

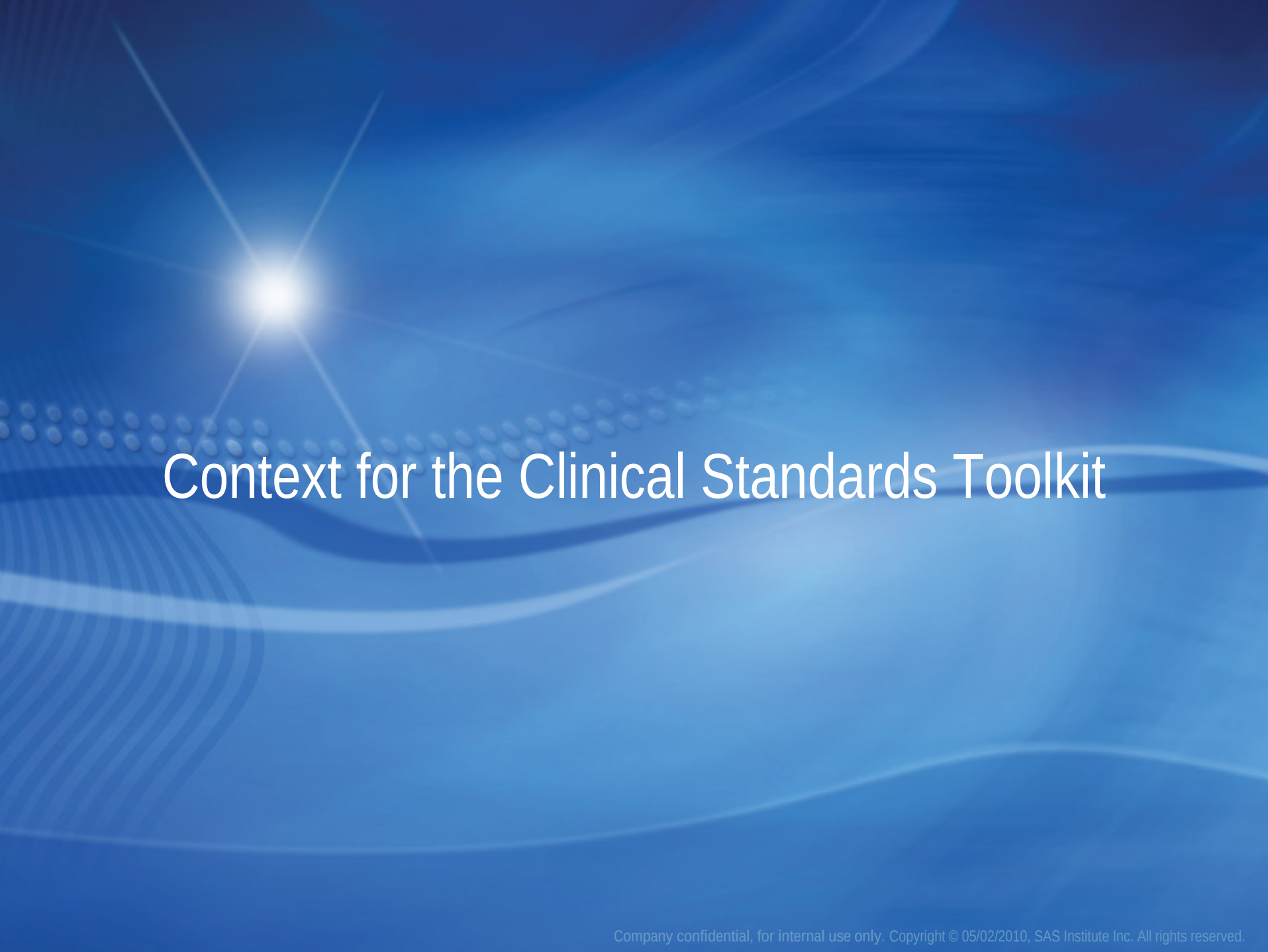


CD06: The SAS Clinical Standards Toolkit

Dave Smith, SAS UK

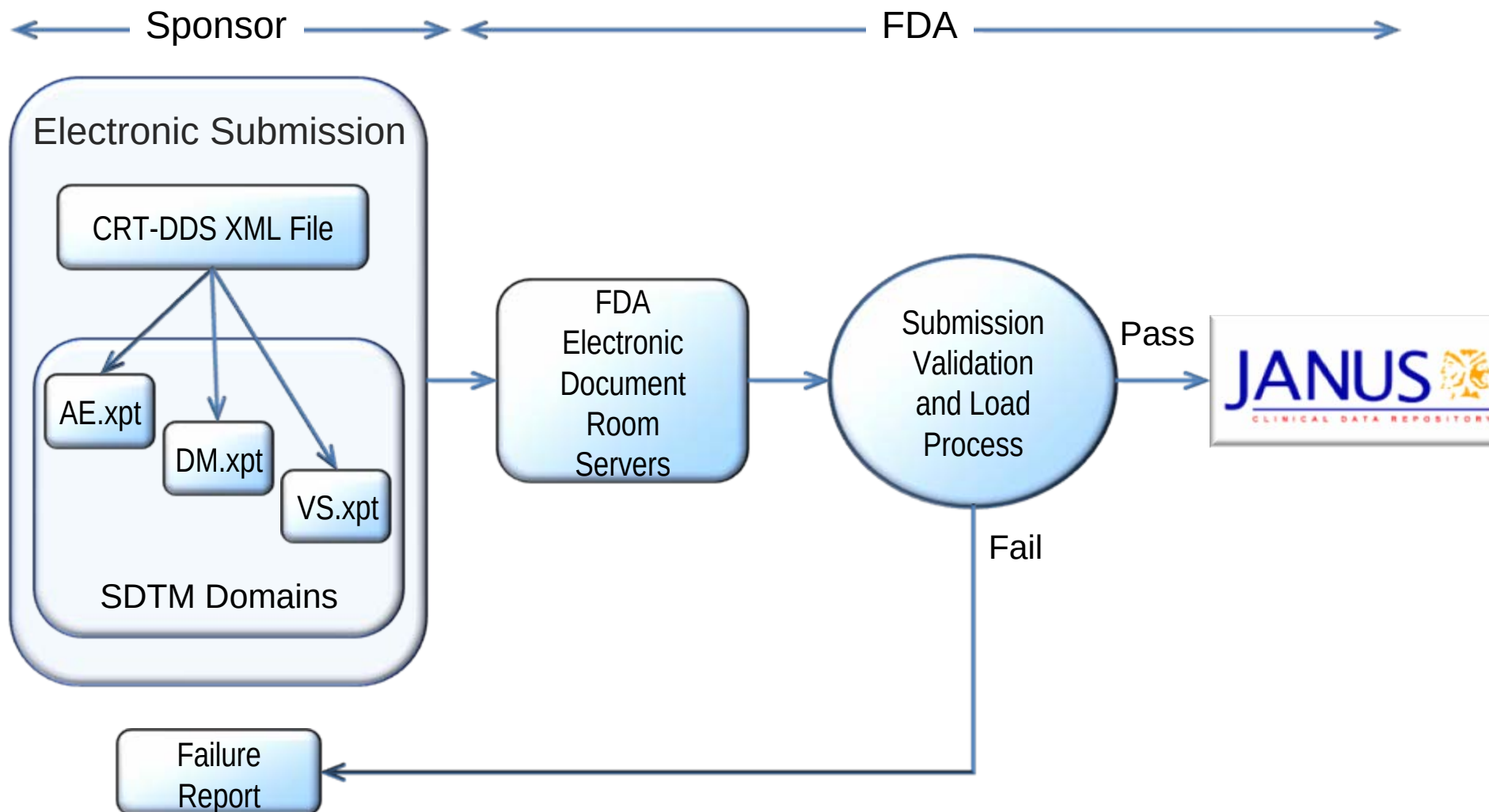
Outline

- Context for the Clinical Standards Toolkit
 - Business Requirements
 - CDISC Technical Challenges
- The Clinical Standards Toolkit
 - Description
 - Demonstration
- Context with other SAS Solutions
- Conclusions

The background is a deep blue with abstract, wavy lines and a bright light source in the upper left corner, creating a lens flare effect. A horizontal band of small, light blue dots is visible behind the main text.

