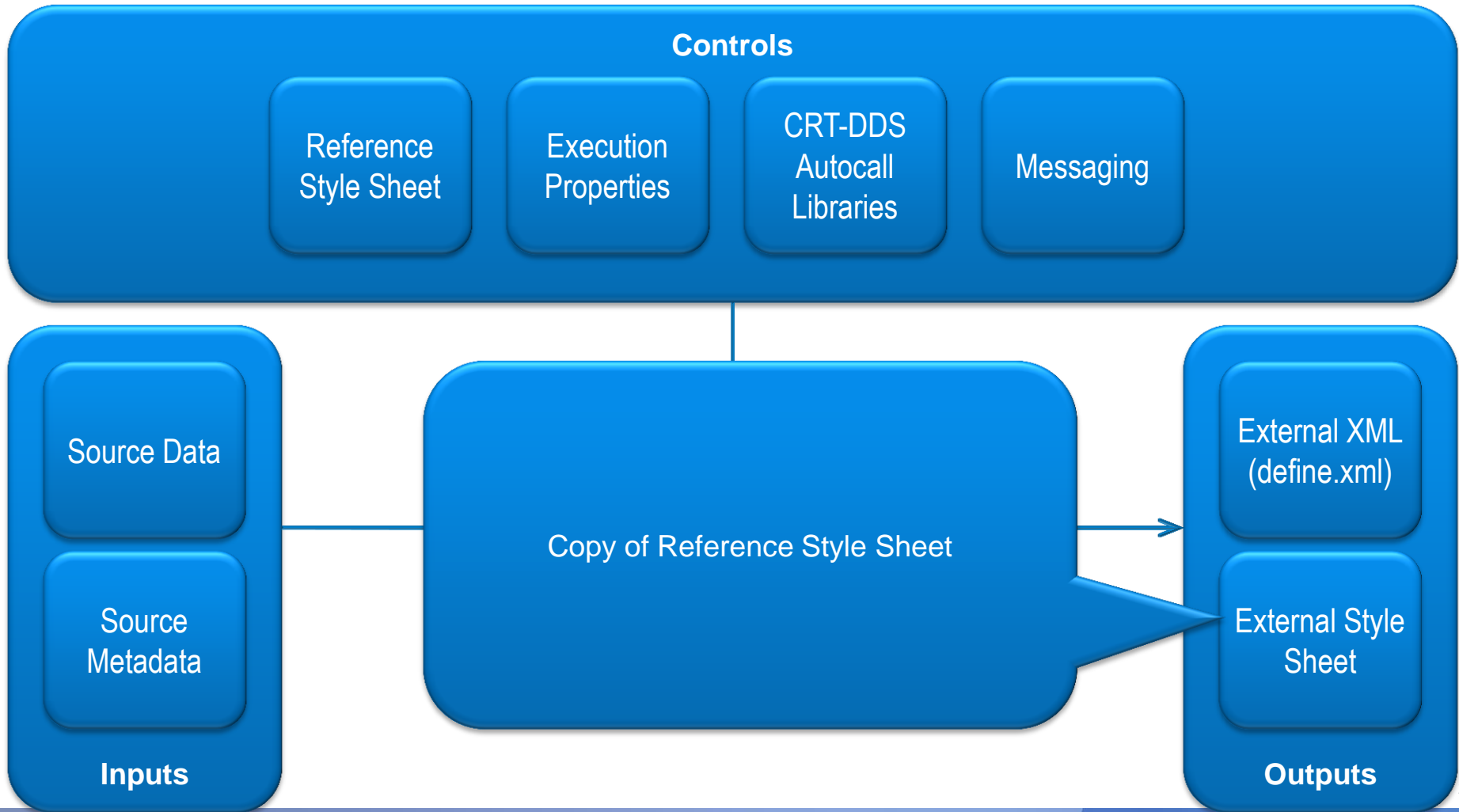
SAS Clinical Standards Toolkit

Define.xml (CDISC CRT-DDS) Creation



SAS Clinical Standards Toolkit

Define.xml (CDISC CRT-DDS) Creation



How to get hold of the Clinical Standards Toolkit

Needs to be licensed

No additional cost

Should get a Plan file for the install

Supported Platforms

Windows

- 32-bit only
- SAS 9.1.3 or SAS 9.2

HP UX Itanium

- SAS 9.2

Solaris

- SAS 9.2

Introduction to...

SAS Clinical Data Integration 2.2

Desired Solutions Characteristics

- Support for CDISC standards
- Flexible implementation options
- Centralized management of integration
- Incorporates data quality management
- Easily extensible
- Support within analytical environment
- Leverage existing IT investments

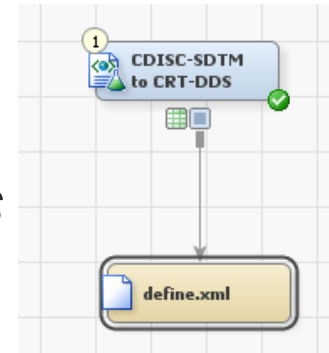
What is SAS Clinical Data Integration?

- SAS Clinical Data Integration is a **data transformation solution** designed to help companies organize, standardize and manage their **clinical research data** and **metadata**.
- The solution enables companies to:
 - **Integrate** data from disparate sources
 - **Standardize** their **in-process** data to industry models
 - **Migrate legacy** data to modern standard models
 - Leverage standardized data to **efficiently prepare data for analysis and submission** to regulatory authorities

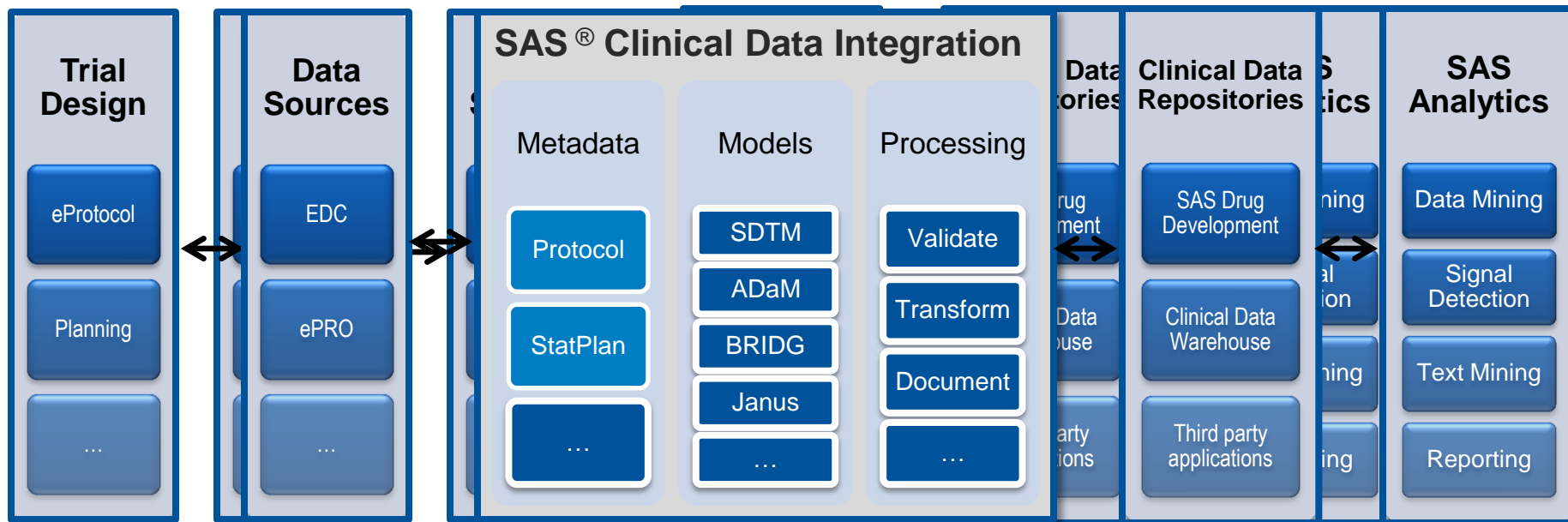
SAS Clinical Data Integration Capabilities

All the capabilities of SAS Data Integration, *plus*

- Pre-built support for CDISC models
 - SDTM
 - CRT-DDS (define.xml)
- Pre-built transformations for CDISC models
- Validation checks for incoming data
- Extensible to new or customized models



