Further Adventures with the SAS Clinical Standards Toolkit

Dave Smith, SAS UK

Outline

- Intro: CDISC Blog
- Framework Structure
- Validation of SDTM – running without the metadata
- Define creation/validation – dataset deepdive
- Calling the Toolkit Macros from Clinical Data Integration
- How to get hold of the Toolkit

CDISC Blog Extracts – Becky Kush

- Highlights of a meeting between CDER and CBER Representatives and the CDISC Executive Committee on 1 February 2010:
  - Use CDISC Standards (SDTM and ADaM) NOW in eSubmissions to CDER (CBER sometime in 2010)
  - If you want high quality eSubmissions (which will be reviewed better and more quickly), start with CDISC CDASH for your case report forms when you plan your study.
  - The expected transport format for the foreseeable future is SASXPT with Define.xml (In fact, the PDUFA IT plan will be corrected; it is erroneous to communicate that in 2013 FDA will only accept HL7 transport formats.)

http://www.cdisc.org/fda-cber-cder

But if you read the comments…(my highlights)

- Let's inject some reality into this discussion: The experience with SDTM in the CDER review divisions, in particular cardiorenal, has not been favorable. I have done 57 NDA submissions, three of them SDTM. Five of the 57 submissions had severe data problems, including ALL THREE SDTM submissions. ALL THREE SDTM submissions missed their PDUFA goal dates because of the data problems; one of them we even refused to file the first time around. My cardiorenal co-reviewers also experienced severe data problems with a fourth SDTM submission and considered refusing to file. Please consider this track record when planning your NDA submissions. "High quality" and "reviewed more quickly" are goals and potential right now, not reality.

- No official support or endorsement of this comment by the Food and Drug Administration is intended or should be inferred.

  Thomas A. Marciniak, M.D.
  Medical Team Leader
  Division of Cardiovascular and Renal Products, CDER

My reaction

CDISC is here to stay and can add exceptional value

- Speed of submission
- Speed of review

It has to be implemented right!

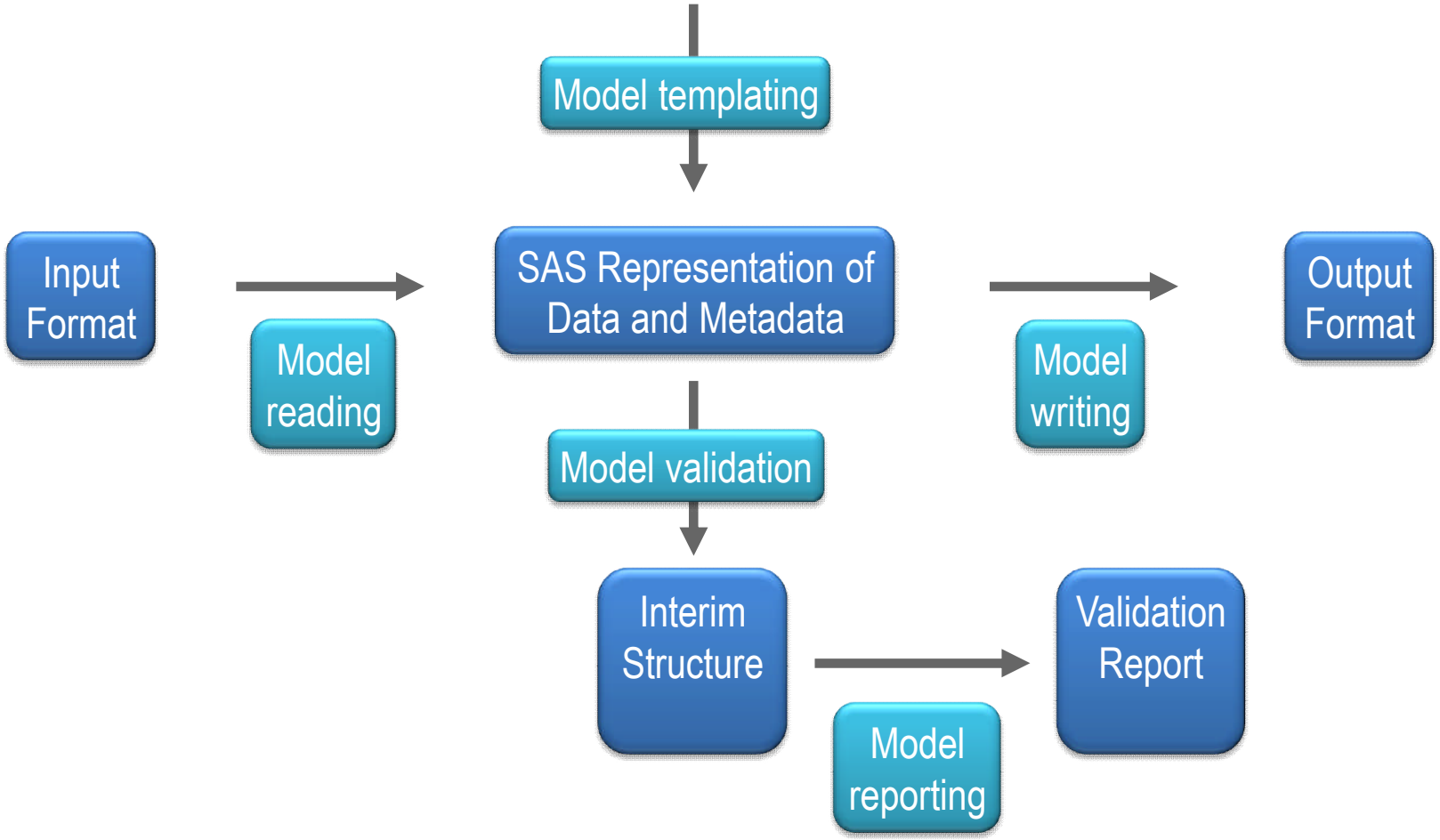
- More consistency in data transformations
- More control of data transformations
- Tighter checking of model adherence

The 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

Clinical Toolkit: Initial Focus



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(…);