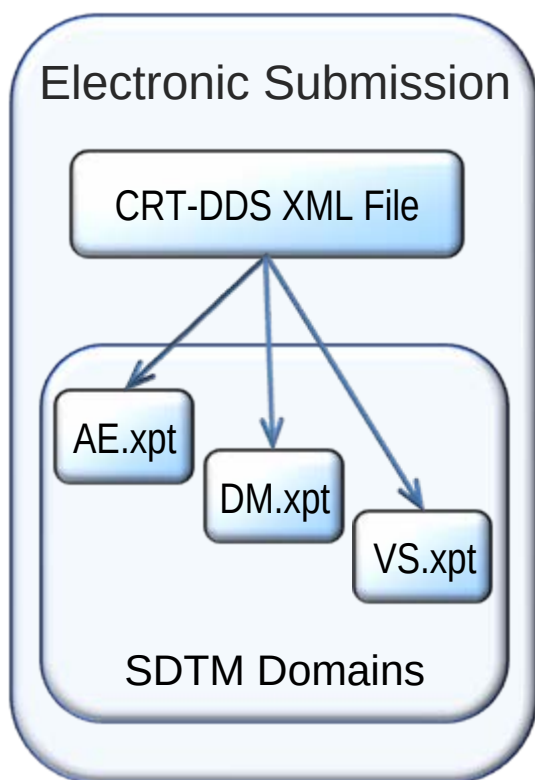
Context for the Clinical Standards Toolkit

Data Flow in Electronic Submissions



Immediate Needs

← Sponsor →



Failure Report

Help us validate the information going into this file

Help us create the XML Correctly

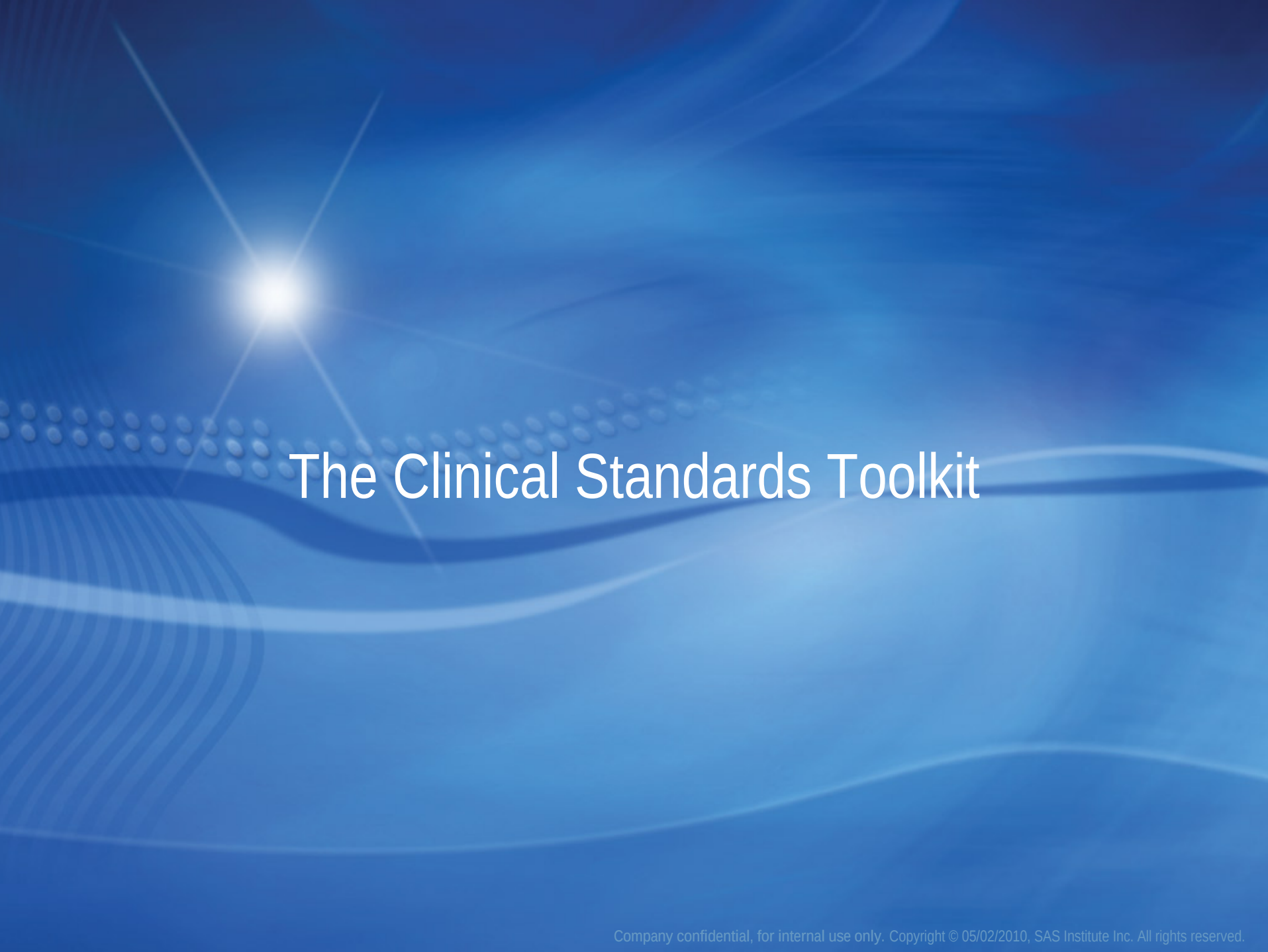
Help us validate our domains against the (our) standard

Support this by using CDISC controlled terminology.

Avoid us getting one of these

CDISC Technical Challenges

- Hitting a moving target
 - Different CDISC versions
 - Variations in Standards e.g. SDTM +/-
- Rapidly increasing adoption
 - Need to scale up quickly
 - Particularly affects CROs
- Need to be sure that submission content will not be rejected

The background is a deep blue with a bright, multi-pointed starburst light in the upper left. Below the light, a series of small, light-blue dots form a horizontal line that curves slightly. The lower half of the image features several broad, wavy, light-blue lines that sweep across the frame, creating a sense of motion and depth.