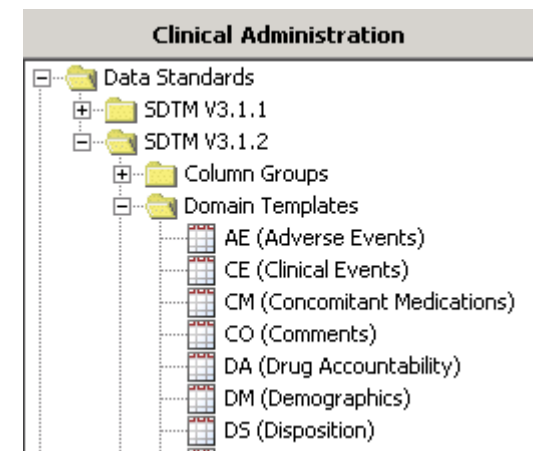
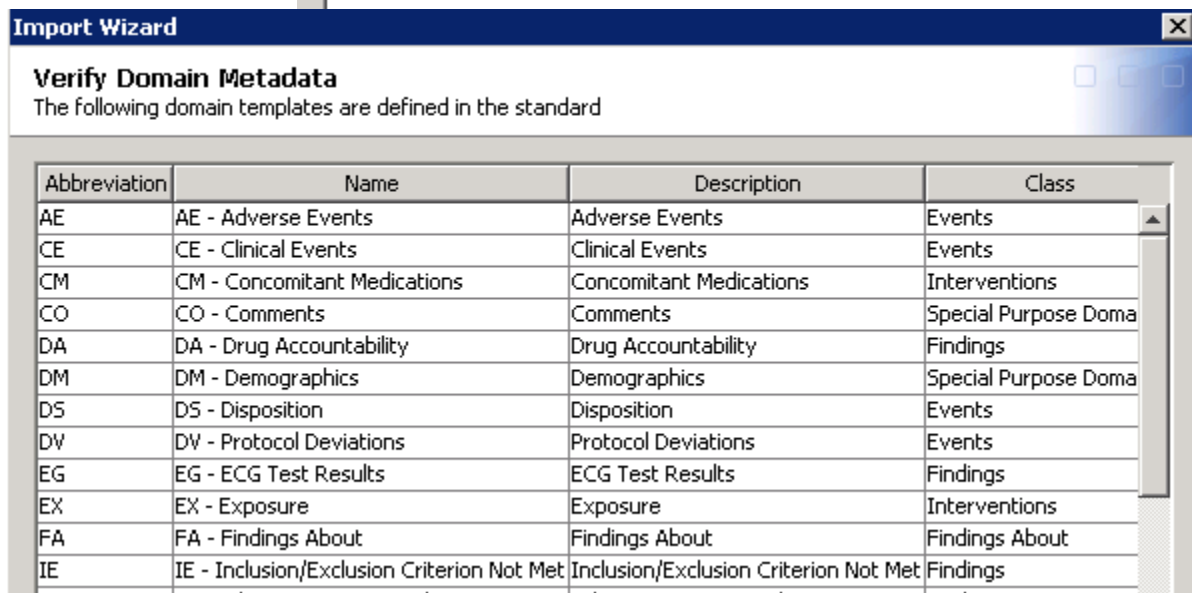
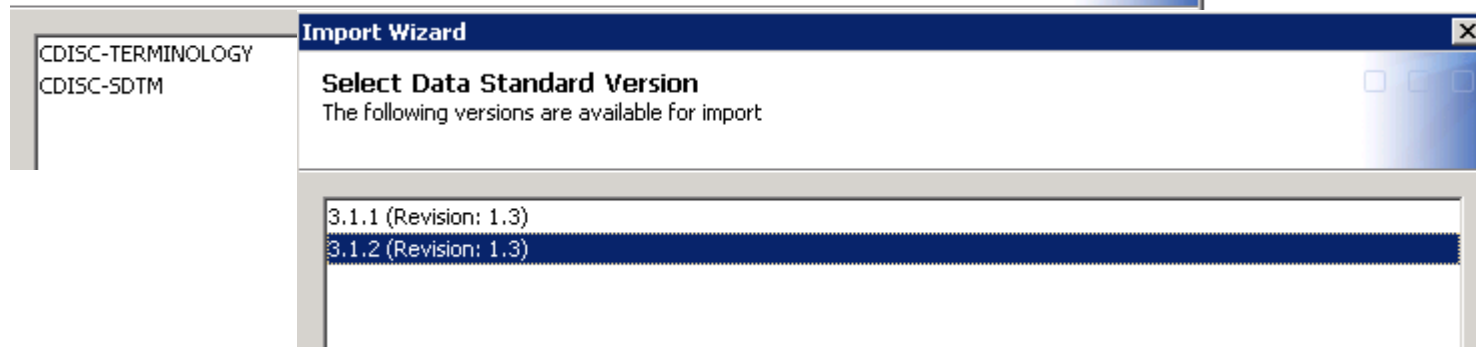
An Enterprise Solution – SAS Health and Life Sciences Framework



Demonstration

SAS Clinical Data Integration 2.2

Administrate Your Standards



Transformation and Folders Tab

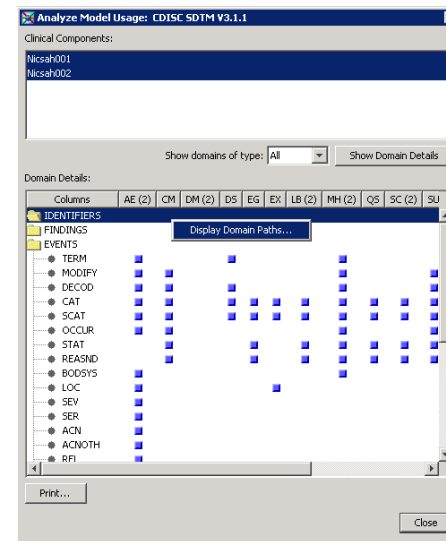
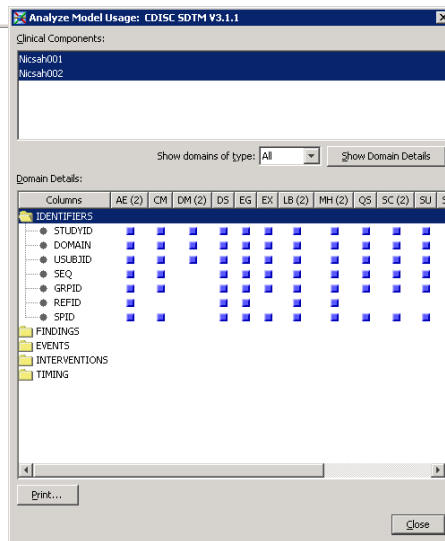
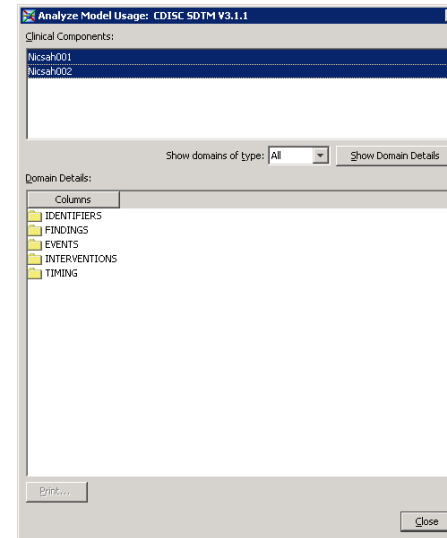
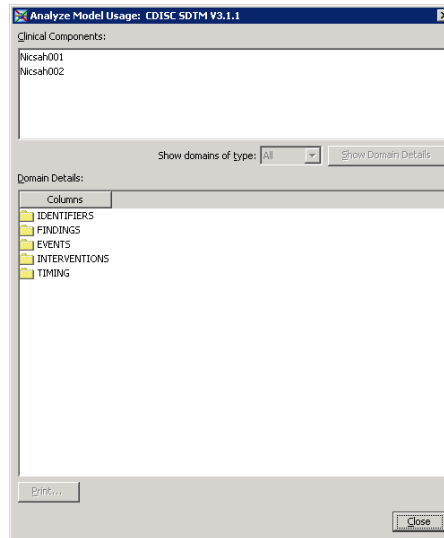
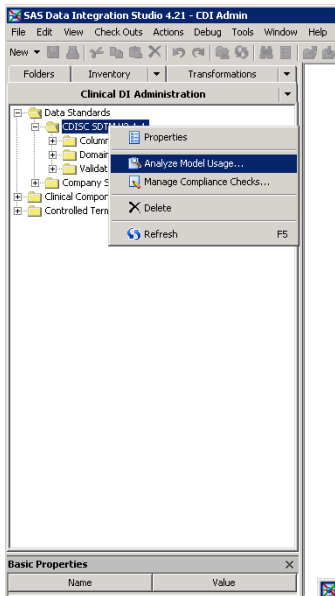
Transformations

- + **Access**
- **Analysis**
 - Correlations
 - Distribution Analysis
 - Forecasting
 - Frequency
 - One-Way Frequency
 - Summary Statistics
 - Summary Tables
- + **Archived**
- + **Change Data Capture**
- **Clinical**
 - CDISC-SDTM Compliance
 - CDISC-SDTM to CRT-DDS
 - Subject Sequence Generator
 - Validate CRT-DDS
- + **Control**
- **Data**
 - Append
 - Data Transfer
 - Data Validation
 - Extract
 - Key Effective Date
 - Lookup
 - Mining Results
 - Rank
 - SCD Type 2 Loader