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

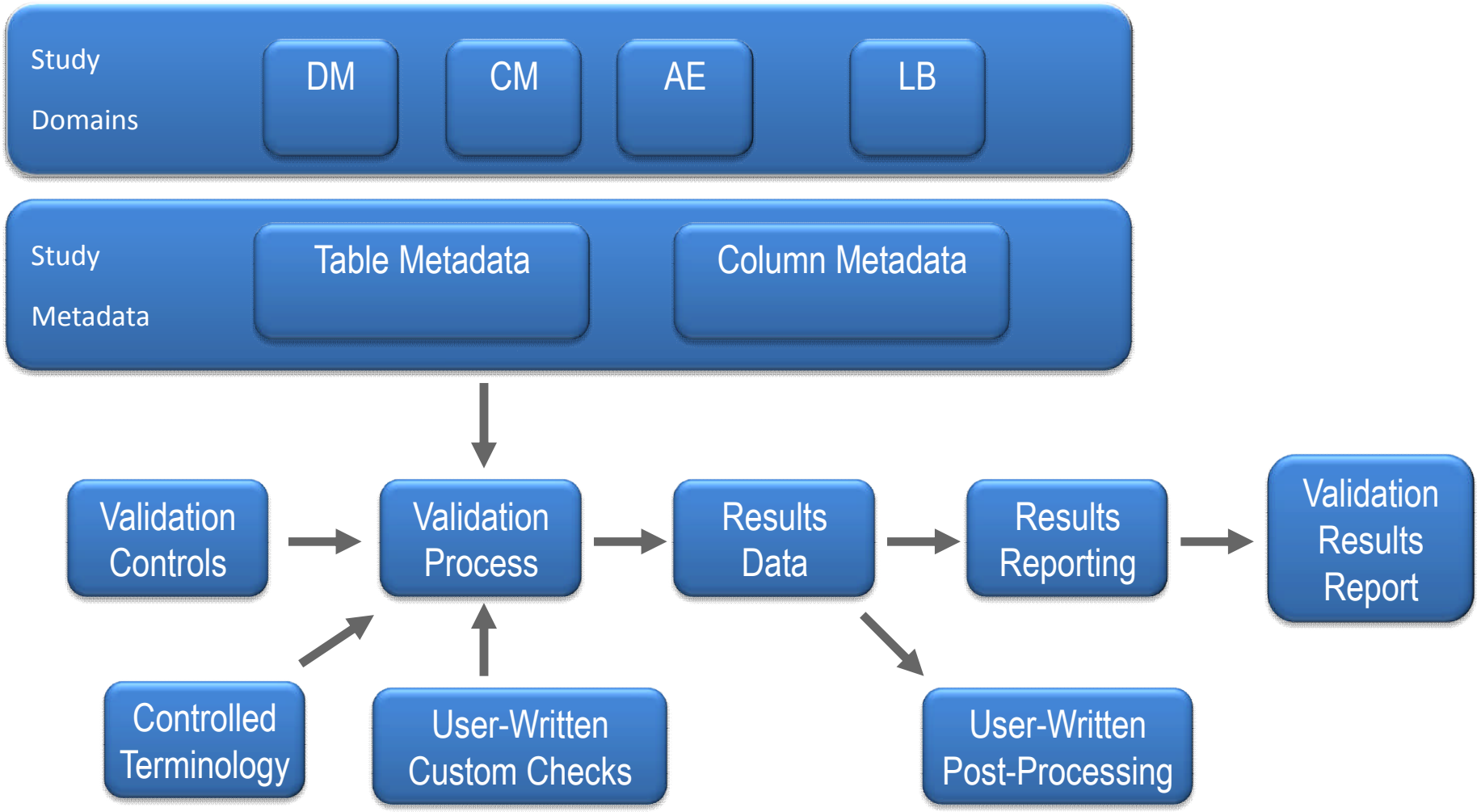
Terminology SDTM-1 Module

Terminology LABTEST Module

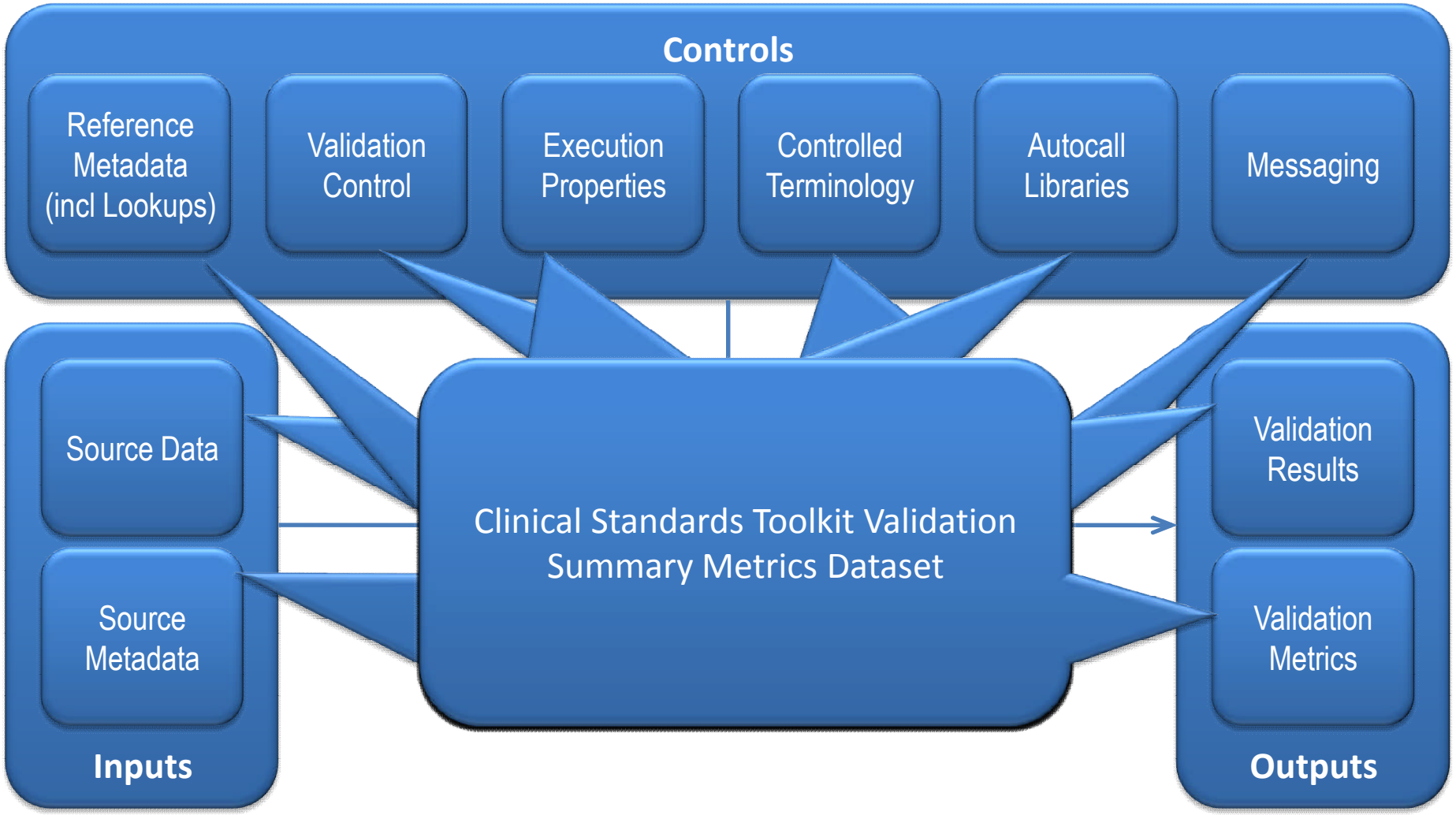
Terminology SDTM-2A Module

Terminology SDTM-2B Module

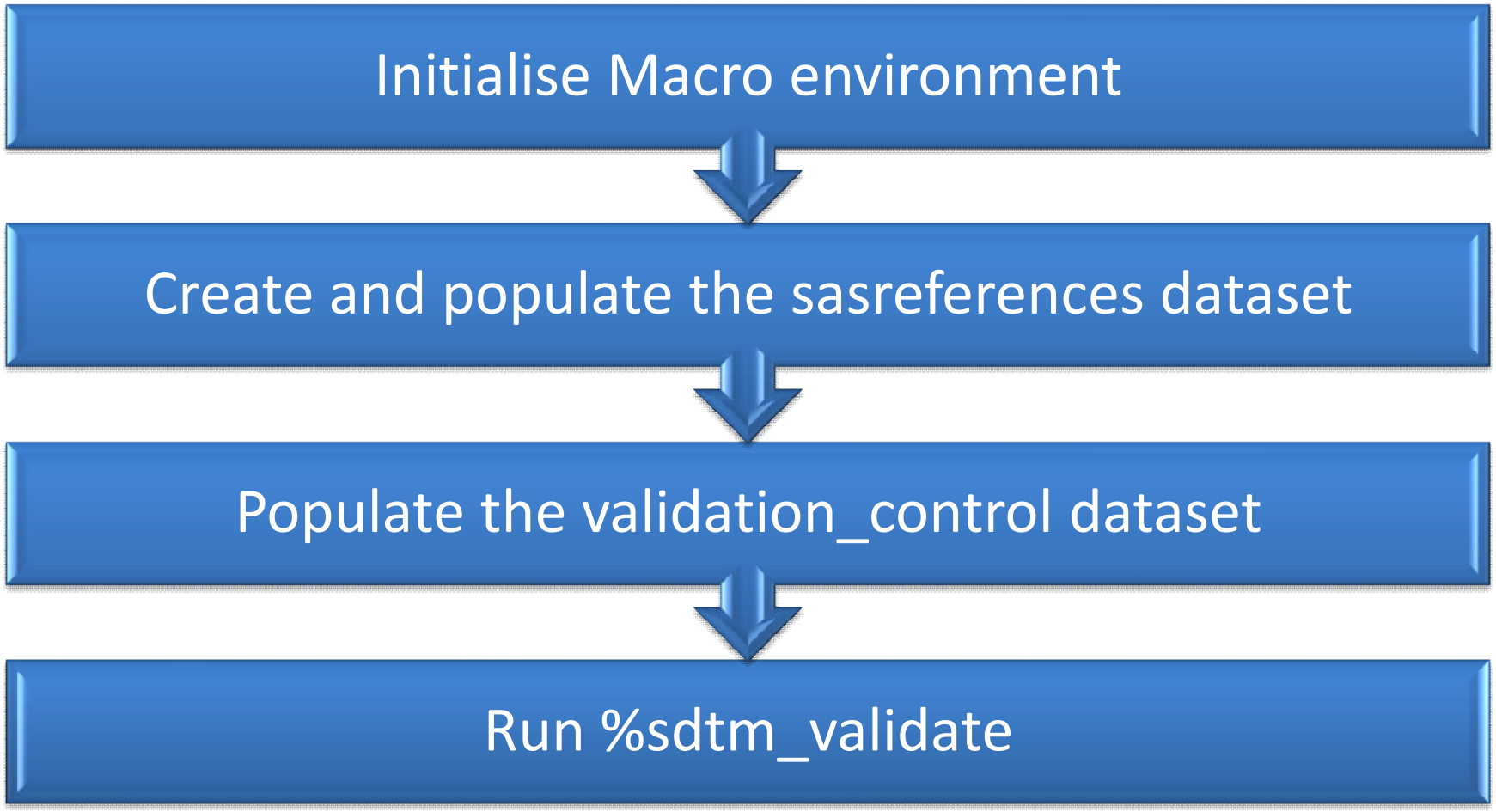
Clinical Toolkit: Validation



CDISC SDTM Validation



SDTM validation - Typical Calling Program



SDTM validation - sasreferences dataset

- 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

SDTM validation - 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		

SDTM validation - 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	

Creating Source_Columns and Source_Tables programmatically

Use proc contents to read metadata

Determine Class from contents

- If **TRT is present then Interventions
- If **TESTCD is present then Findings
- If **TERM is present then Events