The Clinical Standards Toolkit

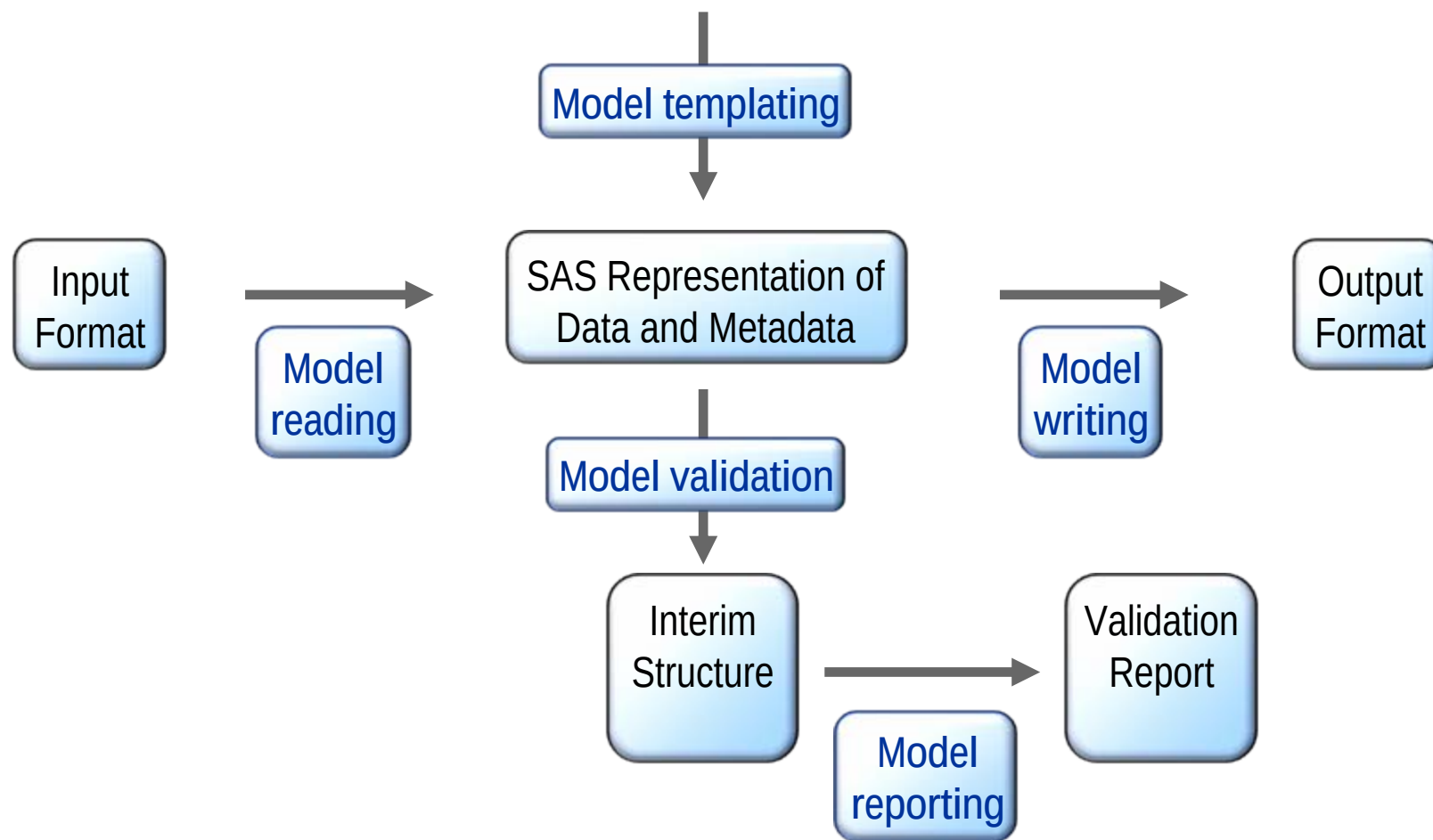
Clinical Standards Toolkit

Set of macros designed to supersede
Proc CDISC

Free to existing SAS customers

Built into Clinical Data Integration

Clinical Toolkit: Initial Focus



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(...);
```

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

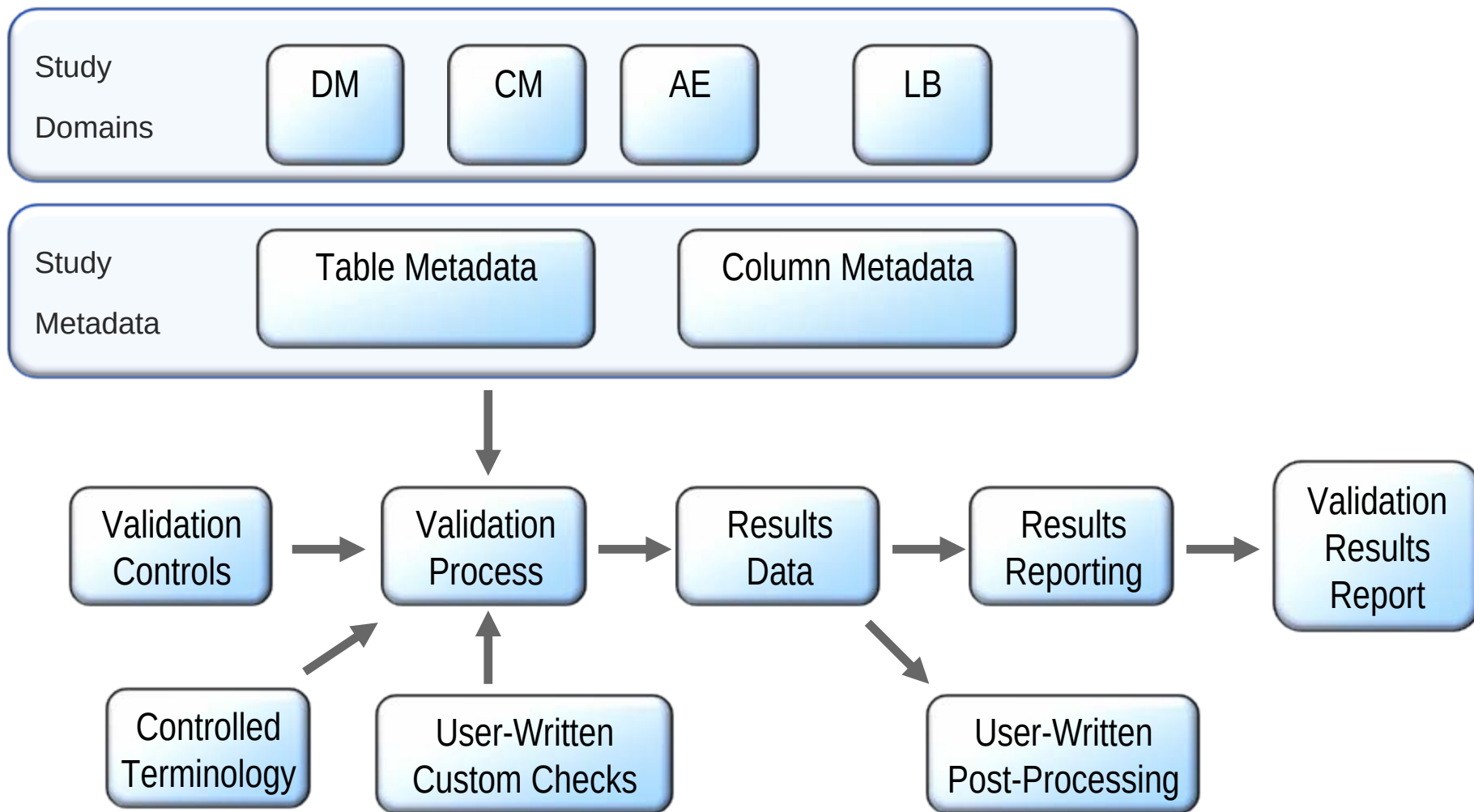
Terminology SDTM-1 Module

Terminology LABTEST Module

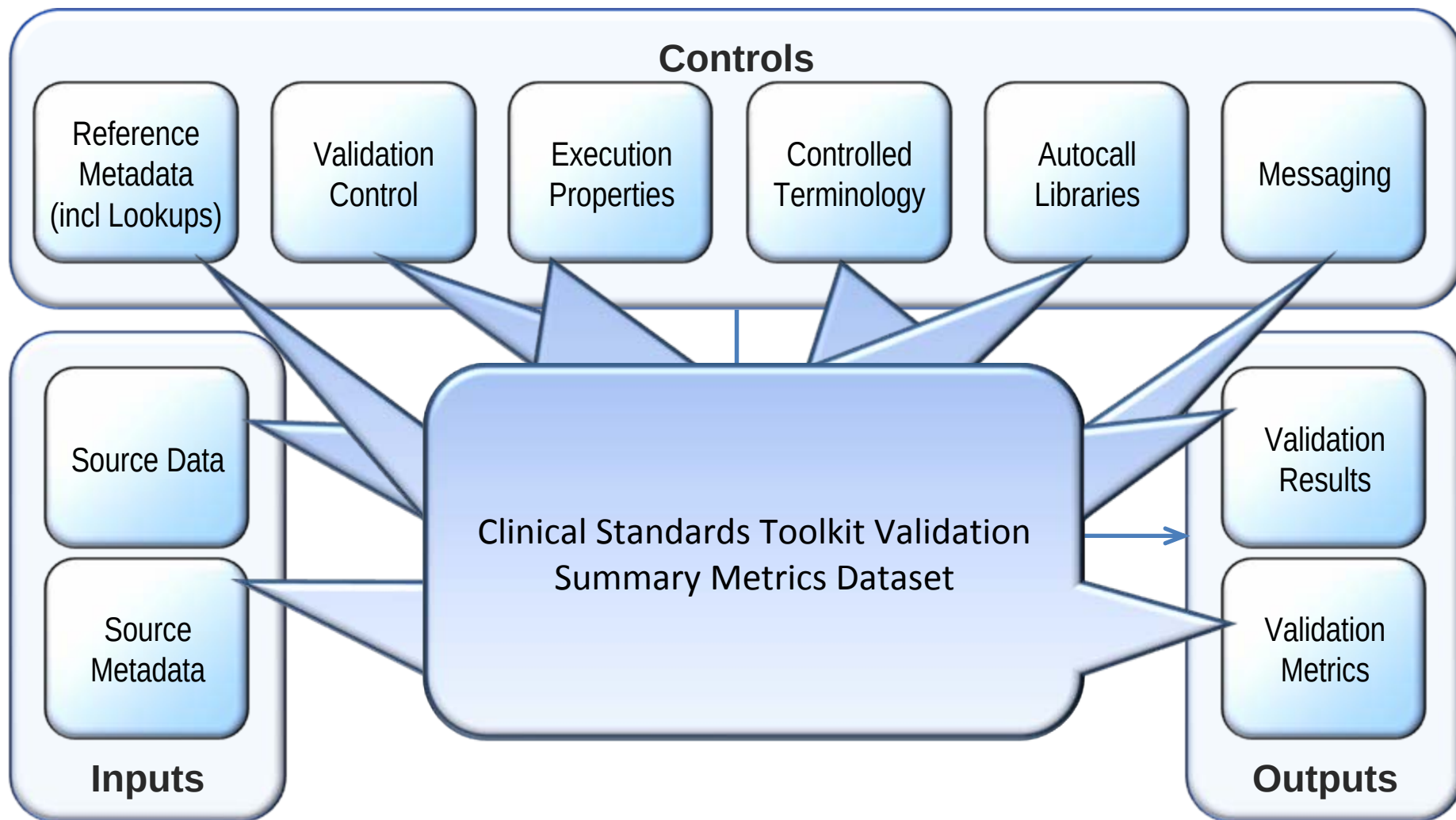
Terminology SDTM-2A Module

Terminology SDTM-2B Module

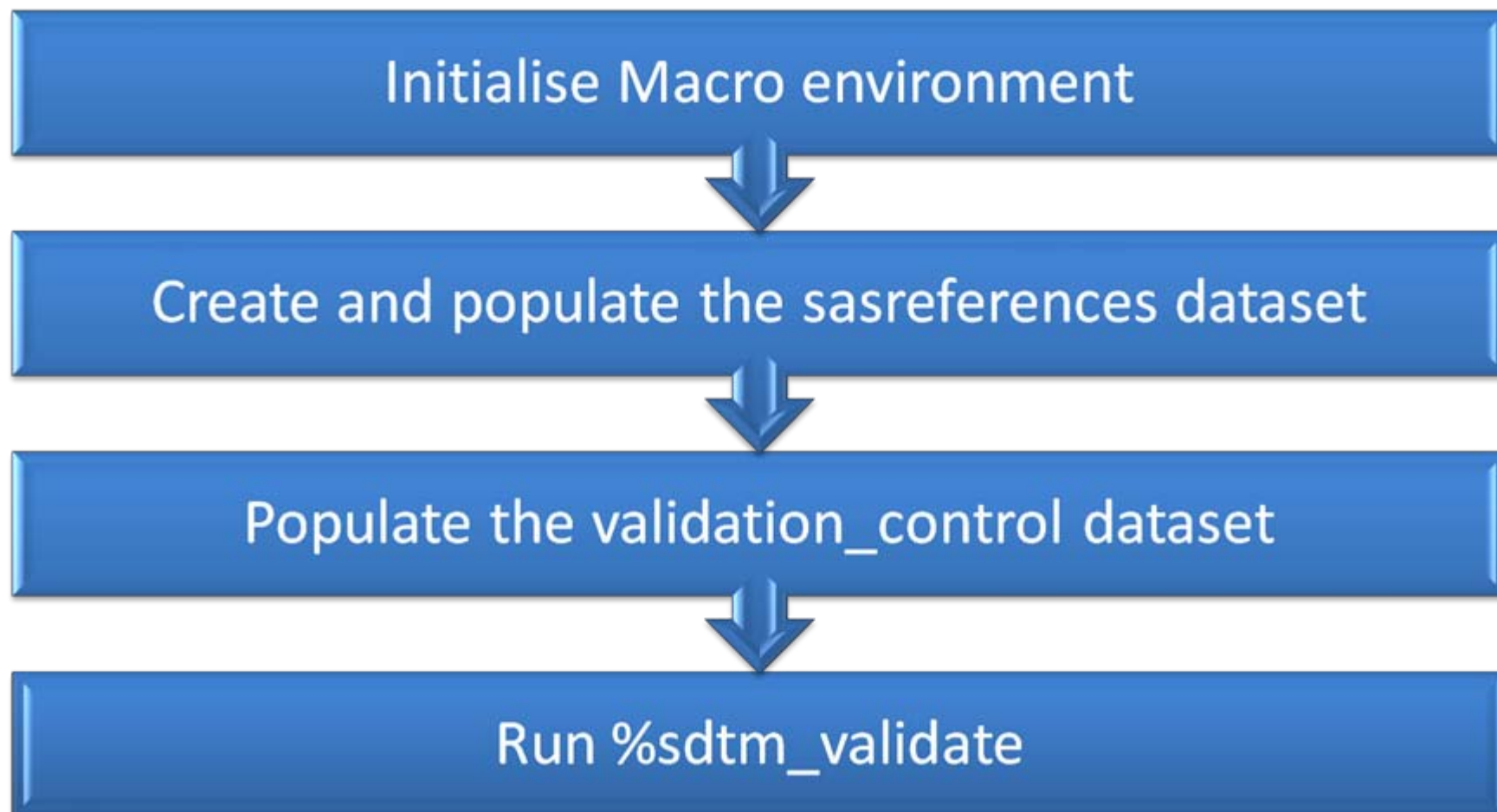
Clinical Toolkit: Validation



CDISC SDTM Validation



Typical Calling Program – SDTM validation



sasreferences dataset – SDTM validation

Location of reference metadata

Location of study data

Location of study metadata (Source_columns, Source_tables)

Locations of formats, codelists, dictionaries

Location of validation_control dataset

Output destination datasets

Source_tables

Obs	SASreferences sourcedata libref	Table Name	Table Label	Observation Class within Standard	(Relative) path to xpt file	Title for xpt file	Table Structure	Purpose	Table Keys