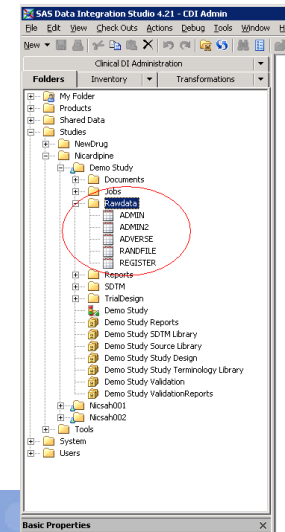
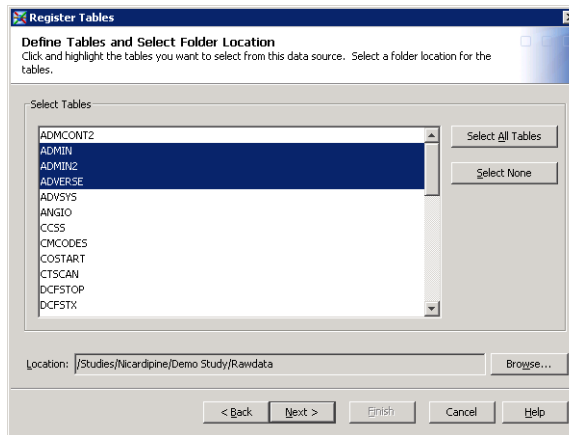
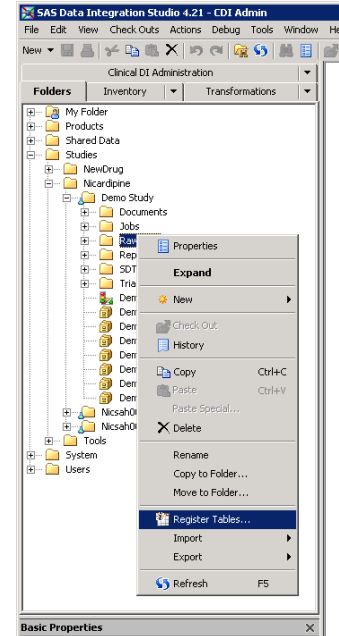
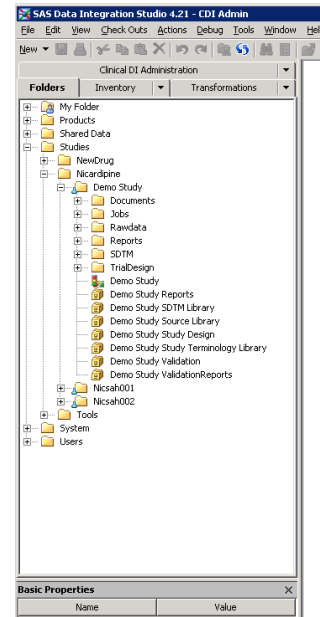
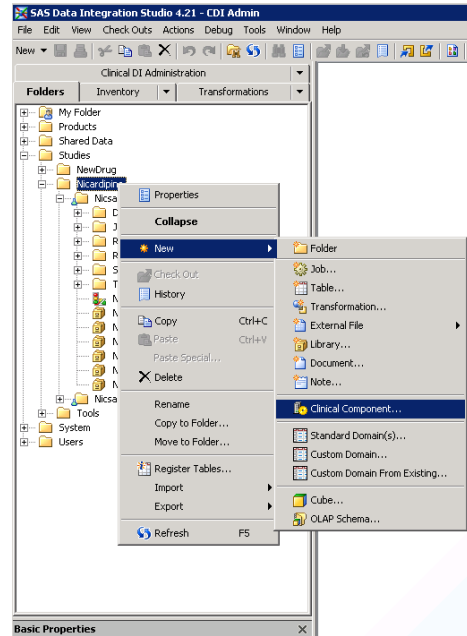
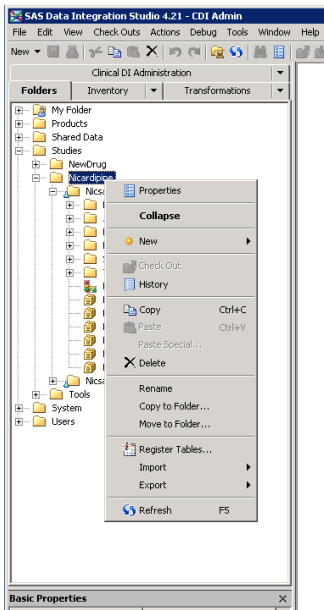
Folders | Inventory

- My Folder
 - ClinicalDI Course
 - PainXD
 - Documents
 - External Domains
 - Jobs
 - Check AE Compliance
 - Check DM Compliance
 - Check QS Compliance
 - Create Standard CDT-DDS Define...
 - Load DM
 - Load QS
 - Load SuppDM
 - Load XP
 - Reports
 - SDTM
 - DM
 - QS
 - SUPPDM
 - XP
 - SrcData
 - External Domains (PainXD)
 - PainXD
 - PainXD Reports
 - PainXD SDTM Domains
 - PainXD Source Data
 - PainXD Study Terminology
 - PainXD2
 - SubjectInfo1
 - Products
 - Shared Data
 - System
 - Users