Merge with model metadata

- Add further metadata items
- Manage SUPPQUAL, Timings variables

SDTM Validation Results: Validation_Metrics

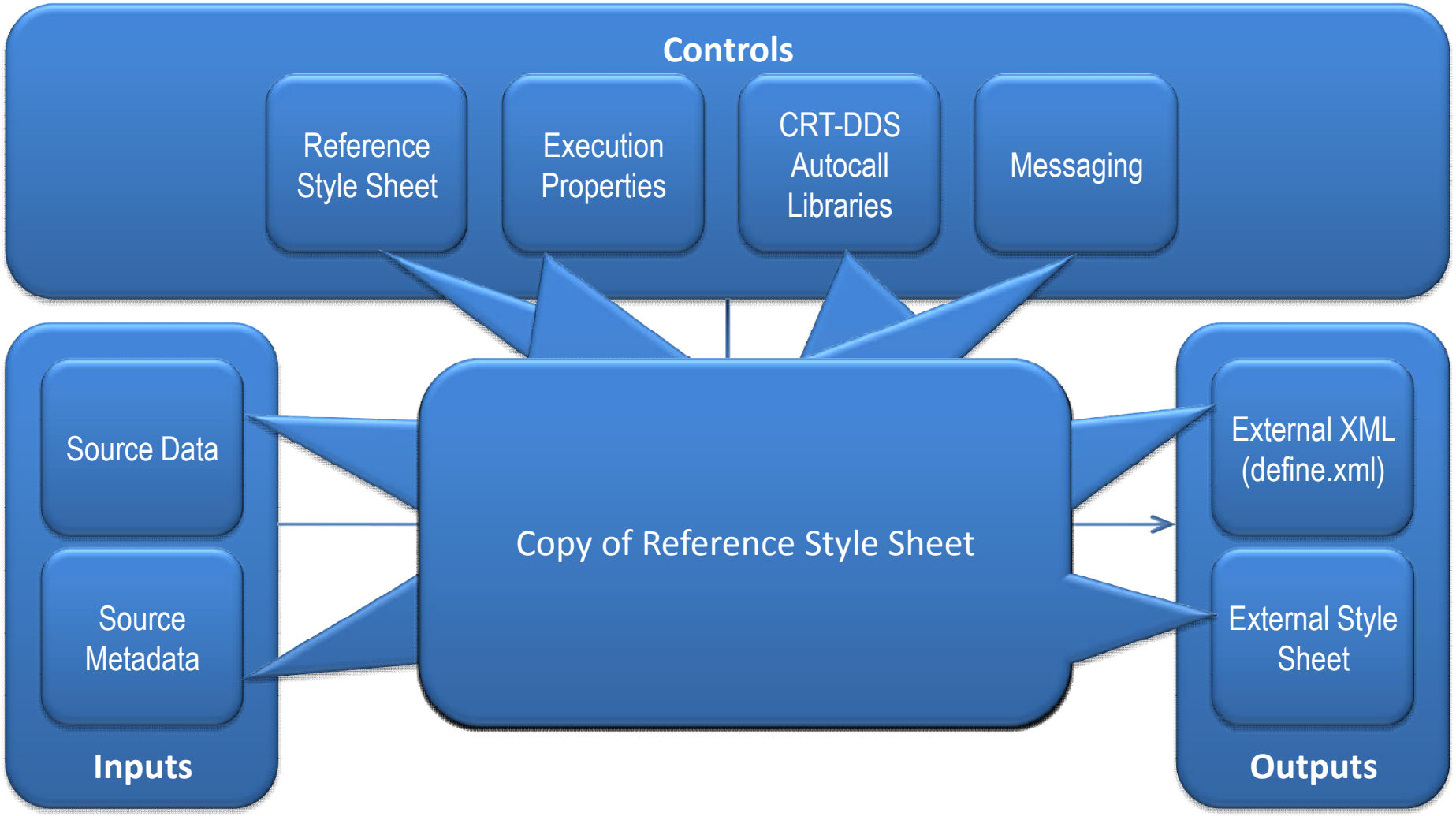
metricparameter	reccount	resultid	srcdata	resultseq
Elapsed time to run check: 0:00:00	.	SDTM0643	CSTCHECK_NOTCONSISTENT	1
Elapsed time to run check: 0:00:00	.	SDTM0671	CSTCHECK_NOTUNIQUE	1
# of distinct check invocations	32	METRICS	SDTM_VALIDATE	1
# check invocations not run	20	METRICS	SDTM_VALIDATE	1
Errors (severity=High) reported	1	METRICS	SDTM_VALIDATE	1
Warnings (severity=Medium) reported	0	METRICS	SDTM_VALIDATE	1
Notes (severity=Low) reported	5	METRICS	SDTM_VALIDATE	1
Structural errors, warnings and notes	6	METRICS	SDTM_VALIDATE	1
Content errors, warnings and notes	36	METRICS	SDTM_VALIDATE	1

SDTM Validation Results: Validation_results

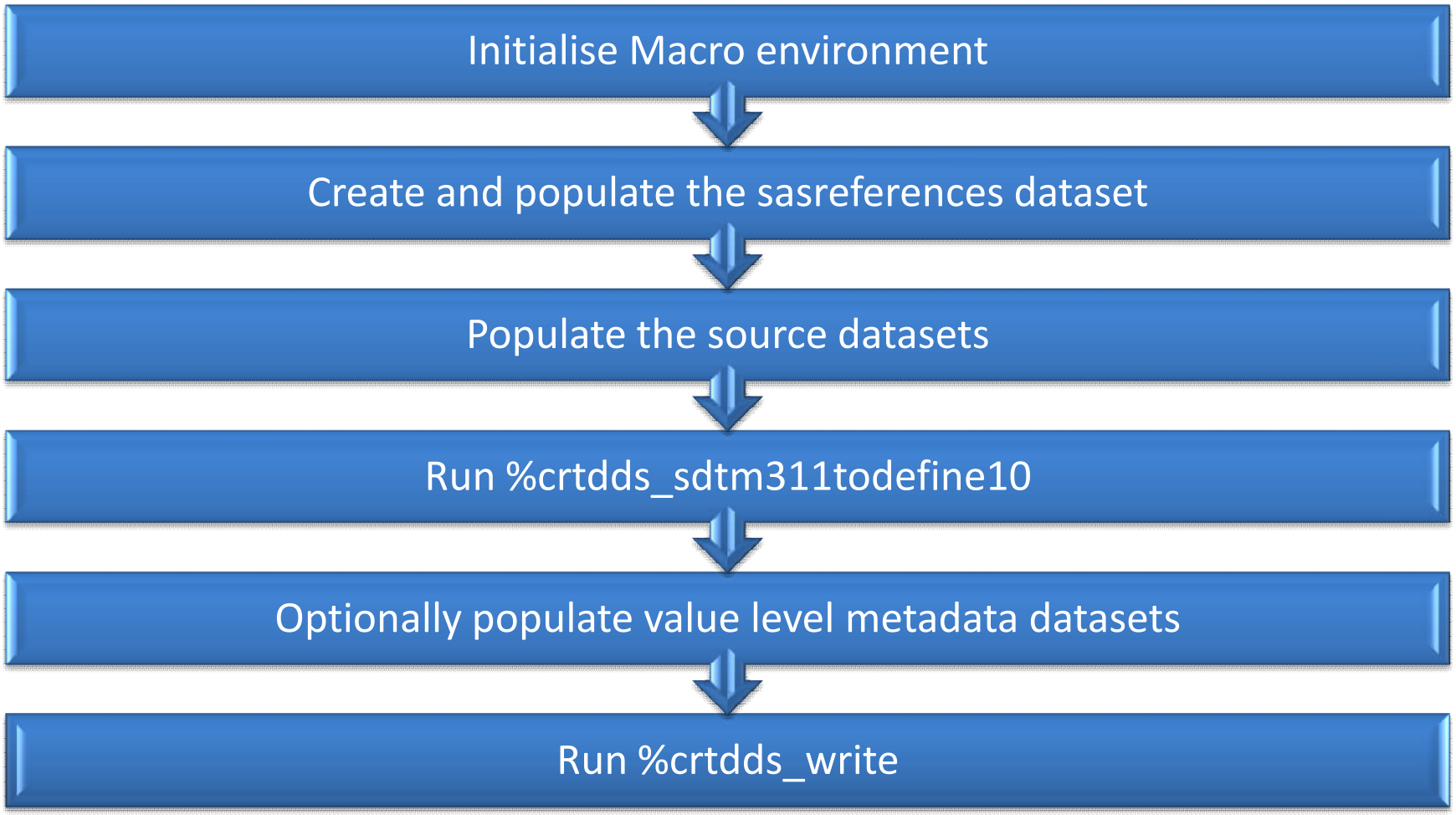
resultid	checkid	resultseq	seqno	srcdata	message	resultseverity	resultflag	actual
SDTM0014	SDTM0014	1	1	AE	SDTM permissible variable AEENRTPT not found	Note	1	
SDTM0014	SDTM0014	1	2	AE	SDTM permissible variable AEENTPT not found	Note	1	
SDTM0014	SDTM0014	1	3	AE	SDTM permissible variable AEPRESP not found	Note	1	
SDTM0030	SDTM0030	1	1	1.AE	Column label inconsistent with label defined in standard for AELOC	Note	1	(base) label=Location of the Reaction, (comp) label=Location of Event
SDTM0030	SDTM0030	1	2	1.DM	Column label inconsistent with label defined in standard for AGE	Note	1	(base) label=Age in AGEU at RFSTDTC, (comp) label=Age
SDTM0031	SDTM0031	1	1	1.AE	Column not subject to controlled terminology for AEOCCUR	Error	1	(base) xmlcodelist=NY, (comp) xmlcodelist=

Define.xml

Define.xml (CDISC CRT-DDS) Creation



Define.xml creation - Typical Calling Program



Define.xml creation - sasreferences dataset

Where do the messages go?

- Framework
- CRTDDS

Where are the autocall macros?