1	1	CM	Concomitant Medications	Interventions			One record per medication intervention episode per subject	Tabulation	STUDYID USUBJID CMTRT CMSTDTC
2	1	DM	Demographics	Special Purpose			One record per subject	Tabulation	STUDYID USUBJID
3	1	QS	Questionnaires	Findings			One record per question per time point per visit per subject	Tabulation	STUDYID USUBJID QSSEQ QSTESTCD VISITNUM QSTPTNUM
Obs	Date Set State (Final, Draft)	Release Date	Name of Standard	Version of Standard	Associated reference(s) in Standard		Comment		
1			CDISC-SDTM	3.1.1					
2			CDISC-SDTM	3.1.1					
3			CDISC-SDTM	3.1.1					

Source_columns

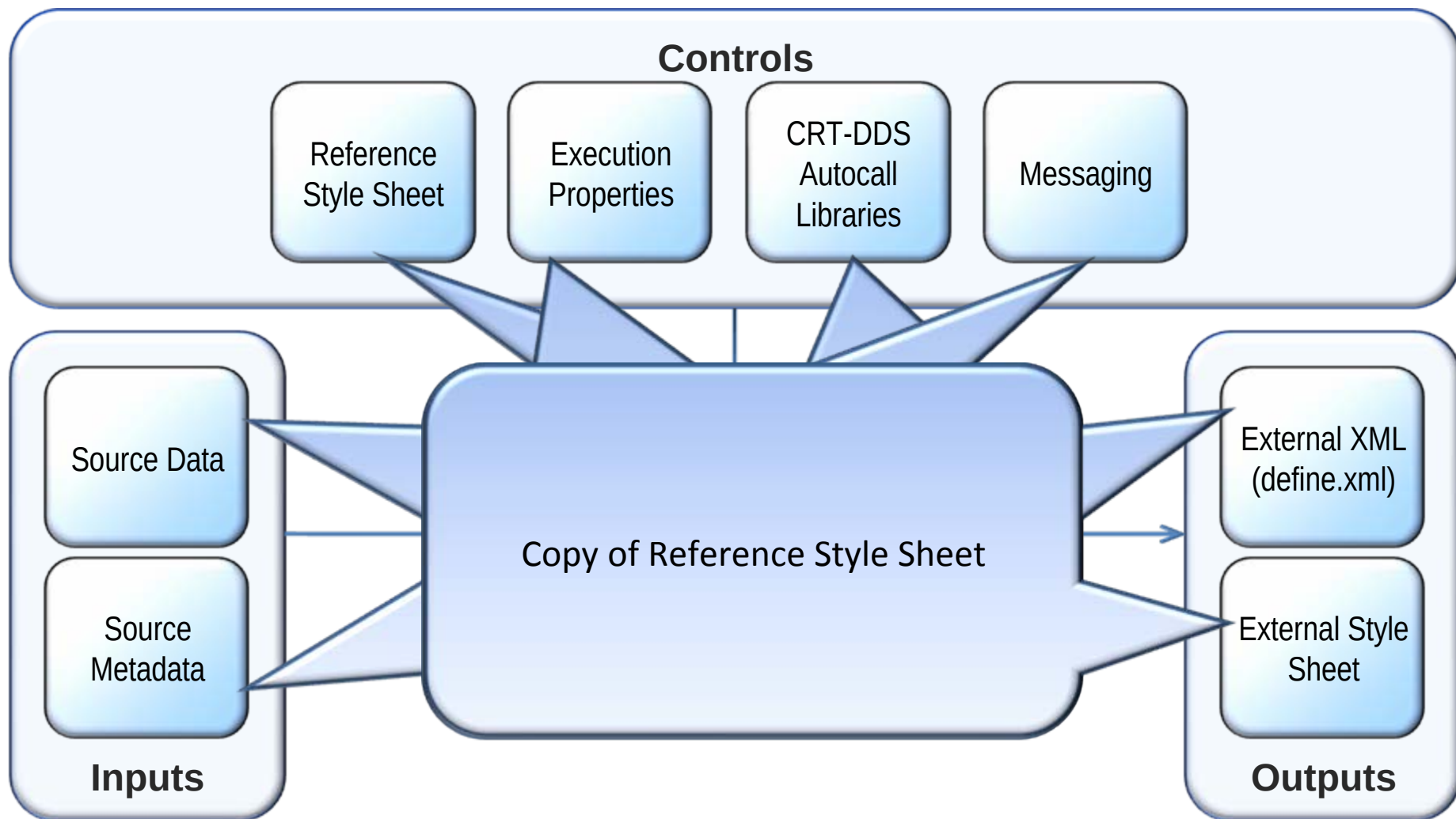
Obs	SASreferences sourcedata libref	Table Name	Column Name	Column Description	Column Order	Column Type	Column Length	Display Format	XML Data Type	SAS Format/XML Codelist
1	1	CM	STUDYID	Study Identifier	1	C	40		text	
2	1	CM	DOMAIN	Domain Abbreviation	2	C	8		text	
3	1	CM	USUBJID	Unique Subject Identifier	3	C	40		text	
4	1	CM	CMSEQ	Sequence Number	4	N	8		integer	
5	1	CM	CMGRPID	Group ID	5	C	40		text	

Obs	Column Required or Optional	Column Origin	Column Role	Controlled Term or Format in Standard	Computational Algorithm or Method	Column qualifiers (space delimited)	Name of Standard	Version of Standard	Associated reference(s) in Standard