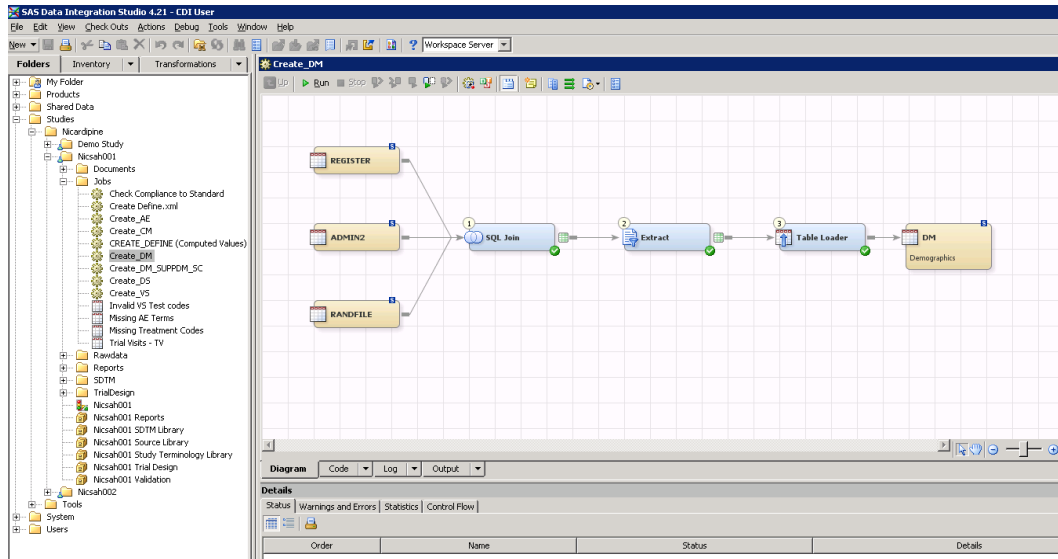
Analyze Model Usage



Define a Clinical Study and Register Tables



Create DM Jobs



Source Table: SQL Join (WSOLQJPS)	Target Table: Extract (WSOLQWFE)
1 STUDYID	1 STUDYID
2 RPTCTR	2 RPTCTR
3 RPTHOSP	3 RPTHOSP
4 RPTINM	4 RPTINM
5 PFINET	5 PFINET
6 CHREGID	6 CHREGID
7 SMDAT	7 SMDAT
8 ADMDAT	8 ADMDAT
9 DOB	9 DOB
10 SEX	10 SEX
11 STATUS	11 STATUS
12 RACE	12 RACE
13 EMPLOY	13 EMPLOY
14 OCCUP	14 OCCUP
15 SMOKE	15 SMOKE
16 PACKS	16 PACKS
17 ETOHCH	17 ETOHCH
18 DRACCON	18 DRACCON
19 HAND	19 HAND
20 DM	20 DM
21 DMRE	21 DMRE
22 FSHNTR	22 FSHNTR
23 FSHNTR	23 FSHNTR
24 FSHNTR	24 FSHNTR

```

17 * Generated by: cdiuser@SASBI
18 * Version: SAS Data Integration Studio 4.21
19 *****/
20
21 /* General macro variables */
22 %let jobId = %quote(ASIO7QGK.AB00000P);
23 %let etls_jobName = %nrquote(Create_DM);
24 %let etls_userID = %nrquote(cdiuser@SASBI);
25
26 /* Performance Statistics require A
27 %macro etls_startPerformanceStats;
28 %log$as ();
29 %log$as_logger (Perf.ARM, 'level
30 options armagent=log$as armsubs
31 %global _armexec;
32 %let _armexec = 1;
33 %performit (appliance="SAS Data Int
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Perform Compliance Check and Report it

The screenshot shows the SAS Data Integration Studio interface. The main window displays a workflow diagram titled 'Check Compliance to Standard'. The workflow starts with a 'CDISC-SDTM Compliance' step, which branches into 'Results' and 'Metrics' steps, both of which lead to a 'Compliance Report' step. The interface includes a file explorer on the left, a toolbar at the top, and a 'Details' pane at the bottom.

The screenshot shows the 'CDISC-SDTM Compliance Properties' dialog box. The 'Domains to Check' section is expanded, showing a list of domains with checkboxes. The domains listed are: AE (Adverse Events), CM (Concomitant Medications), DM (Demographics), DS (Disposition), EX (Exposure), LB (Laboratory Tests), MH (Medical History), QS (Questionnaires), SC (Subject Characteristics), SUPPDM (DM Supplemental Qualifiers), SUPQUAL (Supplemental Qualifiers), VS (Vital Signs), and XQ (Quality of Life Instrument). The 'OK', 'Cancel', and 'Help' buttons are visible at the bottom.

The screenshot shows the 'Add Compliance Check(s)' dialog box. It contains a table of available checks. The table has the following columns: Check ID, Standard, Type, Severity, Source, Status, Domain(s), and Column(s). The table lists 23 checks, including SDTM0001 through SDTM0023. At the bottom of the dialog, there are buttons for 'Select All', 'Deselect All', 'Add Selected', and 'Close'.

Check ID	Standard	Type	Severity	Source	Status	Domain(s)	Column(s)
SDTM0001	CDISC-SDTM	Metadata	Note	Janus	Active	_ALL_	Identifie
SDTM0001	CDISC-SDTM	Metadata	Warning	WebSDM	Active	_ALL_	Identifie
SDTM0002	CDISC-SDTM	Metadata	Error	JanusFR	Active	DM+DS+EX	A load c
SDTM0003	CDISC-SDTM	Metadata	Error	WebSDM	Active	DM	WebSDf
SDTM0004	CDISC-SDTM	Metadata	Note	SAS	Active	_ALL_	Source i
SDTM0005	CDISC-SDTM	Metadata	Note	SAS	Active	_ALL_	Custom
SDTM0006	CDISC-SDTM	Metadata	Warning	SAS	Active	_ALL_	Source i
SDTM0011	CDISC-SDTM	Metadata	Note	Janus	Active	_ALL_	Identifie
SDTM0011	CDISC-SDTM	Metadata	Note	WebSDM	Active	_ALL_	Identifie
SDTM0012	CDISC-SDTM	Metadata	Error	WebSDM	Active	_ALL_	Identifie
SDTM0013	CDISC-SDTM	Metadata	Warning	WebSDM	Active	_ALL_	Identifie
SDTM0015	CDISC-SDTM	Metadata	Warning	Janus	Active	_ALL_	Identifie