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

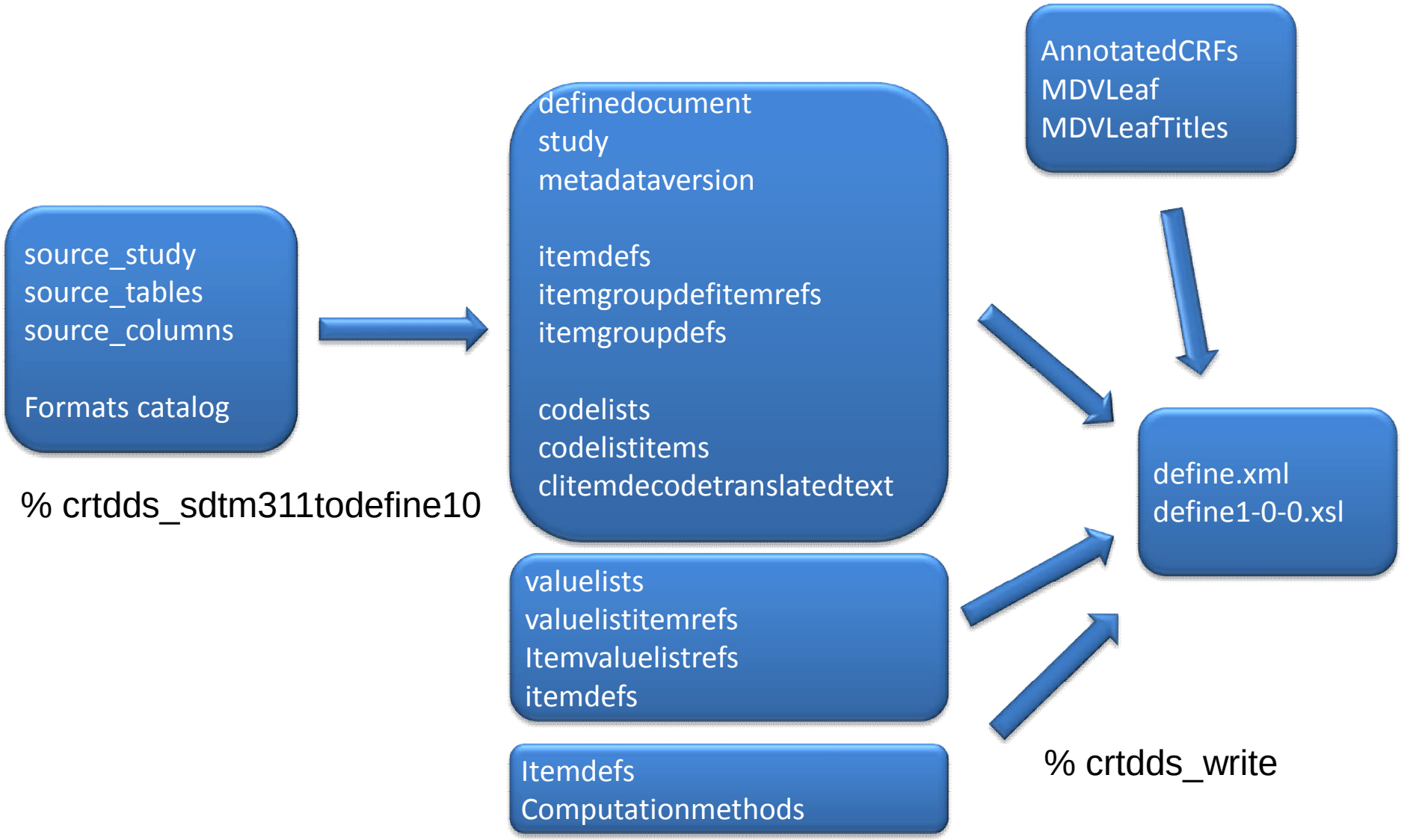
Where is the define.xml file to go?

Where is the stylesheet?

Define.xml creation – metadata datasets

- Study
- Tables
- Columns
- Codelists
- Value-level metadata
- Forms
- Events
- Annotated CRFs
- Computation methods
- Range Checks
- Measurement Units
- …

Define.xml creation – metadata datasets



Define.xml creation - Source_study

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

Define.xml creation - 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
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3			CDISC-SDTM	3.1.1		

Define.xml creation - 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	

Value Level Metadata

Valuelists

Obs	OID	FK_MetaDataVersion
2	ADAS001	1

ValueListItemRefs

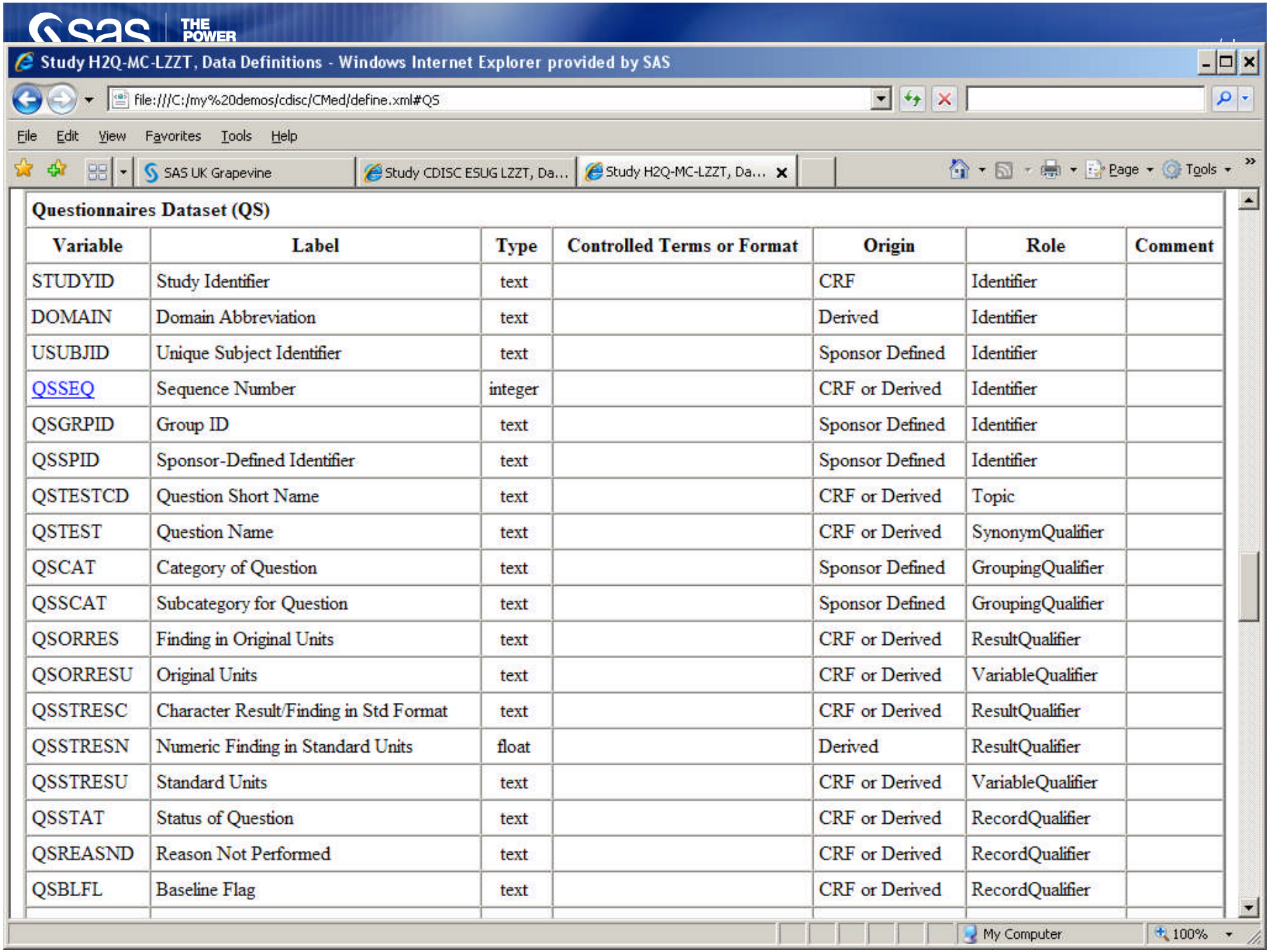
Obs	ItemOID	OrderNumber	Mandatory	KeySequence	Imputation MethodOID	Role	RoleCodeList OID	FK_ValueLists
2	VAL01	1	N	1				ADAS001
3	VAL02	2	N	1				ADAS001
4	VAL03	3	N	1				ADAS001
5	VAL04	4	N	1				ADAS001
6	VAL05	5	N	1				ADAS001
7	VAL06	6	N	1				ADAS001
8	VAL07	7	N	1				ADAS001
9	VAL08	8	N	1				ADAS001
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

Value Level Metadata - Itemdefs (1)

Obs	OID	Column Name	XML Data Type	Column Length	Significant Digits	Column Name	SDSVarName	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

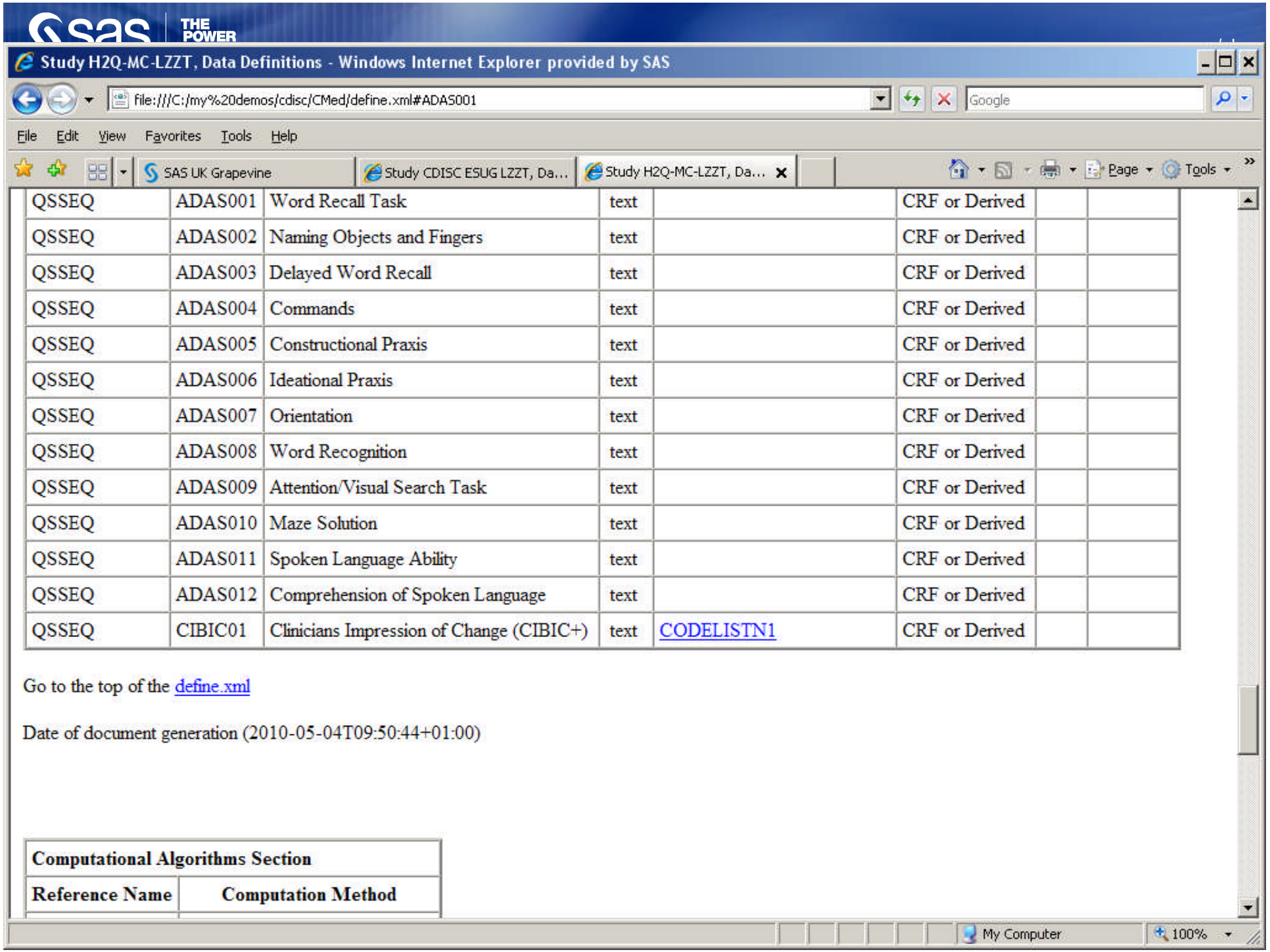
Value Level Metadata - Itemdefs (2)