1	Req	CRF	Identifier			UPPERCASE	CDISC-SDTM	3.1.1	
2	Req	Derived	Identifier	**CM		UPPERCASE	CDISC-SDTM	3.1.1	
3	Req	Sponsor Defined	Identifier			UPPERCASE	CDISC-SDTM	3.1.1	
4	Req	CRF or Derived	Identifier				CDISC-SDTM	3.1.1	
5	Perm	Sponsor Defined	Identifier			UPPERCASE	CDISC-SDTM	3.1.1	

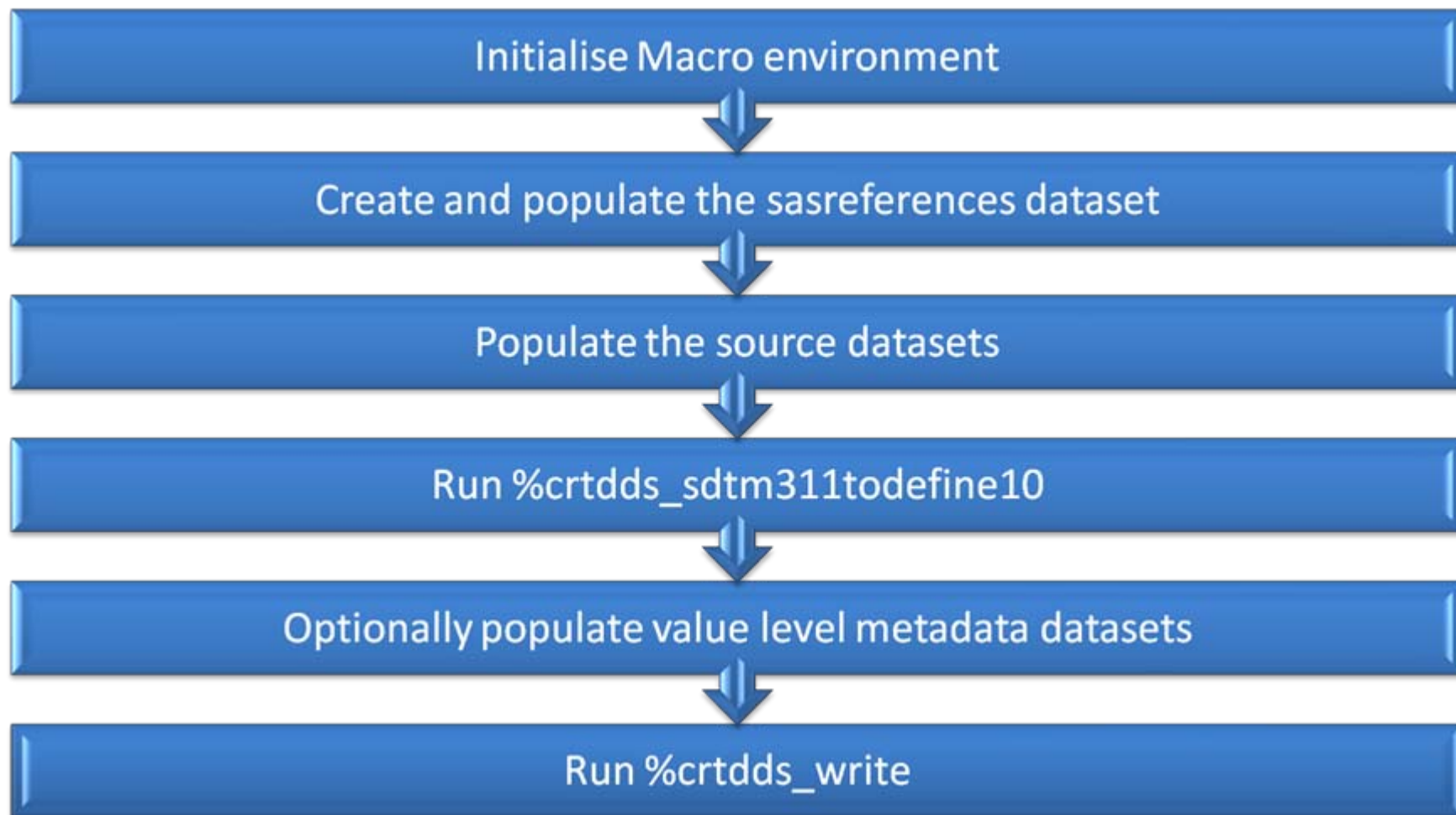


Demonstration – SDTM Validation

CDISC CRT-DDS (define.xml) Creation



Typical Calling Program – Define.xml



sasreferences dataset – define.xml

Where do the messages go?

- Framework
- CRTDDS

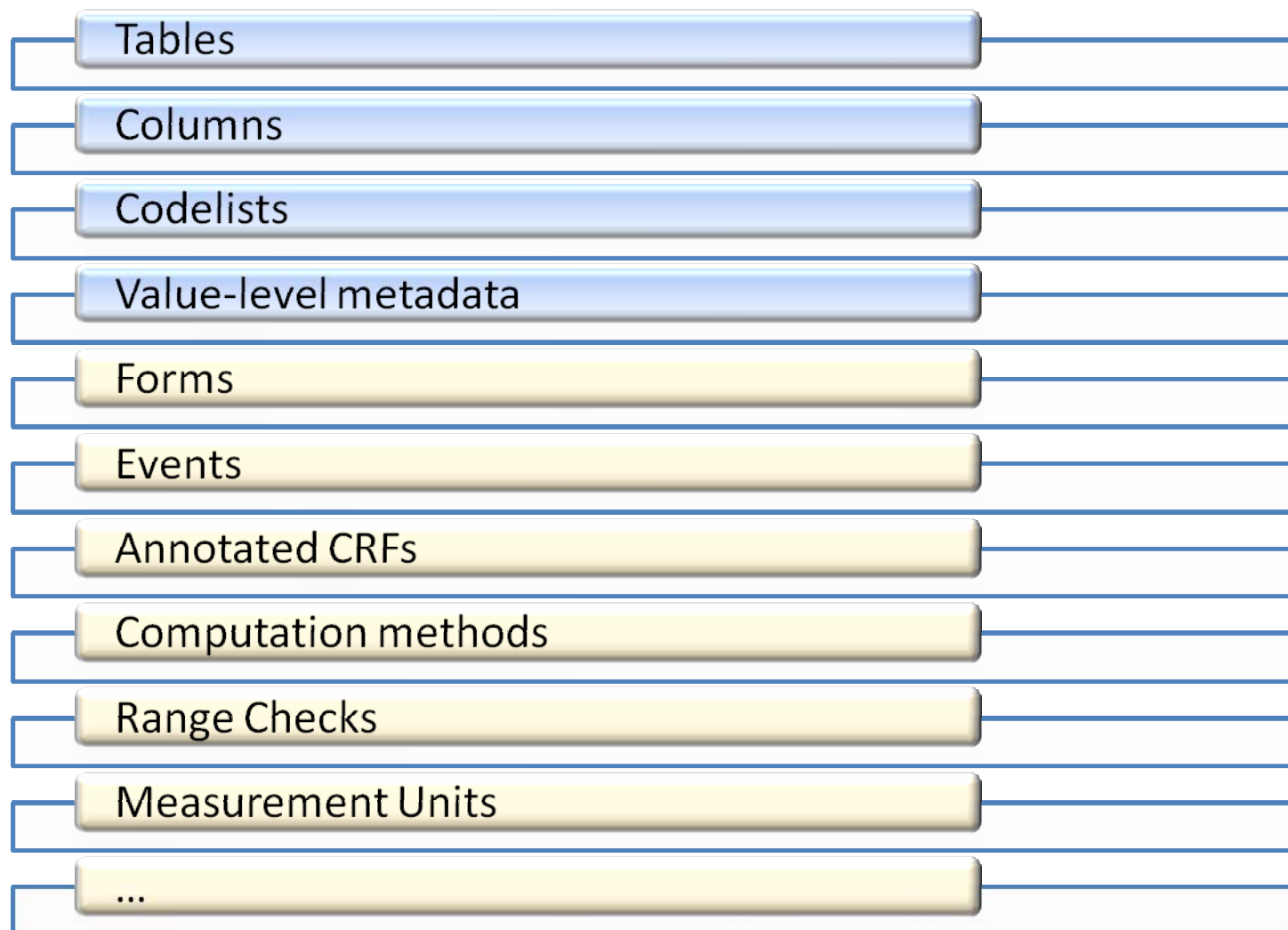
Where are the autocall macros?

Where is the source data? – these are the metadata datasets

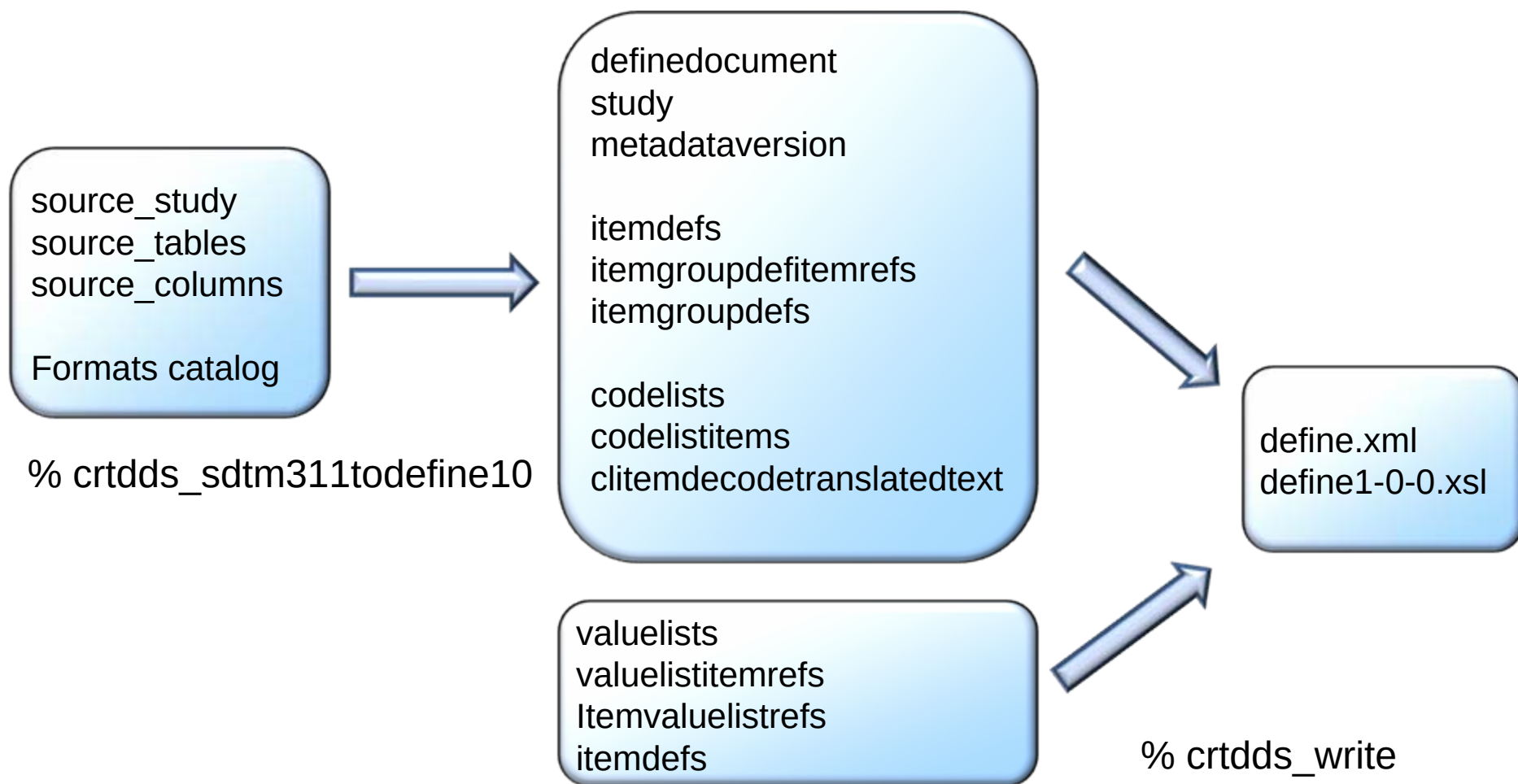
Where is the define.xml file to go?

Where is the stylesheet?

Define.xml – metadata datasets



Define.xml – metadata datasets



Source_study

Obs	SASREF	StudyName	StudyDescription	ProtocolName	DefineDocumentname
1	1	H2Q-MC-LZZT	H2Q-MC-LZZT	H2Q-MC-LZZT	Define.xml

Source_tables

Obs	SASreferences sourcedata libref	Table Name	Table Label	Observation Class within Standard	(Relative) path to xpt file	Title for xpt file	Table Structure	Purpose	Table Keys