SDTM0015	CDISC-SDTM	Metadata	Warning	WebSDM	Active	_ALL_	Identifie
SDTM0017	CDISC-SDTM	Metadata	Error	Janus	Active	SUPP**	Identifie
SDTM0017	CDISC-SDTM	Metadata	Error	WebSDM	Active	SUPP**	Identifie
SDTM0019	CDISC-SDTM	Metadata	Warning	JanusFR	Active	_ALL_	Identifie
SDTM0019	CDISC-SDTM	Metadata	Warning	WebSDM	Active	_ALL_	Identifie
SDTM0020	CDISC-SDTM	Metadata	Warning	SAS	Active	_ALL_	Column
SDTM0023	CDISC-SDTM	Metadata	Error	SAS	Active	ALL	Column

The screenshot shows a web browser window displaying the 'Study Nicsah001, Data Definitions' page. The page contains a table with the following columns: Dataset, Description, Structure, Purpose, Keys, and Location. The table lists several datasets, including AE, CM, DM, DS, SC, SUPPDM, and VS, with their respective descriptions and structures.

Dataset	Description	Structure	Purpose	Keys	Location
AE	Adverse Events	Events - One record per event per subject	Tabulation	STUDYID USUBJID AETERM AESTDTC	
CM	Concomitant Medications	Interventions - One record per medication intervention episode per subject	Tabulation	STUDYID USUBJID CMTRT CMSTDTC	
DM	Demographics	Special Purpose - One record per subject	Tabulation	STUDYID USUBJID	
DS	Disposition	Events - One record per disposition status or protocol milestone per subject	Tabulation	STUDYID USUBJID DSSTDTC	
SC	Subject Characteristics	Findings - One record per characteristic per subject	Tabulation	STUDYID USUBJID SCTESTCD	
SUPPDM	DM Supplemental Qualifiers	Relates - One record per qualifier value	Tabulation	STUDYID RDOMAIN USUBJID IDVAR IDVARVAL QNAM	
VS	Vital Signs	Findings - One record per vital sign measurement per time point	Tabulation	STUDYID USUBJID VSTESTCD VSTINUM	

Create CRT-DDS / Define.xml

The screenshot displays the SAS software interface. On the left, a file explorer shows a hierarchical structure: Clinical Administration > Transformations > Folders > My Folder > ClinicalDI Course > PainXD > Documents > define.xml. The main workspace is titled "Create Standard CDT-DDS Define.xml" and contains a workflow diagram. The diagram starts with a task labeled "1 CDISC-SDTM to CRT-DDS" with a green checkmark. Two arrows from this task point to two other elements: "CRT-DDS Results" (represented by a grid icon) and "define.xml" (represented by a document icon).

Navigate in the Define.xml file



Datasets for Study PainXD					
Dataset	Description	Structure	Purpose	Keys	Location
DM	Demographics	Special Purpose Domains - One record per subject	Tabulation	STUDYID USUBJID	
QS	Questionnaires	Findings - One record per questionnaire per question per time point per visit per subject	Tabulation	STUDYID USUBJID QSTESTCD QSCAT VISITNUM	
SUPPQUAL	DM Supplemental Qualifiers	Special Purpose Datasets - One record per IDVAR, IDVARVAL, and QNAM value per subject	Tabulation	STUDYID RDOMAIN USUBJID QNAM	
XP	Pain Diary	FINDINGS -	Tabulation	STUDYID USUBJID XPSEQ XPTESTCD XPDTC	

Go to Date

Demographics Dataset (DM)							
Variable	Label	Type	Controlled Terms or Format	Origin	Role	Comment	
STUDYID	Study Identifier	text			Identifier		
DOMAIN	Domain Abbreviation	text			Identifier		
USUBJID	Unique Subject Identifier	text					
SUBJID	Subject Identifier for the Study	text					
RFSTDTCT	Subject Reference Start Date/Time	text					
RFENDTCT	Subject Reference End Date/Time	text					
SITEID	Study Site Identifier	text					
INVID	Investigator Identifier	text					
INVNAM	Investigator Name	text					
BRTHDTC	Date/Time of Birth	text					
AGE	Age	float					