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



Questionnaires Dataset (QS)

Variable	Label	Type	Controlled Terms or Format	Origin	Role	Comment
STUDYID	Study Identifier	text		CRF	Identifier	
DOMAIN	Domain Abbreviation	text		Derived	Identifier	
USUBJID	Unique Subject Identifier	text		Sponsor Defined	Identifier	
QSSEQ	Sequence Number	integer		CRF or Derived	Identifier	
QSGRPID	Group ID	text		Sponsor Defined	Identifier	
QSSPID	Sponsor-Defined Identifier	text		Sponsor Defined	Identifier	
QSTESTCD	Question Short Name	text		CRF or Derived	Topic	
QSTEST	Question Name	text		CRF or Derived	SynonymQualifier	
QSCAT	Category of Question	text		Sponsor Defined	GroupingQualifier	
QSSCAT	Subcategory for Question	text		Sponsor Defined	GroupingQualifier	
QSORRES	Finding in Original Units	text		CRF or Derived	ResultQualifier	
QSORRESU	Original Units	text		CRF or Derived	VariableQualifier	
QSSTRESC	Character Result/Finding in Std Format	text		CRF or Derived	ResultQualifier	
QSSTRESN	Numeric Finding in Standard Units	float		Derived	ResultQualifier	
QSSTRESU	Standard Units	text		CRF or Derived	VariableQualifier	
QSSTAT	Status of Question	text		CRF or Derived	RecordQualifier	
QSREASND	Reason Not Performed	text		CRF or Derived	RecordQualifier	
QSBLFL	Baseline Flag	text		CRF or Derived	RecordQualifier	

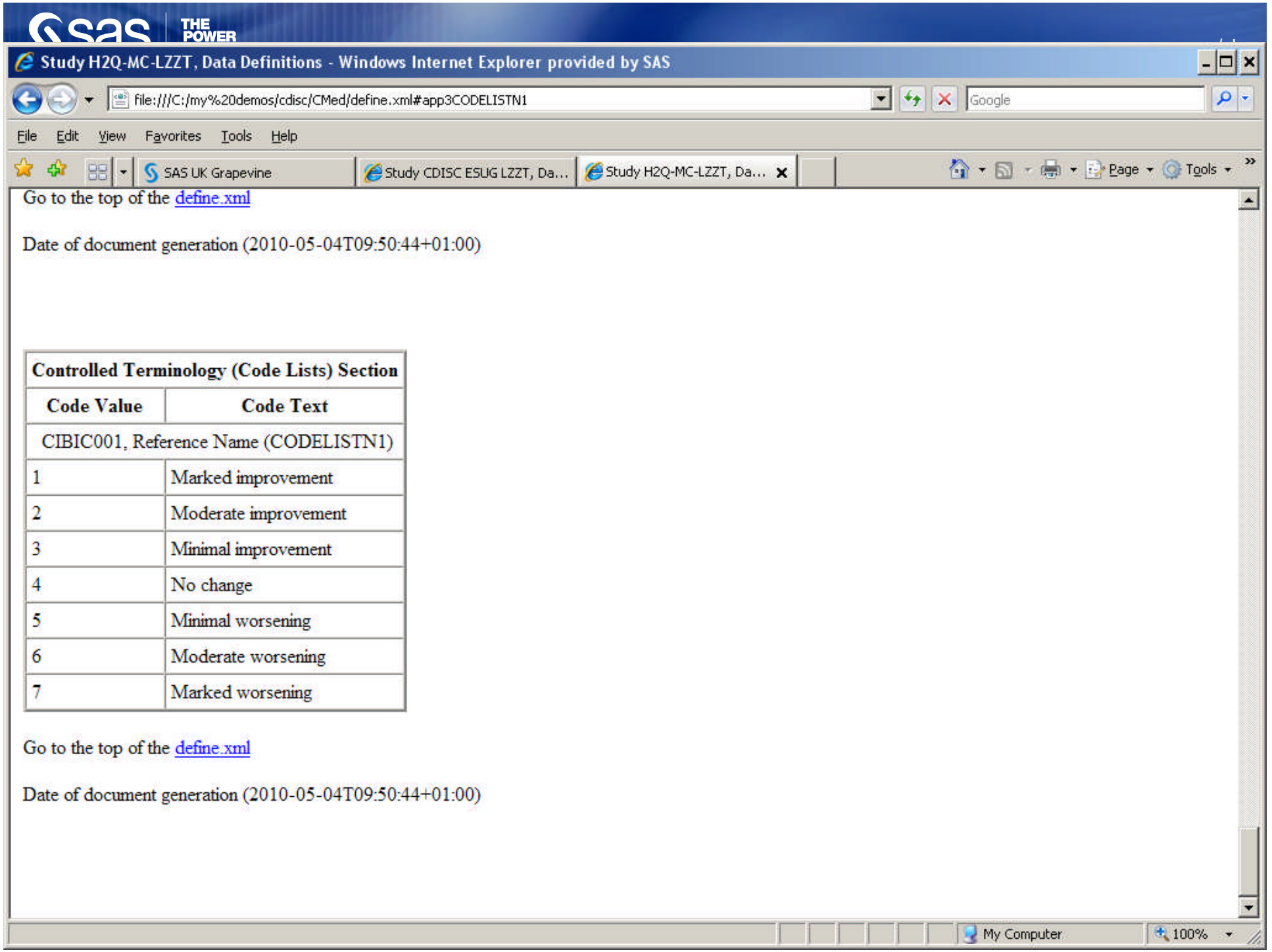


QSSEQ	ADAS001	Word Recall Task	text		CRF or Derived		
QSSEQ	ADAS002	Naming Objects and Fingers	text		CRF or Derived		
QSSEQ	ADAS003	Delayed Word Recall	text		CRF or Derived		
QSSEQ	ADAS004	Commands	text		CRF or Derived		
QSSEQ	ADAS005	Constructional Praxis	text		CRF or Derived		
QSSEQ	ADAS006	Ideational Praxis	text		CRF or Derived		
QSSEQ	ADAS007	Orientation	text		CRF or Derived		
QSSEQ	ADAS008	Word Recognition	text		CRF or Derived		
QSSEQ	ADAS009	Attention/Visual Search Task	text		CRF or Derived		
QSSEQ	ADAS010	Maze Solution	text		CRF or Derived		
QSSEQ	ADAS011	Spoken Language Ability	text		CRF or Derived		
QSSEQ	ADAS012	Comprehension of Spoken Language	text		CRF or Derived		
QSSEQ	CIBIC01	Clinicians Impression of Change (CIBIC+)	text	CODELISTN1	CRF or Derived		

Go to the top of the define.xml

Date of document generation (2010-05-04T09:50:44+01:00)

Computational Algorithms Section	
Reference Name	**Computation Method**


THE POWER
Study H2Q-MC-LZZT, Data Definitions - Windows Internet Explorer provided by SAS
file:///C:/my%20demos/cdisc/CMed/define.xml#app3CODELISTN1
Google
File Edit View Favorites Tools Help
SAS UK Grapevine
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Study H2Q-MC-LZZT, Da...
Page Tools
Go to the top of the define.xml
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Controlled Terminology (Code Lists) Section
Code Value
Code Text
CIBIC001, Reference Name (CODELISTN1)
1 Marked improvement
2 Moderate improvement
3 Minimal improvement
4 No change
5 Minimal worsening
6 Moderate worsening
7 Marked worsening
Go to the top of the define.xml
Date of document generation (2010-05-04T09:50:44+01:00)
My Computer
100%