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Source_columns

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1	1	CM	STUDYID	Study Identifier	1	C	40		text	
2	1	CM	DOMAIN	Domain Abbreviation	2	C	8		text	
3	1	CM	USUBJID	Unique Subject Identifier	3	C	40		text	
4	1	CM	CMSEQ	Sequence Number	4	N	8		integer	
5	1	CM	CMGRPID	Group ID	5	C	40		text	

Obs	Column Required or Optional	Column Origin	Column Role	Controlled Term or Format in Standard	Computational Algorithm or Method	Column qualifiers (space delimited)	Name of Standard	Version of Standard	Associated reference(s) in Standard
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3	Req	Sponsor Defined	Identifier			UPPERCASE	CDISC-SDTM	3.1.1	
4	Req	CRF or Derived	Identifier				CDISC-SDTM	3.1.1	
5	Perm	Sponsor Defined	Identifier			UPPERCASE	CDISC-SDTM	3.1.1	

Valuelists, ValueListItemRefs

Obs	OID	FK_MetaDataVersion
2	ADAS001	1

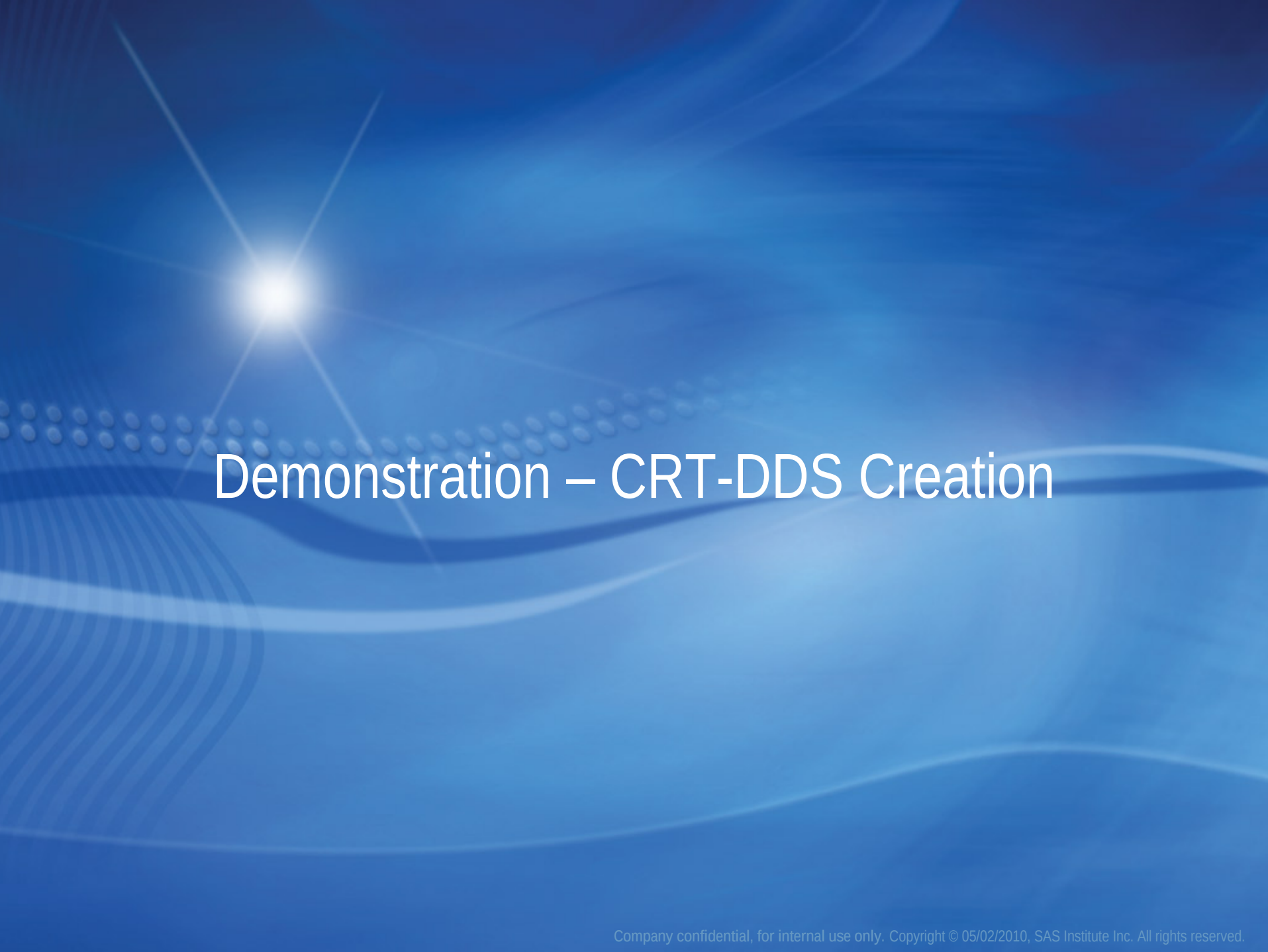
Obs	ItemOID	OrderNumber	Mandato ry	KeySequence	Imputation MethodOID	Role OID	RoleCodeList OID	FK_ValueLists
2	VAL01	1	N	1				ADAS001
3	VAL02	2	N	1				ADAS001
4	VAL03	3	N	1				ADAS001
5	VAL04	4	N	1				ADAS001
6	VAL05	5	N	1				ADAS001
7	VAL06	6	N	1				ADAS001
8	VAL07	7	N	1				ADAS001
9	VAL08	8	N	1				ADAS001