AGEU	Age Units	text	AGEU				
SEX	Sex	text	SEX				
RACE	Race	text	RACE		RecordQualifier		

RACE, Reference Name (RACE)	
AMERICAN INDIAN OR ALASKA NATIVE	AMERICAN INDIAN OR ALASKA NATIVE
ASIAN	ASIAN
BLACK OR AFRICAN AMERICAN	BLACK OR AFRICAN AMERICAN
NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER
WHITE	WHITE

Introduction to...

JMP Clinical

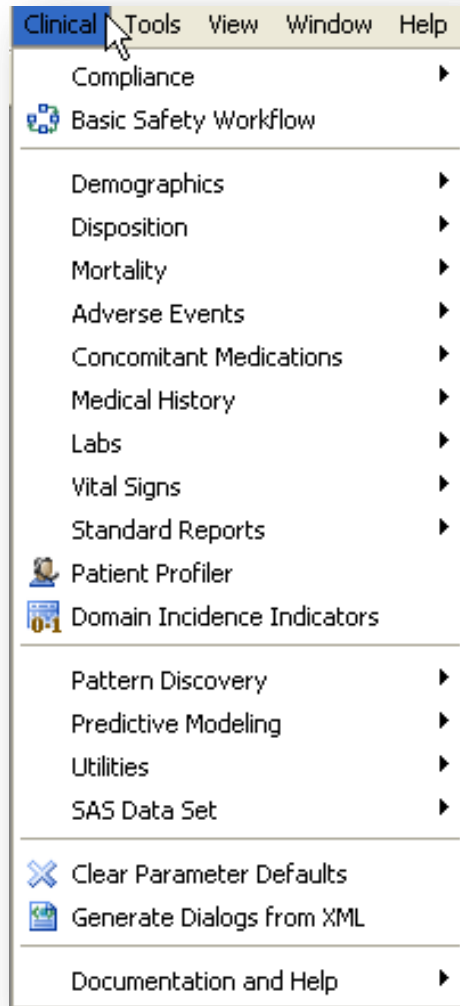
Explore the Hidden Patterns in Clinical Trials Data with JMP Clinical

- JMP Clinical creates analytical reports on CDISC data
- SAS® Analytics running behind a JMP® user interface
- Interactive JMP® features for dynamics analysis
- An intuitive dashboard makes it easy to get started
- Examine patient profiles from many perspectives
- Apply trusted statistical methods with flexible options
- Use sophisticated pattern-discovery capabilities

From the ICH E3 reviewer guidance, what types of reports the FDA looks at

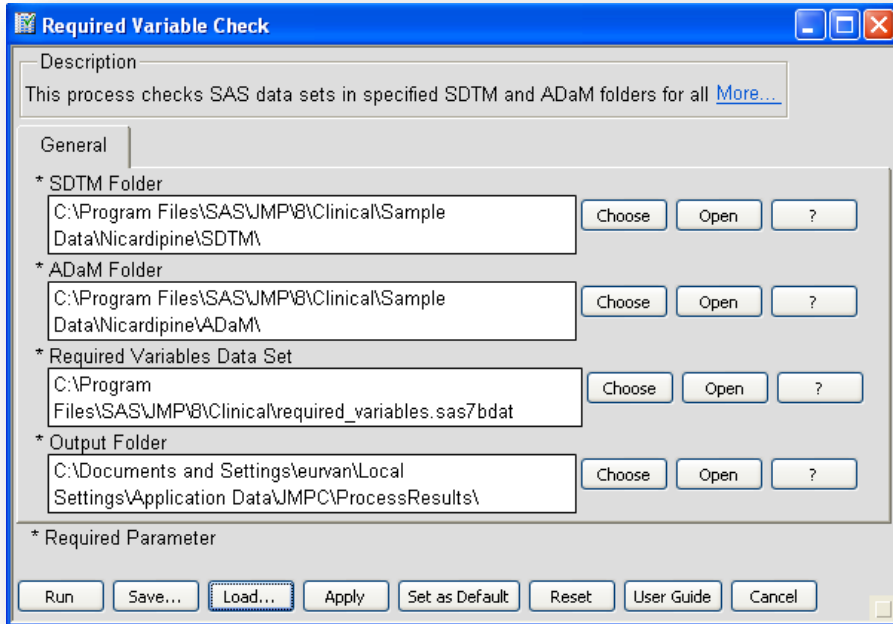
- Deaths
 - Overall mortality
 - Cause specific
 - Expected vs unexpected
 - Dose response
 - Time to death analysis
 - Subgroup analysis
 - Interaction analysis
- SAEs
 - Overall rates
 - Rates by event
 - Dose response
 - By duration of exposure
 - By person-time exposure
 - Assessment according to severity
 - Assessment of interaction
- Dropouts and other SAEs
 - Overall rates
 - Profile of dropouts (by event)
 - AEs associated with dropouts
 - Exposure response
 - Time dependency
- Other significant AEs as defined
 - Marked lab abnormalities
 - Any AE leading to dropout
 - Potentially important adverse events
- Construct of algorithms of
 - Identify possible combination of events as a marker for a particular event
- Identify possible consequences of a safety signal from any source
 - Common AEs
- AE incidence by interaction (cont.)
 - Relative risks and attributable risks for subgroup differences
 - Life table/ time-to-event analyses/ cumulative incidence analyses
 - Hazard rates – risk over time estimation
- Less common AEs
 - Identify and group by body system for rates
- Laboratories
 - Overview of
 - Analysis of
 - Analysis of
 - Marked outliers
 - Dose dependent
 - Time dependent
 - Demographic
 - Drug-drug interaction
 - Underlying mechanism
 - Special sections
 - Shift tables
 - Scatter plots
 - Box plots
 - Cumulative
 - Tables of data
- Vital signs
 - Overview of
 - Analysis of
 - Analysis of
 - Marked outliers
- ECG's
 - Describe baseline
 - Analysis of
 - Analysis of
 - Marked outliers
- Immunogenicity
 - Summarize and assess available data
- Carcinogenicity
 - Summarize and assess
- Special Safety Studies
 - Summarize any such studies
 - Similar to other drugs in pharmacological class?
- Additional Clinical Issues
 - Level of confidence for dose/regimen
 - Dose-toxicity and dose response relationships
 - Dose modification for special populations
- General assessment of adequacy of Special Animal and/or In Vitro testing
 - Pre-clinical animal models
 - QT studies
- Adequacy of routine clinical testing
 - Labs, vital signs, ECGs, assessment of certain events
- Adequacy of metabolic, clearance, and interaction workup
 - P450 and p-glycoprotein pathways
 - Other drug-drug interaction studies
 - Specify potential safety consequences
- Adequacy of evaluation for potentially problematic AEs that might be expected for a new drug
 - Assess adequacy and note pertinent negative findings (absences of findings)
- Assessment of Quality and completeness of data