Adding Annotated CRFs

AnnotatedCRFs

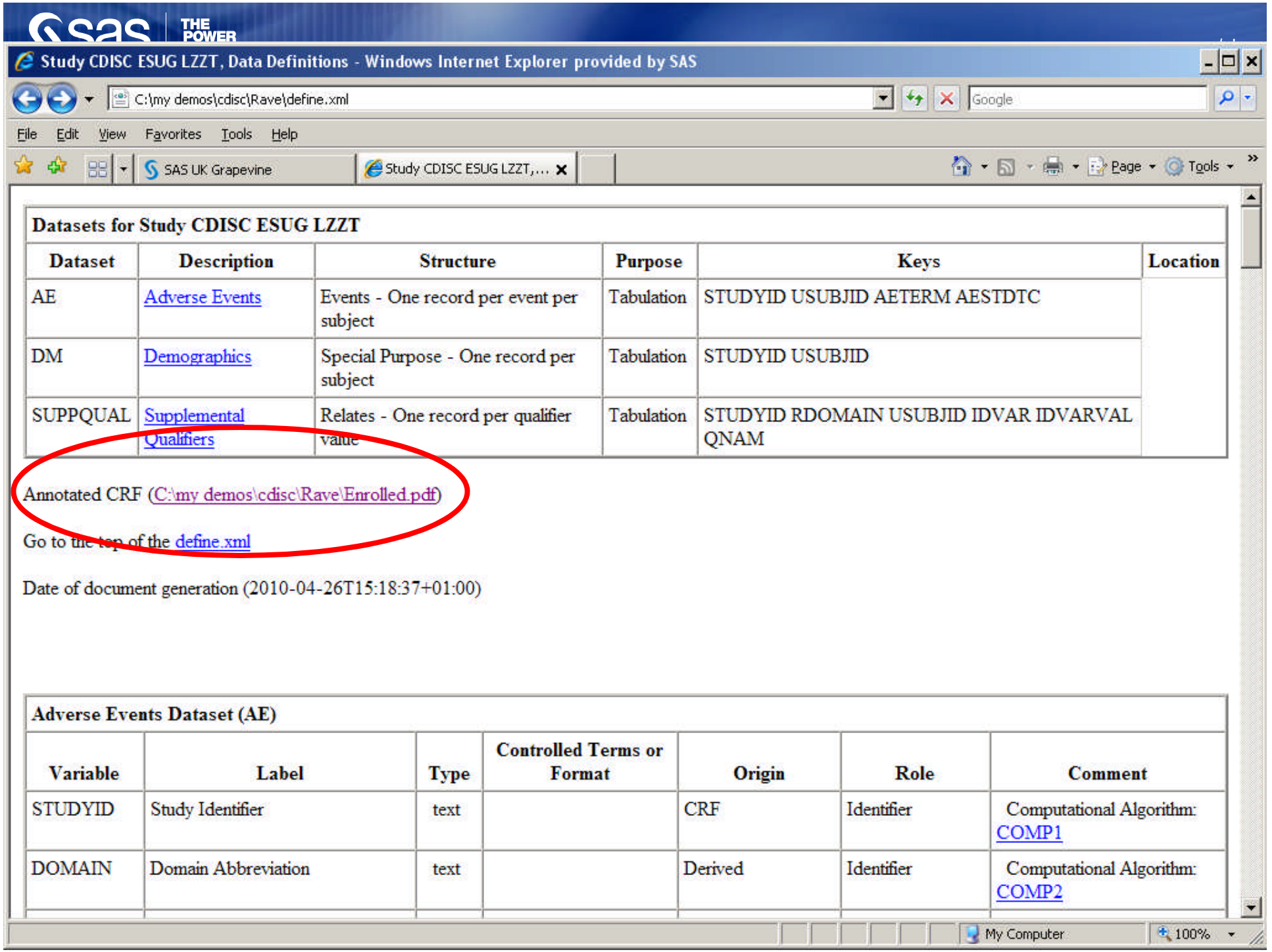
Obs	DocumentRef	leafID	FK_MetaDataVersion
1	DocRef	Annotated	1

MDVLeaf

Obs	ID	href	FK_MetaDataVersion
1	Annotated	C:\my demos\cdisc\Rave\Enrolled.pdf	1

MDVLeafTitles

Obs	title	FK_MDVLeaf
1	Annotated CRF	Annotated


Study CDISC ESUG LZZT, Data Definitions - Windows Internet Explorer provided by SAS
C:\my demos\cdisc\Rave\define.xml
File Edit View Favorites Tools Help
SAS UK Grapevine
Study CDISC ESUG LZZT,...
Page Tools
Datasets for Study CDISC ESUG LZZT
Dataset | Description | Structure | Purpose | Keys | Location
AE | Adverse Events | Events - One record per event per subject | Tabulation | STUDYID USUBJID AETERM AESTDTC
DM | Demographics | Special Purpose - One record per subject | Tabulation | STUDYID USUBJID
SUPPQUAL | Supplemental Qualifiers | Relates - One record per qualifier value | Tabulation | STUDYID RDOMAIN USUBJID IDVAR IDVARVAL QNAM
Annotated CRF (C:\my demos\cdisc\Rave\Enrolled.pdf)
Go to the top of the define.xml
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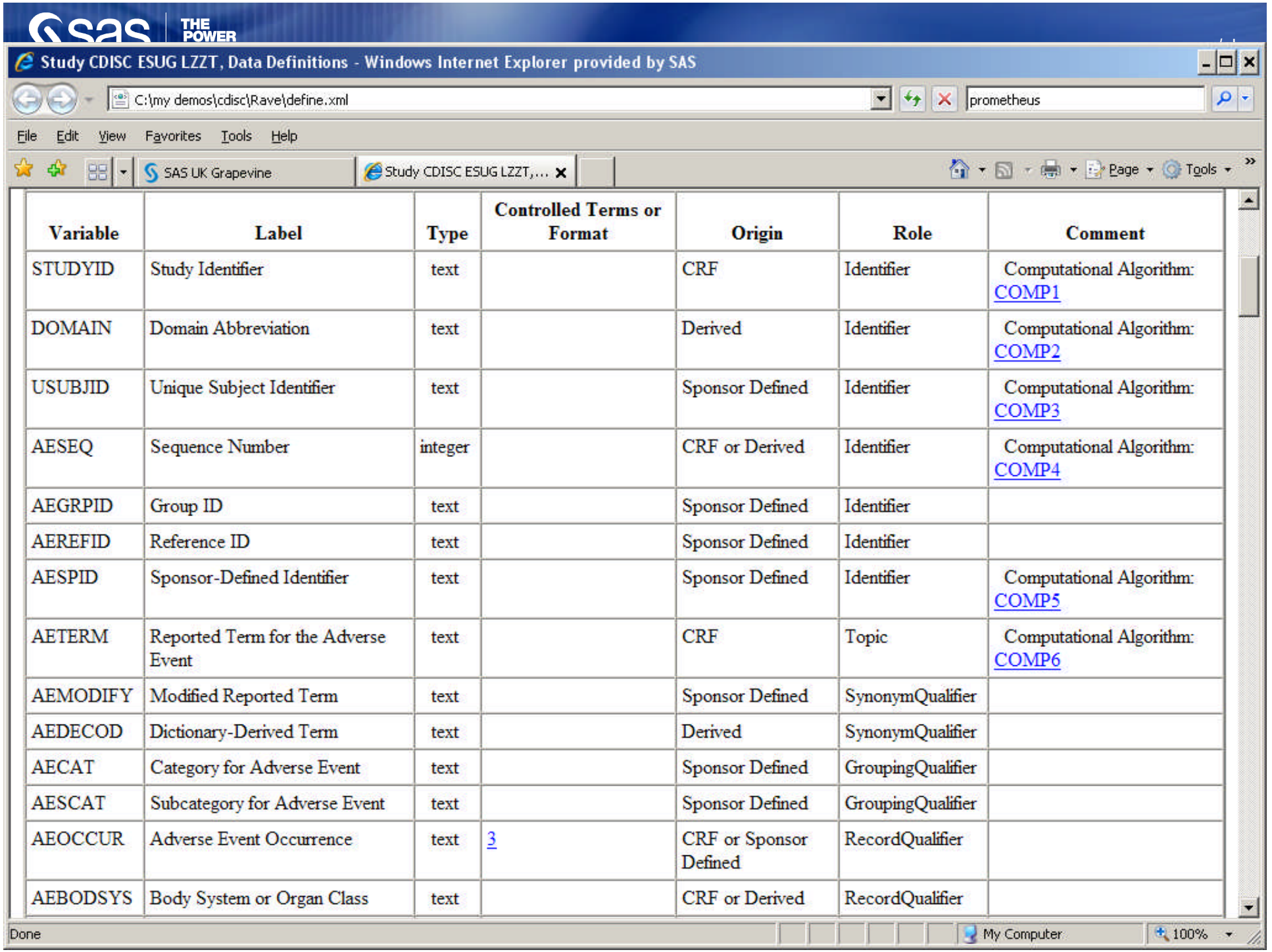
Adverse Events Dataset (AE)
Variable | Label | Type | Controlled Terms or Format | Origin | Role | Comment
STUDYID | Study Identifier | text | | CRF | Identifier | Computational Algorithm: COMP1
DOMAIN | Domain Abbreviation | text | | Derived | Identifier | Computational Algorithm: COMP2
My Computer
100%