10	VAL09	9	N	1				ADAS001
11	VAL10	10	N	1				ADAS001
12	VAL11	11	N	1				ADAS001
13	VAL12	12	N	1				ADAS001
14	VAL13	13	N	1				ADAS001

Itemdefs (1)

Obs	OID	Column Name	XML Data Type	Column Length	Significant Digits	Column Name	SDSVar Name	Column Origin	Comment	CodeListRef
69	VAL01	ADAS001	text	8	.	ADAS001		CRF or Derived		
70	VAL02	ADAS002	text	8	.	ADAS001		CRF or Derived		
71	VAL03	ADAS003	text	8	.	ADAS001		CRF or Derived		
72	VAL04	ADAS004	text	8	.	ADAS001		CRF or Derived		
73	VAL05	ADAS005	text	8	.	ADAS001		CRF or Derived		
74	VAL06	ADAS006	text	8	.	ADAS001		CRF or Derived		
75	VAL07	ADAS007	text	8	.	ADAS001		CRF or Derived		
76	VAL08	ADAS008	text	8	.	ADAS001		CRF or Derived		
77	VAL09	ADAS009	text	8	.	ADAS001		CRF or Derived		
78	VAL10	ADAS010	text	8	.	ADAS001		CRF or Derived		
79	VAL11	ADAS011	text	8	.	ADAS001		CRF or Derived		
80	VAL12	ADAS012	text	8	.	ADAS001		CRF or Derived		
81	VAL13	CIBIC01	text	8	.	CIBIC01		CRF or Derived		CODELISTN1

Itemdefs (2)

Obs	Column Description	Display Format	Computation MethodOID	FK_MetaDataVersion
69	Word Recall Task			1
70	Naming Objects and Fingers			1
71	Delayed Word Recall			1
72	Commands			1
73	Constructional Praxis			1
74	Ideational Praxis			1
75	Orientation			1