 - General overall assessment of the quality and completeness of data with a description of the basis for this assessment
- Additional submissions, including safety update
 - Particularly those submission whose data were not incorporated into the rest of the review
- Summary assessment of important identified adverse events
 - Not important limitations of data and make conclusions
- General Methodology
 - Discussion of general methodological issues
- Pooled data vs. individual study data
- Causality determination
- Exploration of predictive factors
 - Plasma levels, duration of treatment, concomitant meds, concomitant illnesses, age, sex, race
- Special populations
- Pediatrics
- AC meeting
- Literature review
- Post-marketing Risk management plan
- Other relevant materials
 - Result of consultations with DDMAC, ODS reviews, actual use and labeling comprehension studies, marketing studies
- Overall assessment
 - Conclusions
 - Recommendation (regulatory)
 - Recommendations on post-marketing actions
- Risk management activity
 - Include all such recommended activity with rationale
- Required phase 4 commitments
 - Include the agreed upon studies, the timeline for submission, and basis for each phase 4 commitment
- Labeling review

JMP Clinical Process Flow



*The order of this menu is important.
The order follows the order layout for
the FDA reviewer guidance*

JMP Clinical Ease of Use

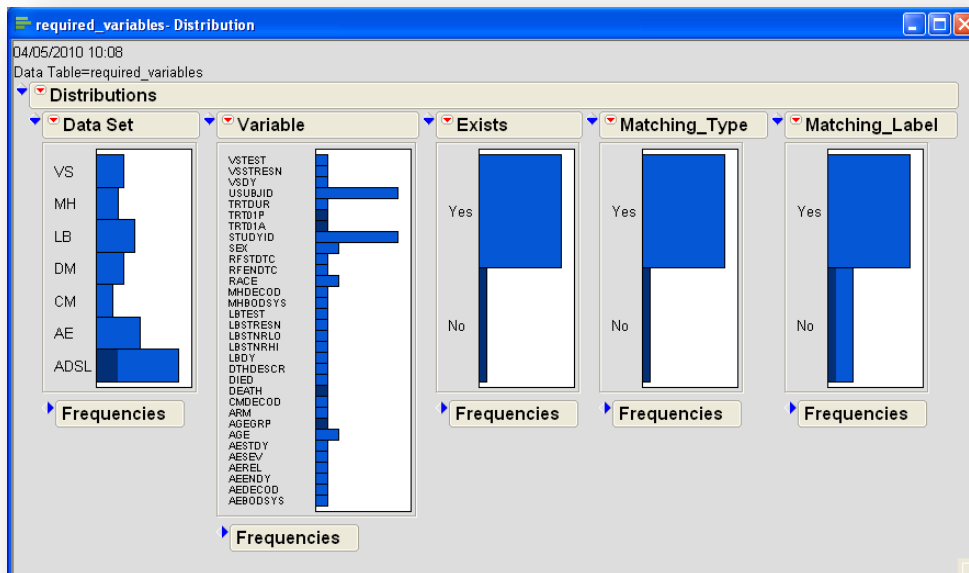


- *Dialogs are organised such as only the SDTM and ADaM folders needs to be defined*
- *Once an application has ran, the next dialogs will automatically populate the same settings (same folder definition)*
- **BENEFITS**
 - *Easy to use*
 - *Reduced learning curve*
 - *No programming requirements*

JMP Clinical Output Files

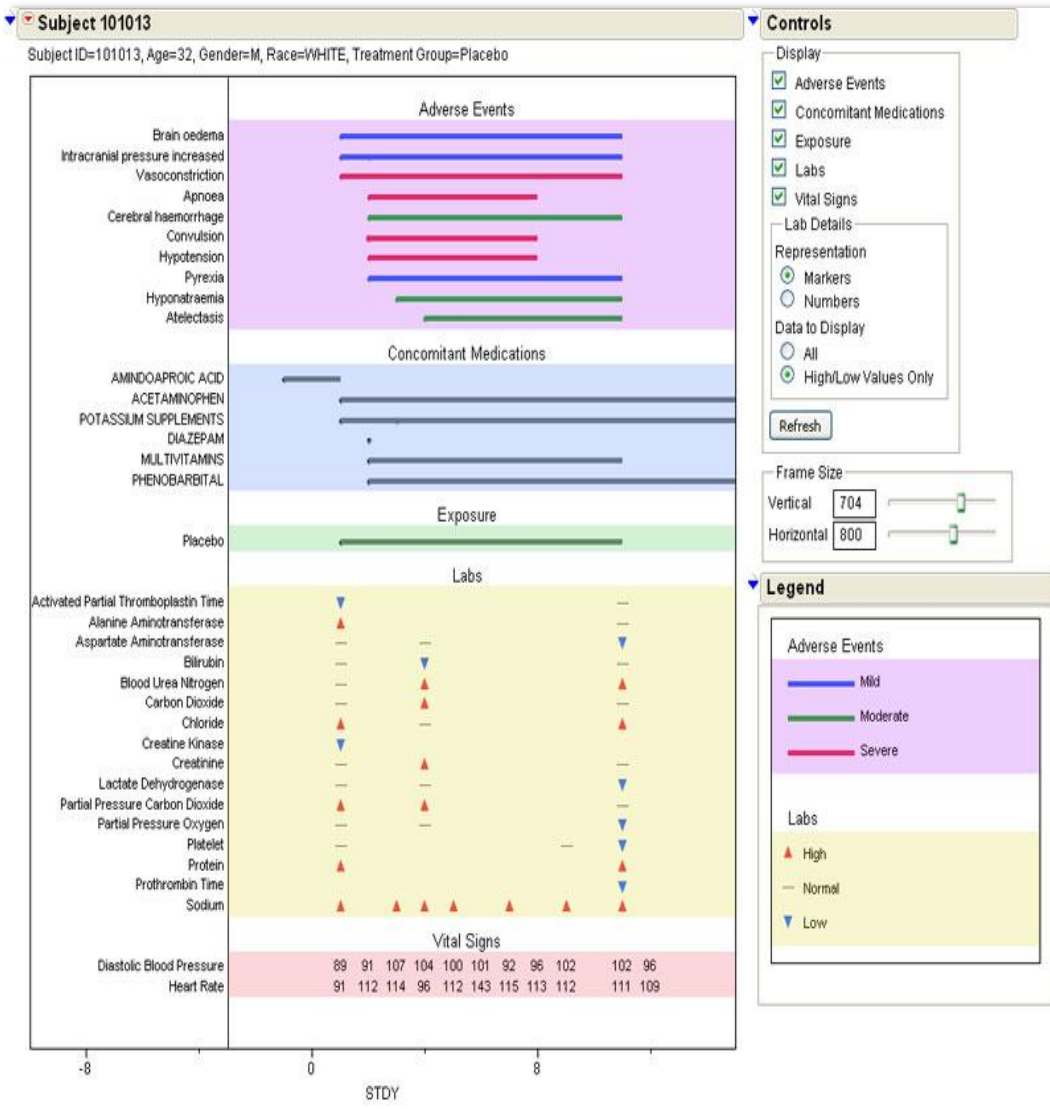
Run

_processinfo.sas7bdat	17 KB	SAS Data Set
ProjectLog_Test.txt	1 KB	Text Document
required_variables.sas7bdat	17 KB	SAS Data Set
RequiredVariableCheck_Script.jsl	1 KB	JMP Script
RequiredVariableCheck.log	14 KB	SAS.OutputLog.701
RequiredVariableCheck__required_variables.sas	3 KB	SAS System Program
sasclean.jsl	5 KB	JMP Script



- *SAS data sets*
- *ProcessInfo files to track what has been performed, when it has been performed, how much time this process ran*
- *SAS logs to track SAS runs*
- *SAS program with the settings of the application*
- *JSL scripts generating the dynamic and interactive graphics*
- **BENEFITS**
 - *All the SAS files that is needed for the submission*

JMP Clinical Patient Profiles



- Create interactive patient profiles instantly for any individual or group of subjects
- You can also select from patient details – adverse events, medical history, vital signs, etc. – to customize patient profiles
- **BENEFITS**
 - Easy to use
 - No programming requirements
 - Create customized patient profile templates to select display of relevant safety domains.
 - See the medical history for any subject

Demonstration

JMP Clinical 2.1



Verify CDISC Data Consistency

Required Variable Check

Description
This process checks SAS data sets in specified SDTM and ADaM folders for all [More...](#)

General

* SDTM Folder

* ADaM Folder

* Required Variables Data Set

* Output Folder

* Required Parameter

Data Filter for required_va...

2 matching rows

Select Show Include

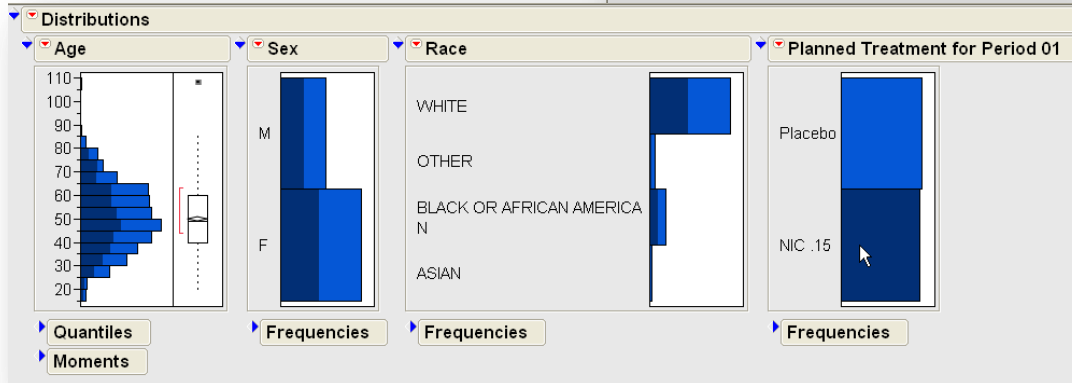
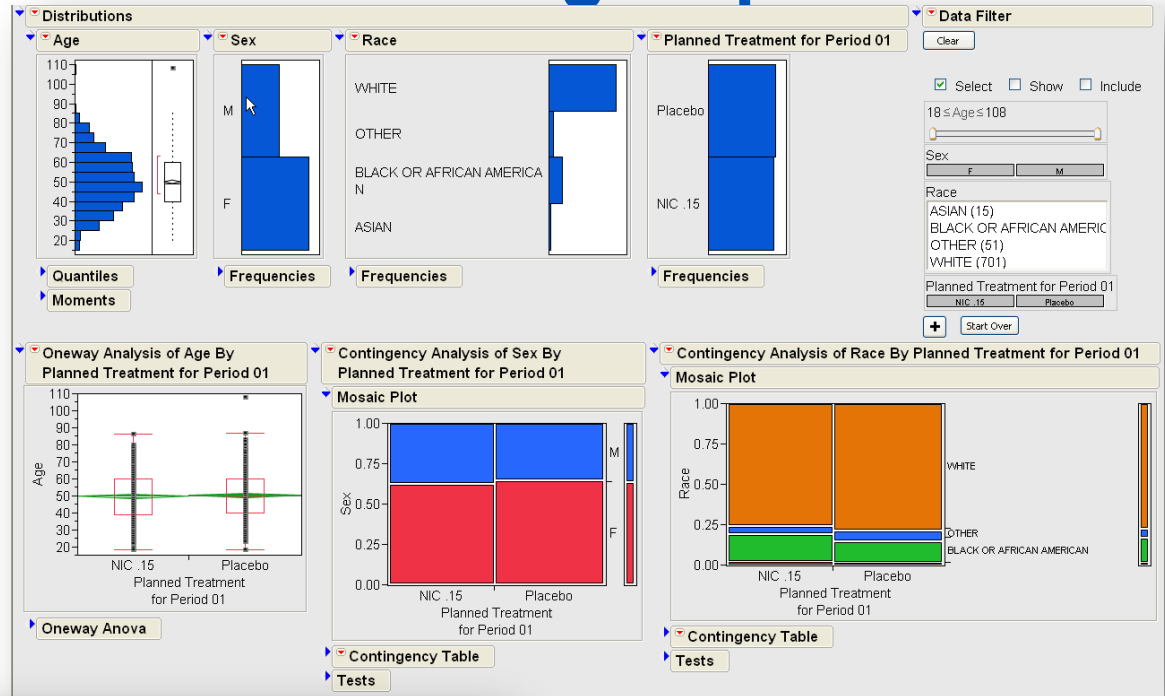
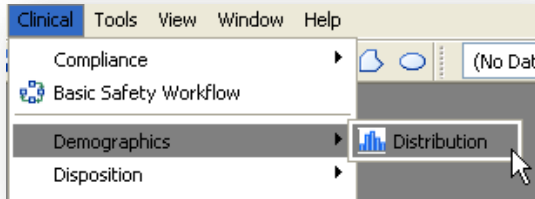
Exists