Computed Columns - Itemdefs

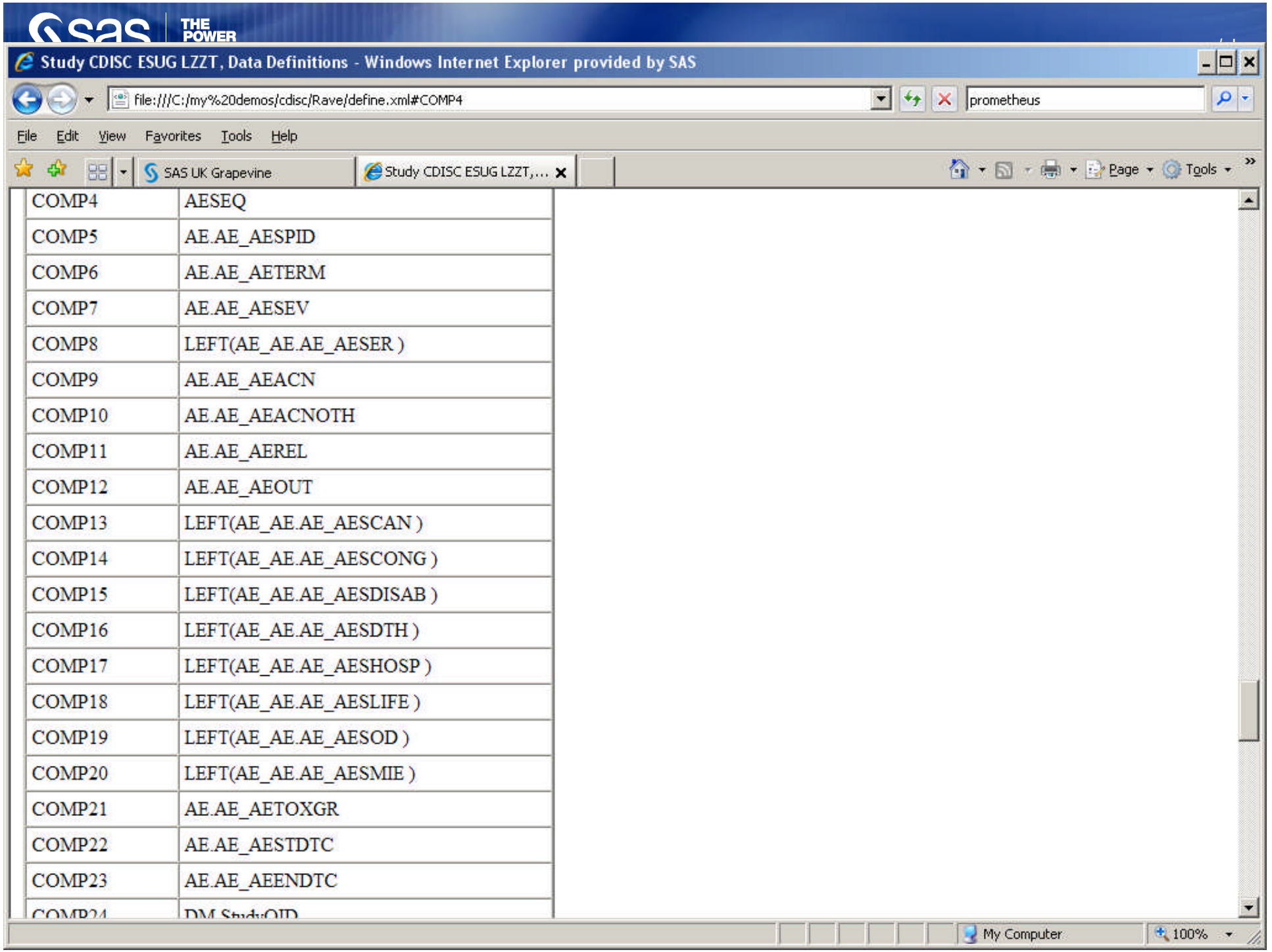
OID	Name	DataType	Length	label	ComputationMethodOID
COL1	STUDYID	text	40	Study Identifier	COMP1
COL2	DOMAIN	text	8	Domain Abbreviation	COMP2
COL3	USUBJID	text	40	Unique Subject Identifier	COMP3
COL4	AESEQ	integer	8	Sequence Number	COMP4
COL5	AEGRPID	text	40	Group ID	
COL6	AEREFID	text	40	Reference ID	
COL7	AESPID	text	40	Sponsor-Defined Identifier	COMP5
COL8	AETERM	text	200	Reported Term for the Adverse Event	COMP6
COL9	AEMODIFY	text	200	Modified Reported Term	
COL10	AEDECOD	text	200	Dictionary-Derived Term	
COL11	AECAT	text	40	Category for Adverse Event	
COL12	AESCAT	text	40	Subcategory for Adverse Event	
COL13	AEOCCUR	text	1	Adverse Event Occurrence	
COL14	AEBODSYS	text	80	Body System or Organ Class	
COL15	AELOC	text	40	Location of the Reaction	

Computed Columns - ComputationMethodOID

OID	method	FK_MetadataVersion
COMP1	AE.StudyOID	1
COMP2	"AE"	1
COMP3	LEFT(AE.StudyOID) || LEFT(AE.SubjectKey)	1
COMP4	AESEQ	1
COMP5	AE.AE_AESPID	1
COMP6	AE.AE_AETERM	1
COMP7	AE.AE_AESEV	1
COMP8	LEFT(AE_AE.AE_AESER)	1
COMP9	AE.AE_AEACN	1
COMP10	AE.AE_AEACNOTH	1
COMP11	AE.AE_AEREL	1
COMP12	AE.AE_AEOUT	1
COMP13	LEFT(AE_AE.AE_AESCAN)	1
COMP14	LEFT(AE_AE.AE_AESCONG)	1
COMP15	LEFT(AE_AE.AE_AESDISAB)	1



Variable	Label	Type	Controlled Terms or Format	Origin	Role	Comment
STUDYID	Study Identifier	text		CRF	Identifier	Computational Algorithm: COMP1
DOMAIN	Domain Abbreviation	text		Derived	Identifier	Computational Algorithm: COMP2
USUBJID	Unique Subject Identifier	text		Sponsor Defined	Identifier	Computational Algorithm: COMP3
AESEQ	Sequence Number	integer		CRF or Derived	Identifier	Computational Algorithm: COMP4
AEGRPID	Group ID	text		Sponsor Defined	Identifier	
AEREFID	Reference ID	text		Sponsor Defined	Identifier	
AESPID	Sponsor-Defined Identifier	text		Sponsor Defined	Identifier	Computational Algorithm: COMP5
AETERM	Reported Term for the Adverse Event	text		CRF	Topic	Computational Algorithm: COMP6
AEMODIFY	Modified Reported Term	text		Sponsor Defined	SynonymQualifier	
AEDECOD	Dictionary-Derived Term	text		Derived	SynonymQualifier	
AECAT	Category for Adverse Event	text		Sponsor Defined	GroupingQualifier	
AESCAT	Subcategory for Adverse Event	text		Sponsor Defined	GroupingQualifier	
AEOCCUR	Adverse Event Occurrence	text	3	CRF or Sponsor Defined	RecordQualifier	
AEBODSYS	Body System or Organ Class	text		CRF or Derived	RecordQualifier	


THE POWER
Study CDISC ESUG LZZT, Data Definitions - Windows Internet Explorer provided by SAS
file:///C:/my%20demos/cdisc/Rave/define.xml#COMP4
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COMP4 AESEQ
COMP5 AE.AE_AESPID
COMP6 AE.AE_AETERM
COMP7 AE.AE_AESEV
COMP8 LEFT(AE_AE.AE_AESER)
COMP9 AE.AE_AEACN
COMP10 AE.AE_AEACNOTH
COMP11 AE.AE_AEREL
COMP12 AE.AE_AEOUT
COMP13 LEFT(AE_AE.AE_AESCAN)
COMP14 LEFT(AE_AE.AE_AESCONG)
COMP15 LEFT(AE_AE.AE_AESDISAB)
COMP16 LEFT(AE_AE.AE_AESDTH)
COMP17 LEFT(AE_AE.AE_AESHOSP)
COMP18 LEFT(AE_AE.AE_AESLIFE)
COMP19 LEFT(AE_AE.AE_AESOD)
COMP20 LEFT(AE_AE.AE_AESMIE)
COMP21 AE.AE_AETOXGR
COMP22 AE.AE_AESTDTC
COMP23 AE.AE_AEENDTC
COMP24 DM.StudyOID
My Computer
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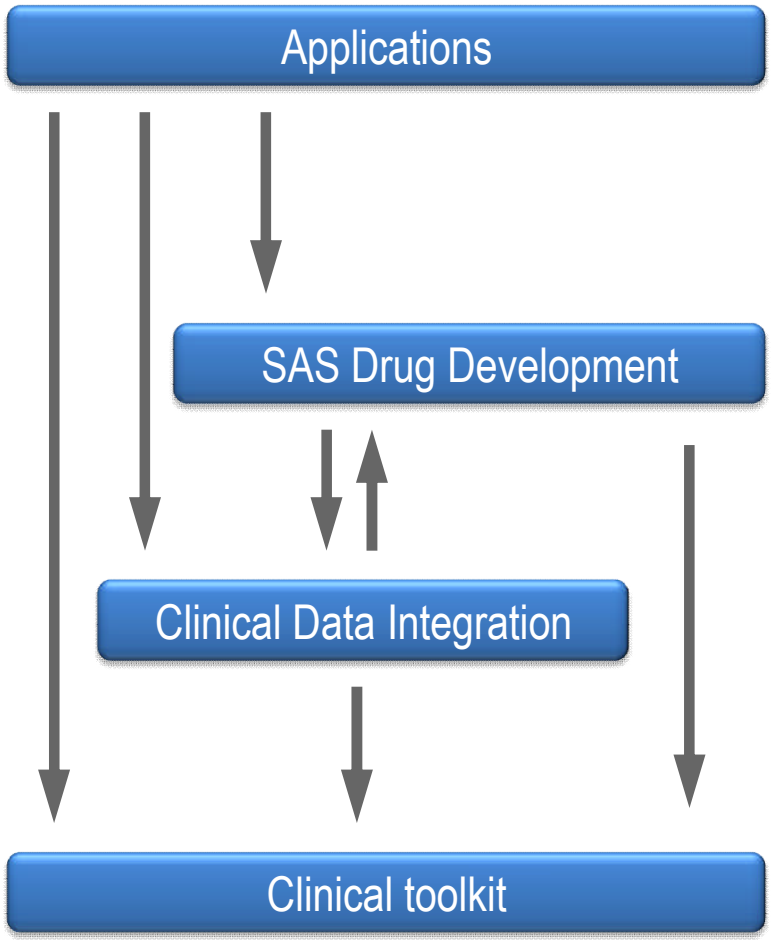
Calling the Toolkit from SAS Clinical Data Integration