76	Word Recognition			1
77	Attention/Visual Search Task			1
78	Maze Solution			1
79	Spoken Language Ability			1
80	Comprehension of Spoken Language			1
81	Clinicians Impression of Change (CIBIC+)			1

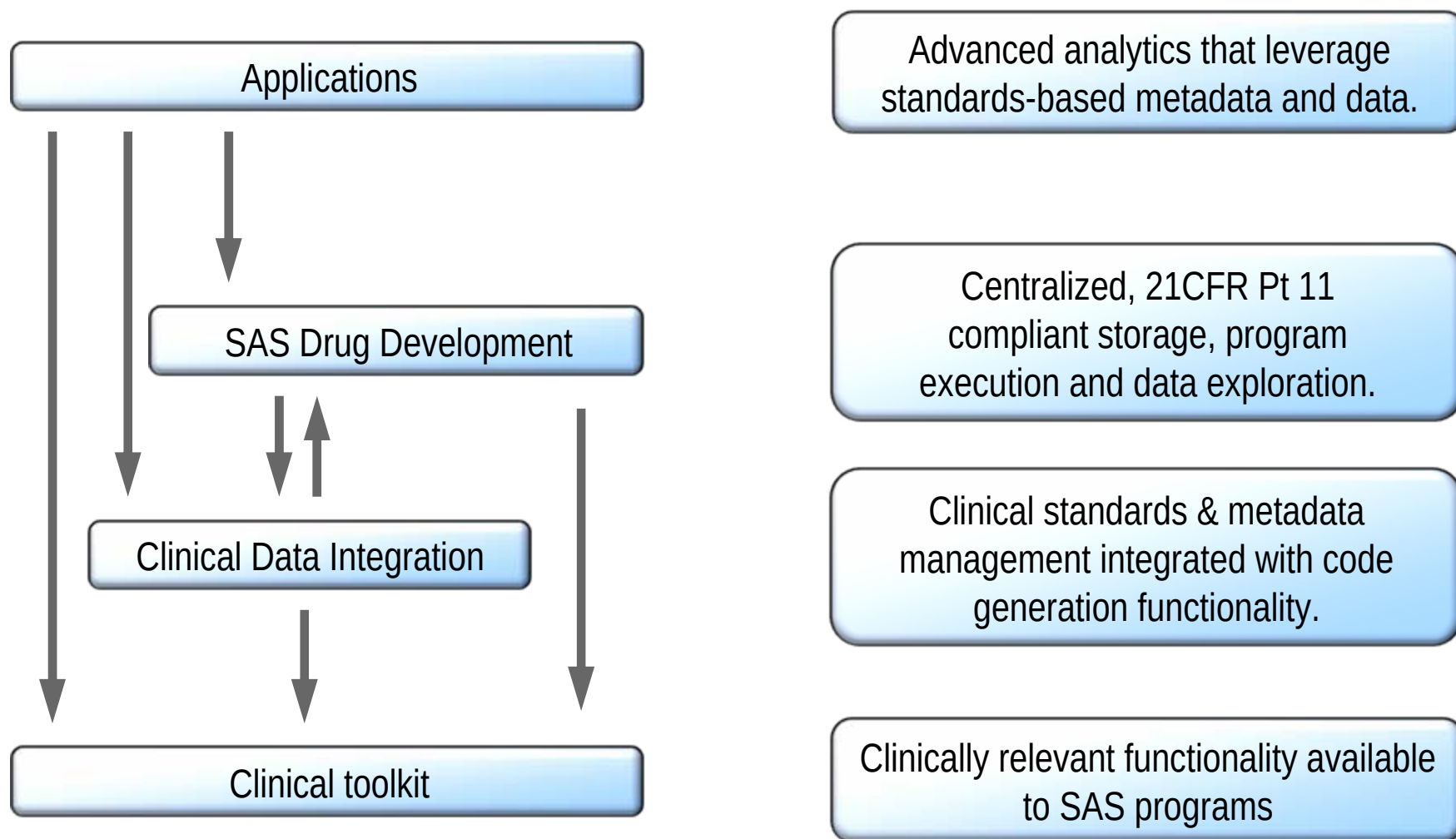


Demonstration – CRT-DDS Creation

The background is a deep blue with a bright, multi-pointed starburst light source in the upper left quadrant. Several thin, white, wavy lines sweep across the frame, creating a sense of motion and depth. A horizontal band of small, light blue, oval-shaped elements is visible behind the main text.

Context with other SAS Solutions

Clinical Standards Toolkit – Context





Conclusions

Conclusions

The Clinical Standards Toolkit :

- Provides a Flexible, Extensible Framework
- Enables the validation of data standards
- Allows the production of non-SAS files such as XML
- Allows customised data standards and validation checks to support those data standards

SAS is committed to supporting existing and emerging industry standards

Contact

Dave Smith
SAS UK
Wittington House
Henley Road
Medmenham
Marlow
Bucks
SL7 2EB

Work Phone: 01628 404379

Email: david.smith@suk.sas.com



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