Matching_Type

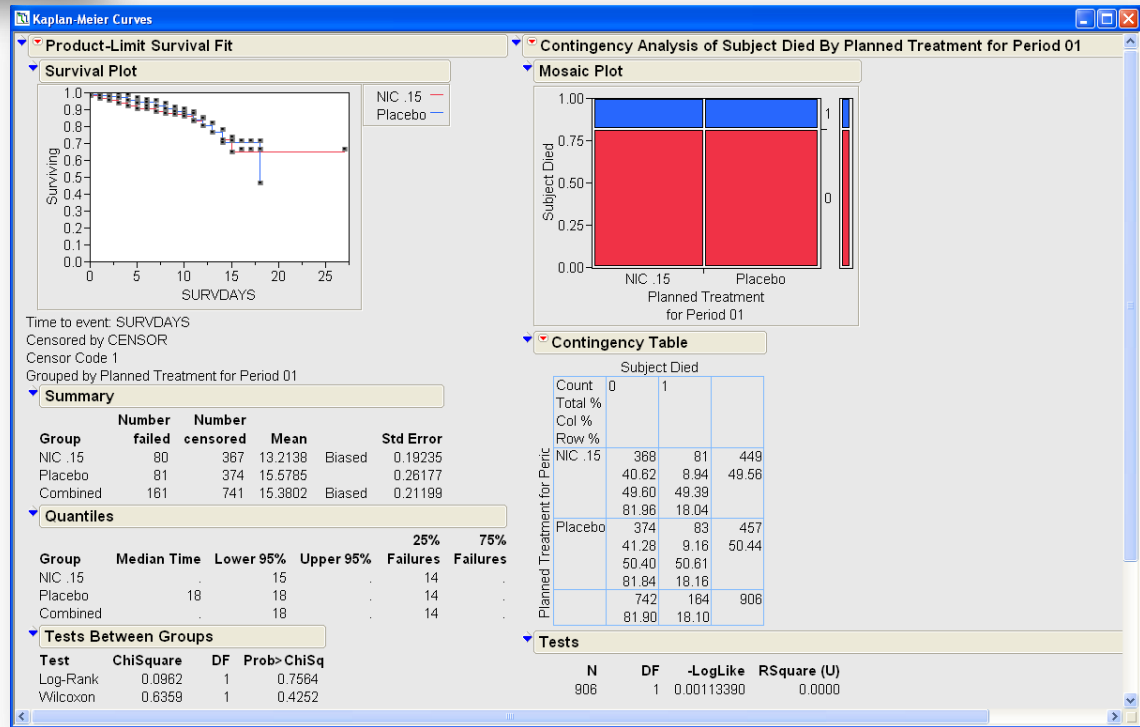
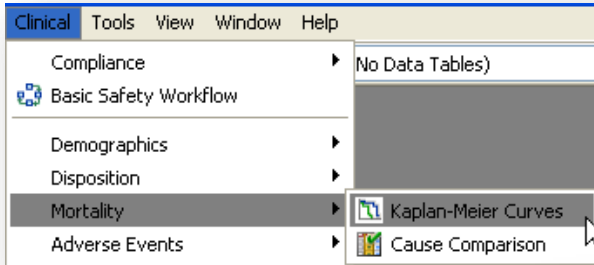
Matching_Label

Folder	Data Set	Variable	Type	Label	Notes	E	
		AGE	N	Age		Ye	
		AGEGR1	C	Age Group 1		Ye	
		ARM	C	Description of Planned Arm	Only one of ARM, TRT01A, or TRT01P is required	Ye	
		DEATHDSC	C	Death Description	Nonstandard, used only in Mortality Cause Comparison	Ye	
		RACE	C	Race		Ye	
		SEX	C	Sex		Ye	
		STUDYID	C	Study Identifier	Must be coded consistently across data sets	Ye	
		TRTEDT	N	Date of Last Exposure to Treatment	Either TRTEDT or TRTEDTM is required	Ye	
		TRTEDTM	N	Datetime of Last Exposure to Treatment	Either TRTEDT or TRTEDTM is required	Ye	
		TRTSDDT	N	Date of First Exposure to Treatment	Either TRTSDDT or TRTSDDTM is required	Ye	
		TRTSDDTM	N	Datetime of First Exposure to Treatment	Either TRTSDDT or TRTSDDTM is required	Ye	
		TRT01A	C	Actual Treatment for Period 01	Only one of ARM, TRT01A, or TRT01P is required	Nc	
		TRT01P	C	Planned Treatment for Period 01	Only one of ARM, TRT01A, or TRT01P is required	Ye	
		USUBJID	C	Unique Subject Identifier	Must be coded consistently across data sets	Ye	
15	SDTM	AE	AEBODSYS	C	Body System or Organ Class	Ye	
16	SDTM	AE	AEDECOD	C	Dictionary-Derived Term	Ye	
17	SDTM	AE	AEENDY	N	Study Day of End of Adverse Event	Ye	
18	SDTM	AE	AEREL	C	Causality	Ye	
19	SDTM	AE	AESEV	C	Severity/Intensity	Either AESEV or AETOXGR is required, values must be Mil	Ye
20	SDTM	AE	AESTDY	N	Study Day of Start of Adverse Event	Ye	
21	SDTM	AE	AETOXGR	C	Toxicological Grade	Either AESEV or AETOXGR is required, values must be Mil	Nc
22	SDTM	AE	STUDYID	C	Study Identifier	Must be coded consistently across data sets	Ye
23	SDTM	AE	USUBJID	C	Unique Subject Identifier	Must be coded consistently across data sets	Ye
24	SDTM	CM	CMDECOD	C	Standardized Medication Name	Ye	
25	SDTM	CM	CMENDY	C	Study Day of End of Medication	Ye	
26	SDTM	CM	CMSTDY	C	Study Day of Start of Medication	Ye	
27	SDTM	CM	STUDYID	C	Study Identifier	Must be coded consistently across data sets	Ye
28	SDTM	CM	USUBJID	C	Unique Subject Identifier	Must be coded consistently across data sets	Ye
29	SDTM	DM	AGE	N	Age	Ye	
30	SDTM	DM	ARM	C	Description of Planned Arm	Ye	
31	SDTM	DM	RACE	C	Race	Ye	

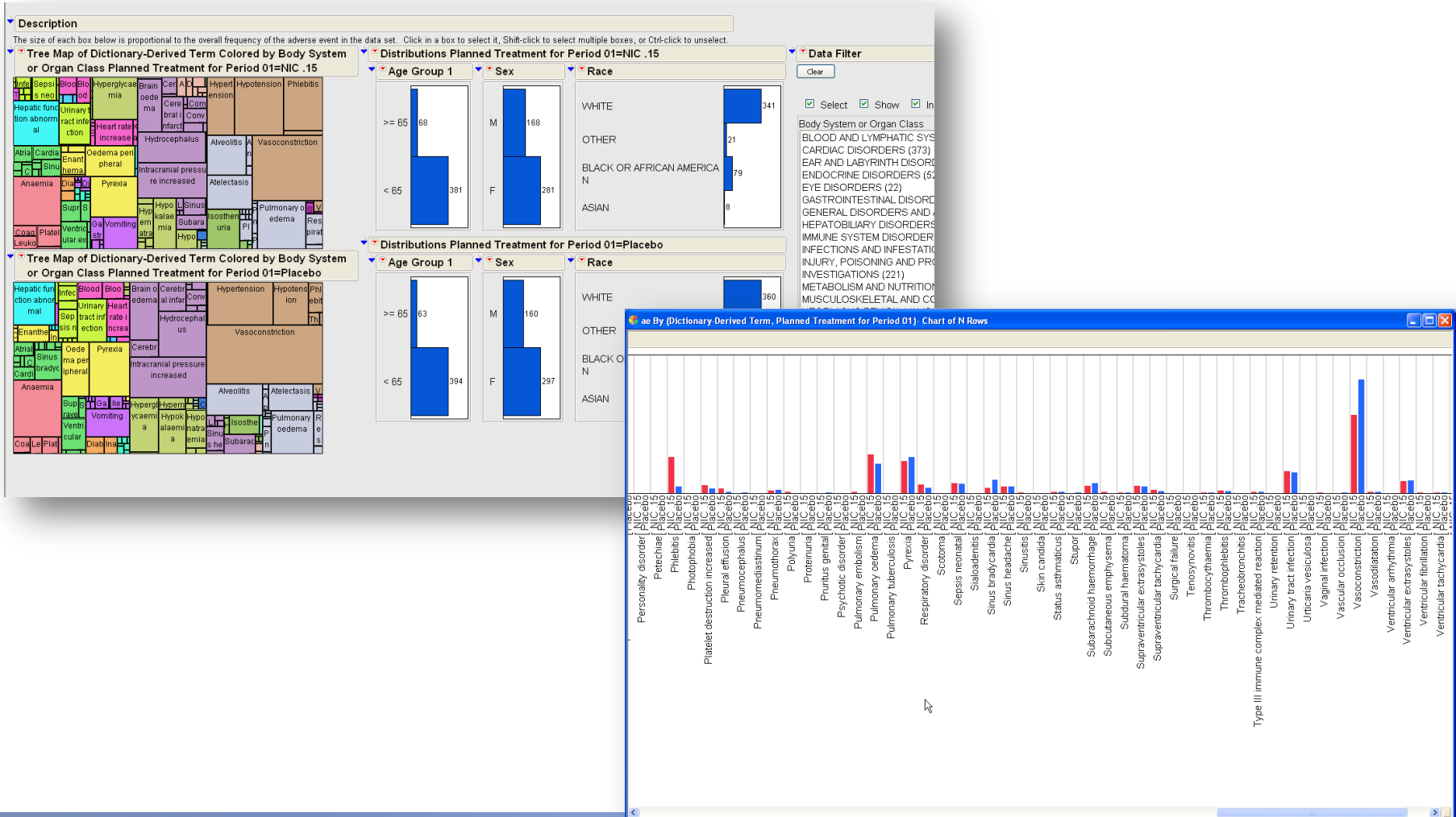
Relationships between demographic characteristics and treatment group



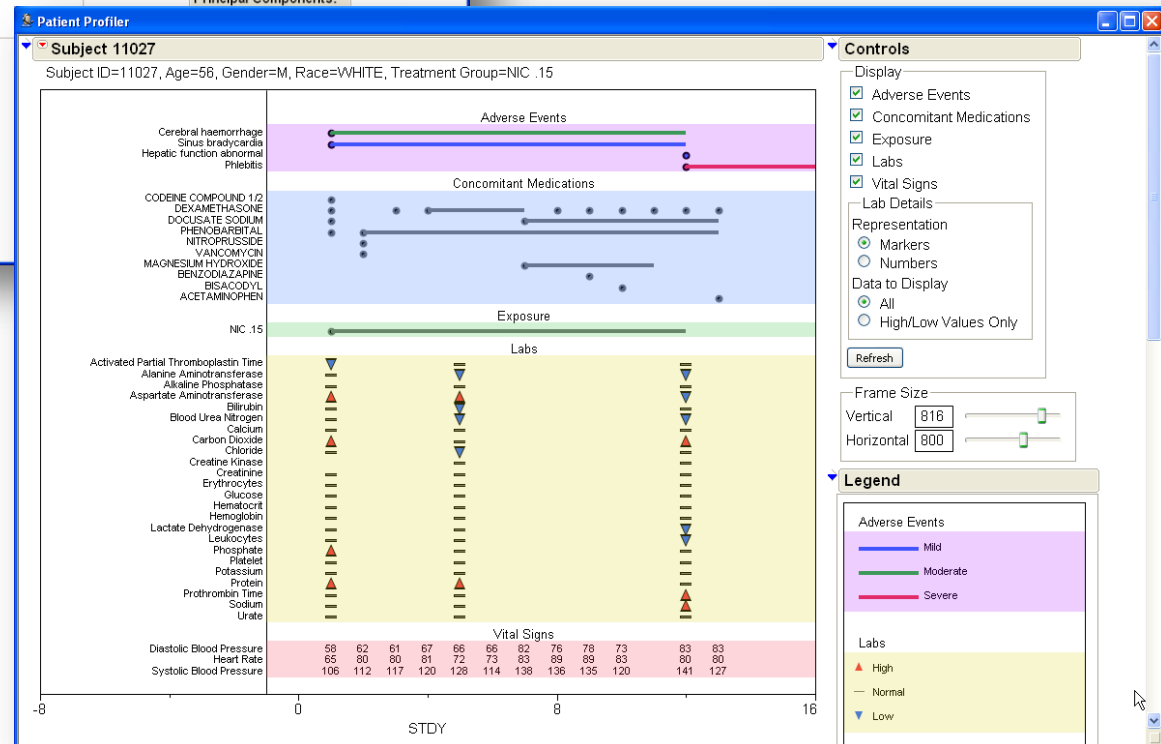
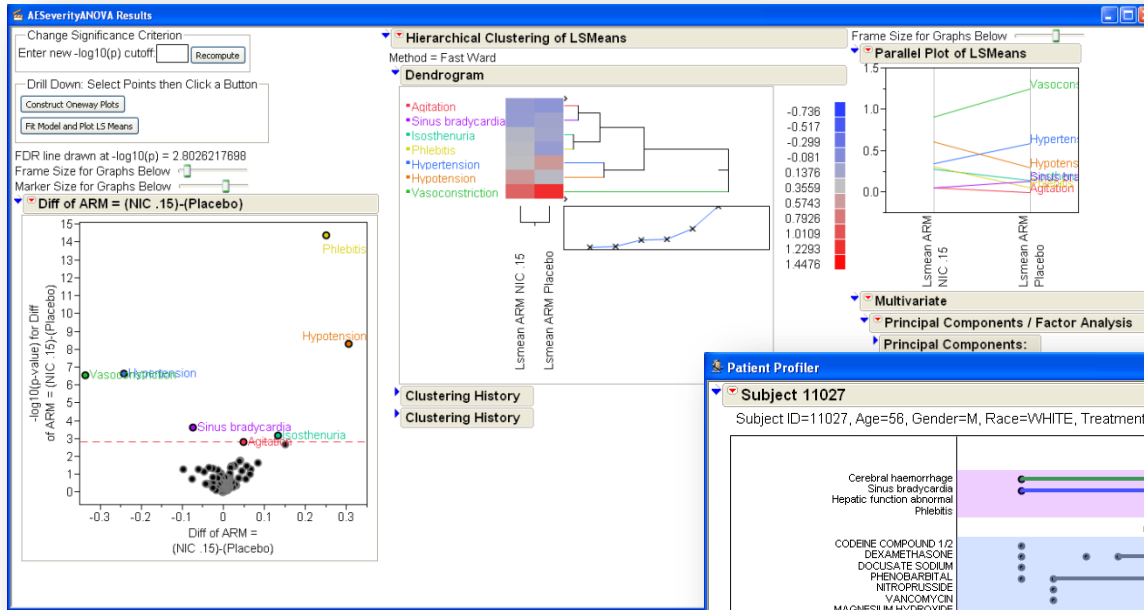
Visualize Relationships between Mortality Rate and treatment groups



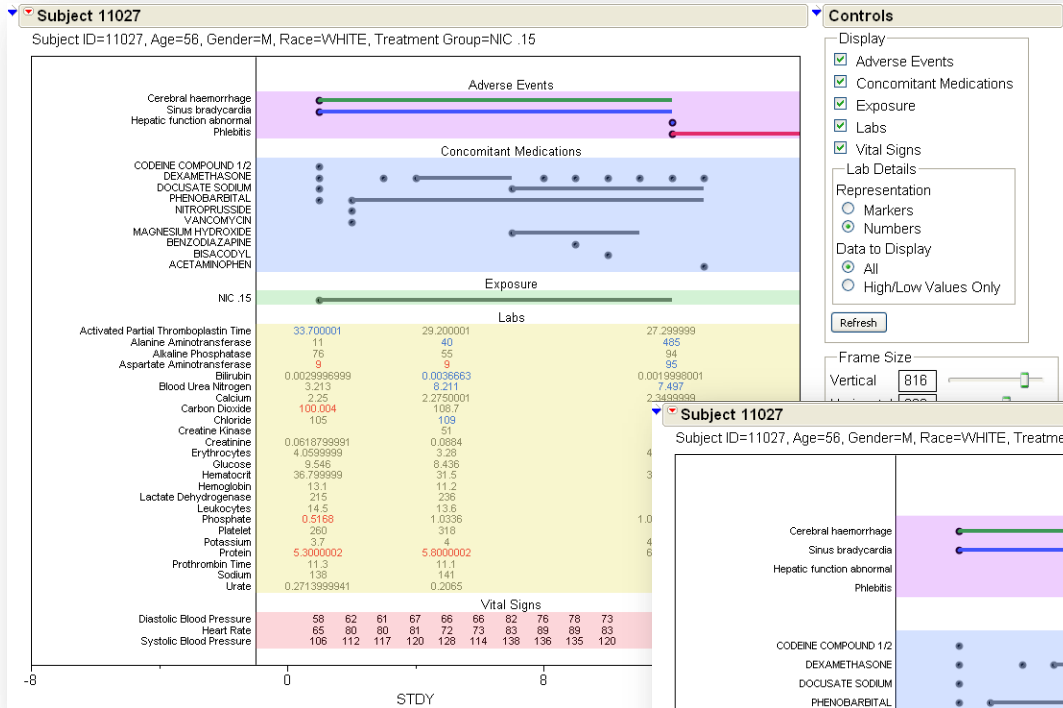
Visualize Frequency Rates of Adverse Events and Correlation with Demographic Characteristics



Visualise Adverse Events Mixed Model Analysis Reports linked to Patient Profiler



Patient Profiler



Controls

Display

- Adverse Events
- Concomitant Medications
- Exposure
- Labs
- Vital Signs

Lab Details

Representation

- Markers
- Numbers

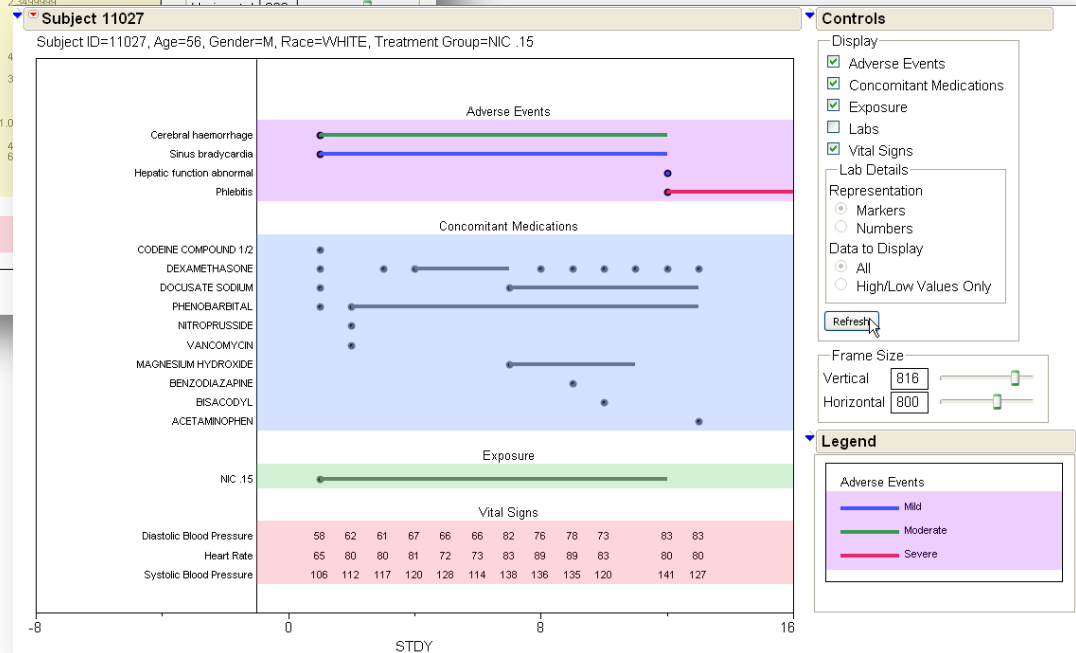
Data to Display

- All
- High/Low Values Only

Refresh

Frame Size

Vertical: 816



Controls

Display

- Adverse Events
- Concomitant Medications
- Exposure
- Labs
- Vital Signs

Lab Details

Representation

- Markers
- Numbers

Data to Display

- All
- High/Low Values Only

Refresh

Frame Size

Vertical: 816

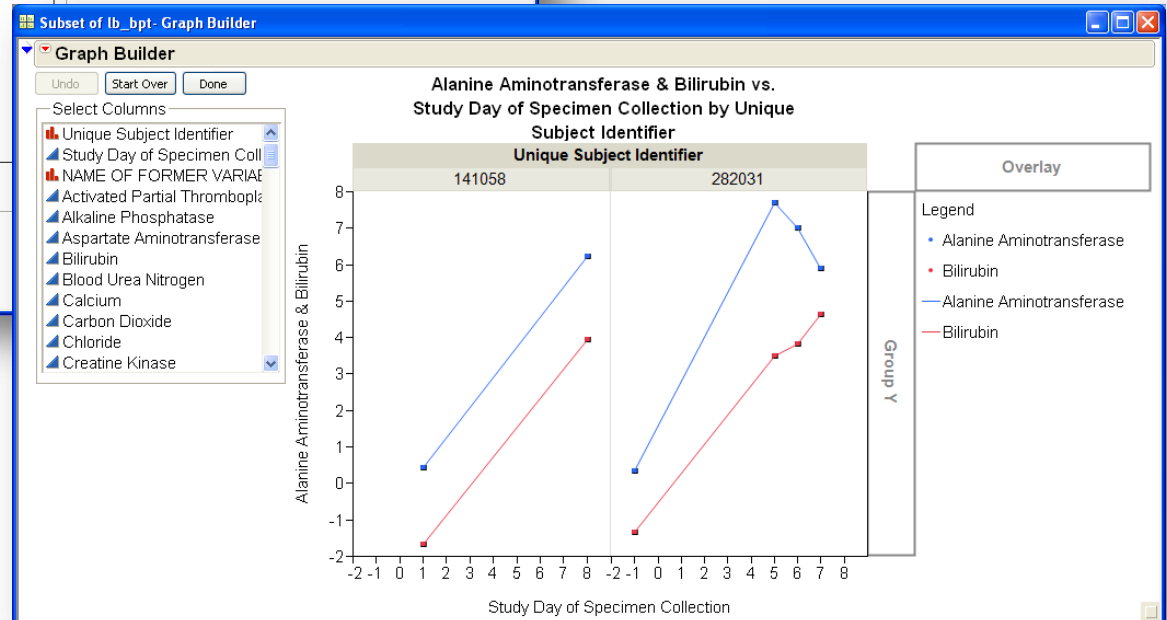
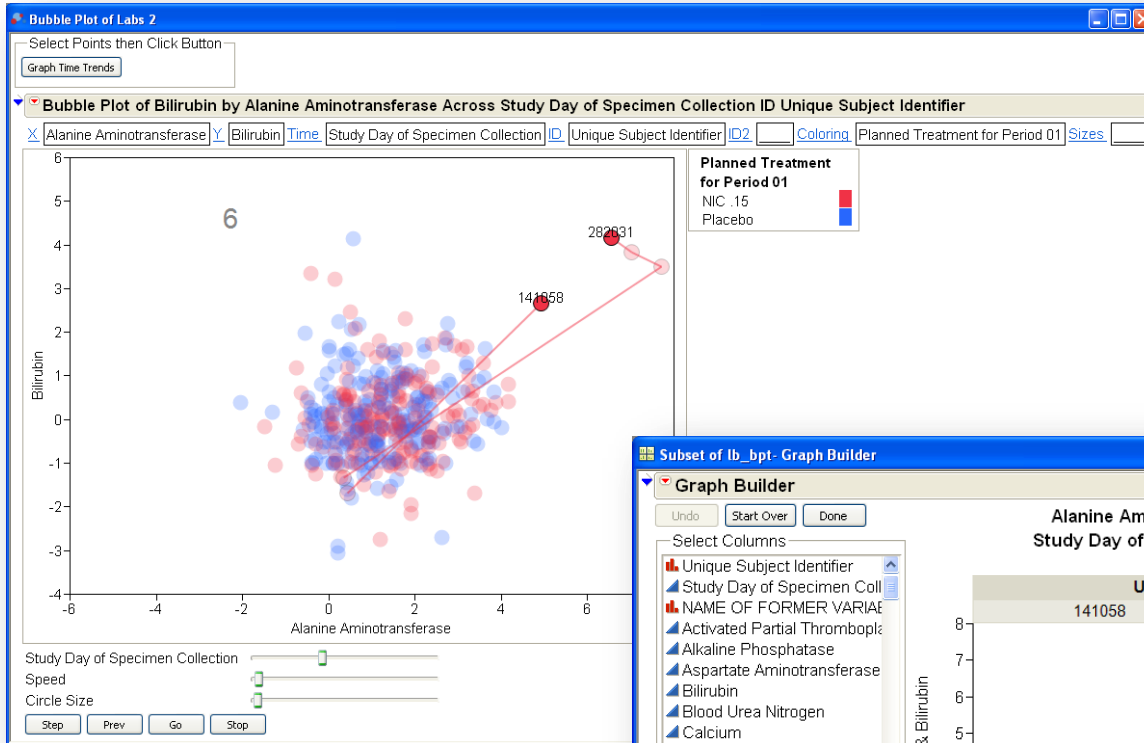
Horizontal: 800

Legend

Adverse Events

- Mild
- Moderate
- Severe

Monitor Animated Patients Laboratory Tests





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