Clinical Standards Toolkit – Context

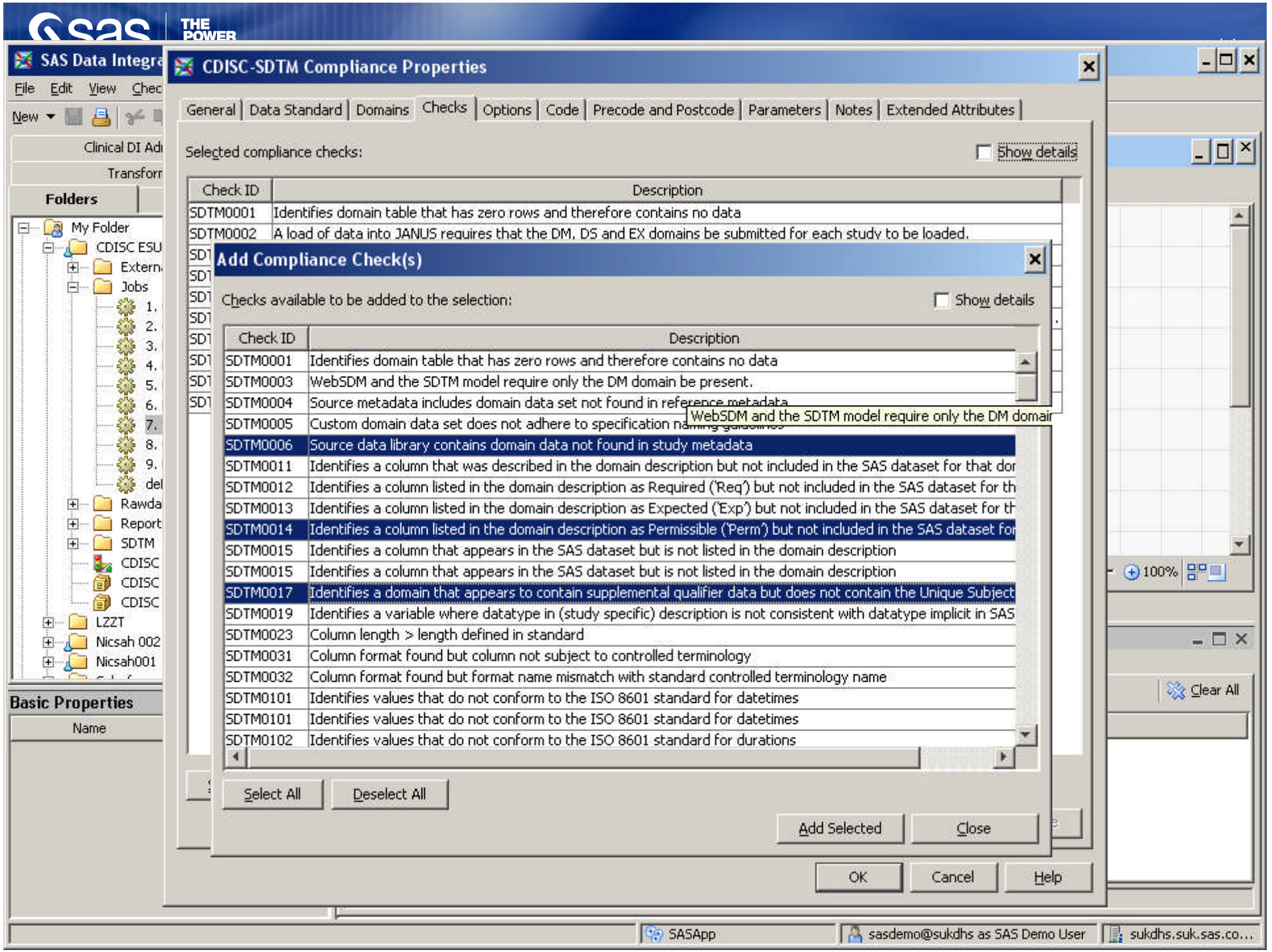


Advanced analytics that leverage standards-based metadata and data.

Centralized, 21CFR Pt 11 compliant storage, program execution and data exploration.

Clinical standards & metadata management integrated with code generation functionality.

Clinically relevant functionality available to SAS programs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Checks
Options
Code
Precode and Postcode
Parameters
Notes
Extended Attributes
Selected compliance checks:
Show details
Check ID
Description
SDTM0001 Identifies domain table that has zero rows and therefore contains no data
SDTM0002 A load of data into JANUS requires that the DM, DS and EX domains be submitted for each study to be loaded.
Add Compliance Check(s)
Checks available to be added to the selection:
Show details
Check ID
Description
SDTM0001 Identifies domain table that has zero rows and therefore contains no data
SDTM0003 WebSDM and the SDTM model require only the DM domain be present.
SDTM0004 Source metadata includes domain data set not found in reference metadata
WebSDM and the SDTM model require only the DM domain
SDTM0005 Custom domain data set does not adhere to specification naming guidelines
SDTM0006 Source data library contains domain data not found in study metadata
SDTM0011 Identifies a column that was described in the domain description but not included in the SAS dataset for that dor
SDTM0012 Identifies a column listed in the domain description as Required ('Req') but not included in the SAS dataset for th
SDTM0013 Identifies a column listed in the domain description as Expected ('Exp') but not included in the SAS dataset for th
SDTM0014 Identifies a column listed in the domain description as Permissible ('Perm') but not included in the SAS dataset for
SDTM0015 Identifies a column that appears in the SAS dataset but is not listed in the domain description
SDTM0015 Identifies a column that appears in the SAS dataset but is not listed in the domain description
SDTM0017 Identifies a domain that appears to contain supplemental qualifier data but does not contain the Unique Subject
SDTM0019 Identifies a variable where datatype in (study specific) description is not consistent with datatype implicit in SAS
SDTM0023 Column length > length defined in standard
SDTM0031 Column format found but column not subject to controlled terminology
SDTM0032 Column format found but format name mismatch with standard controlled terminology name
SDTM0101 Identifies values that do not conform to the ISO 8601 standard for datetimes
SDTM0101 Identifies values that do not conform to the ISO 8601 standard for datetimes
SDTM0102 Identifies values that do not conform to the ISO 8601 standard for durations
Select All
Deselect All
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Close
OK
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100%
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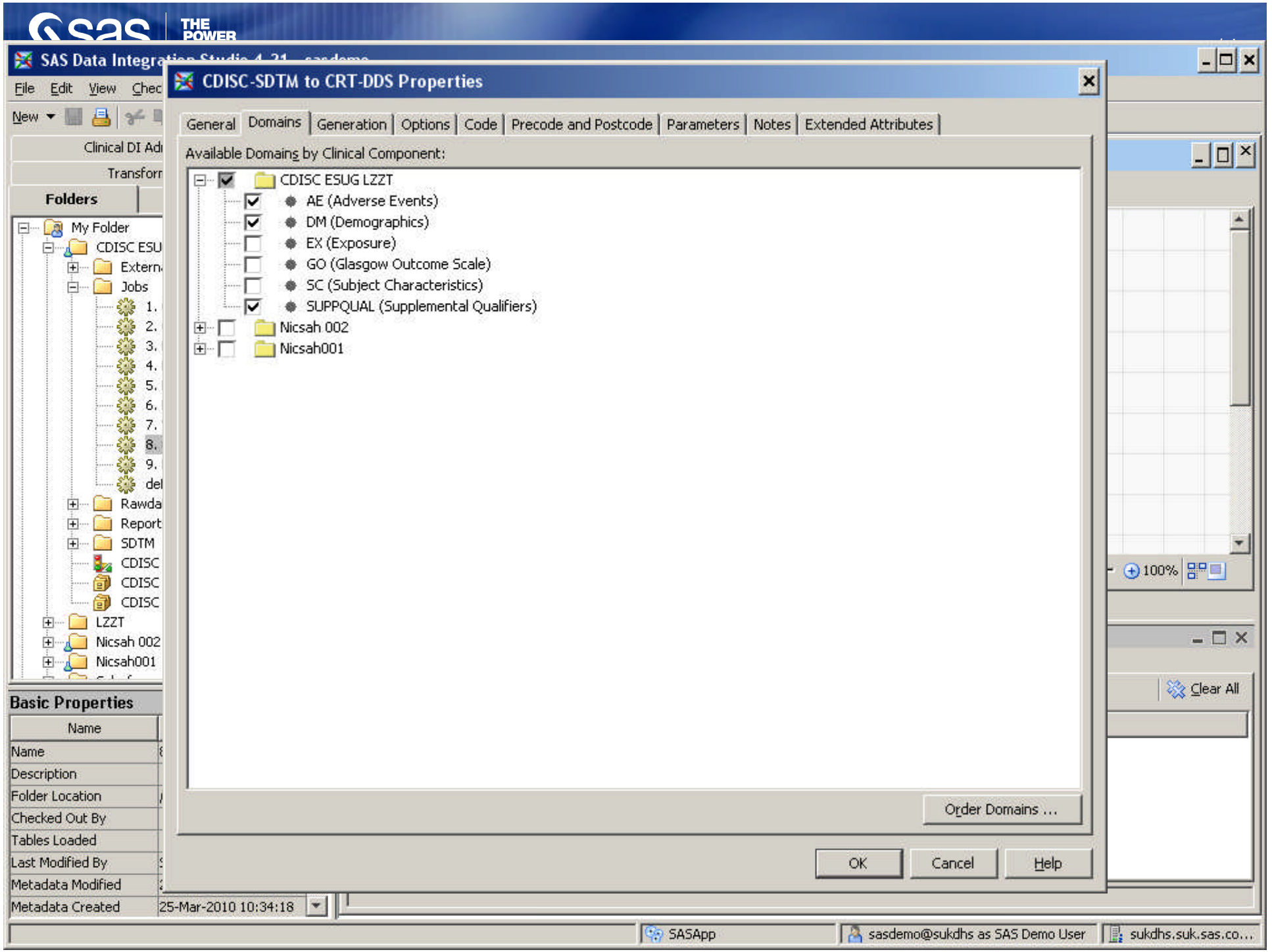
SASApp
sasdemo@sukdhs as SAS Demo User
sukdhs.suk.sas.co...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Last Modified By
Metadata Modified
Metadata Created
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CDISC-SDTM to CRT-DDS Properties
General
Domains
Generation
Options
Code
Precode and Postcode
Parameters
Notes
Extended Attributes
Available Domains by Clinical Component:
CDISC ESUG LZZT
AE (Adverse Events)
DM (Demographics)
EX (Exposure)
GO (Glasgow Outcome Scale)
SC (Subject Characteristics)
SUPPQUAL (Supplemental Qualifiers)
Nicsah 002
Nicsah001
Order Domains ...
OK
Cancel
Help
100%
Clear All
SASApp
sasdemo@sukdhs as SAS Demo User
sukdhs.suk.sas.co...

How to get hold of the Clinical Standards Toolkit

- Needs to be licensed
- No additional cost
- Paperwork needs to be completed
- 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

Conclusions

Conclusions

CDISC is here to stay

- But you need to get it right

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

Contact

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