

SASとExcelを用いたCDISC ADaM標準における 作業効率化の試み

高浪 洋平

武田薬品工業株式会社医薬開発本部日本開発センター
クリニカルデータサイエンス部統計グループ

Approach to Reduction in Workload of CDISC ADaM Standard Using SAS and Excel

Yohei Takanami

Takeda Pharmaceutical Company, Ltd.

要旨：

SASプログラムとExcel Metadata及びExcel VBAの基本的な機能のみを用いて、ADaMのDefine.xmlの作成や解析及びバリデーションの実施における作業効率化の試みを紹介する。

Propose the approach to reduction in the workload of the creation of ADaM Define.xml and analysis reports and the execution of the validation with SAS, Excel metadata and VBA

キーワード：CDISC, ADaM, Excel, Metadata, VBA, Define.xml, OpenCDISC

Outline

- Background
 - Circumstances surrounding CDISC
- ADaM Datasets and Metadata
 - ADaM Datasets
 - ADaM Metadata in Excel format
- Approach to Reduction in Workload using SAS and Excel
 - Workflow and Directory Structure
 - Execution of SAS Program with Excel VBA
 - Import of Excel Data with SAS libname excel engine
 - Creation of Define.xml with SAS and VBA
 - Creation of Analysis Reports with SAS and VBA
 - Execution of the OpenCDISC Validator with SAS and VBA

Outline

- Background
 - Circumstances surrounding CDISC
- ADaM Datasets and Metadata
 - ADaM Datasets
 - ADaM Metadata in Excel format
- Approach to Reduction in Workload using SAS and Excel
 - Workflow and Directory Structure
 - Execution of SAS Program with Excel VBA
 - Import of Excel Data with SAS libname excel engine
 - Creation of Define.xml with SAS and VBA
 - Creation of Analysis Reports with SAS and VBA
 - Execution of the OpenCDISC Validator with SAS and VBA

Circumstances surrounding CDISC

- Japan
 - PMDA has started to construct business process to receive electronic data of clinical trials in accordance with CDISC format for NDA.
<http://www.pmda.go.jp/operations/shonin/info/iyaku/jisedai.html>
 - The submission of electronic data of clinical trials will be mandatory by 2016 in Japan.
 - Need to submit SDTM, ADaM datasets, Define.xml and other documents
- US
 - FDA announced Draft Guidance for submission of electronic data of clinical trials.
<http://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm>
 - The submission of electronic data of clinical trials will be mandatory in the near future.

Working on the ADaM Standard

- Workload of ADaM standard for NDA
 - Creation of ADaM datasets, TLFs, programs, define.xml and validation of these files
- This presentation proposes the approach to reduce the workload of ADaM standard
- Topics in this presentation
 - Creation of Excel metadata for ADaM datasets
 - Creation of Define.xml
 - Creation of Analysis reports
 - Execution of the Validation for ADaM datasets
- Make the maximum use of Excel VBA and SAS in the workload above

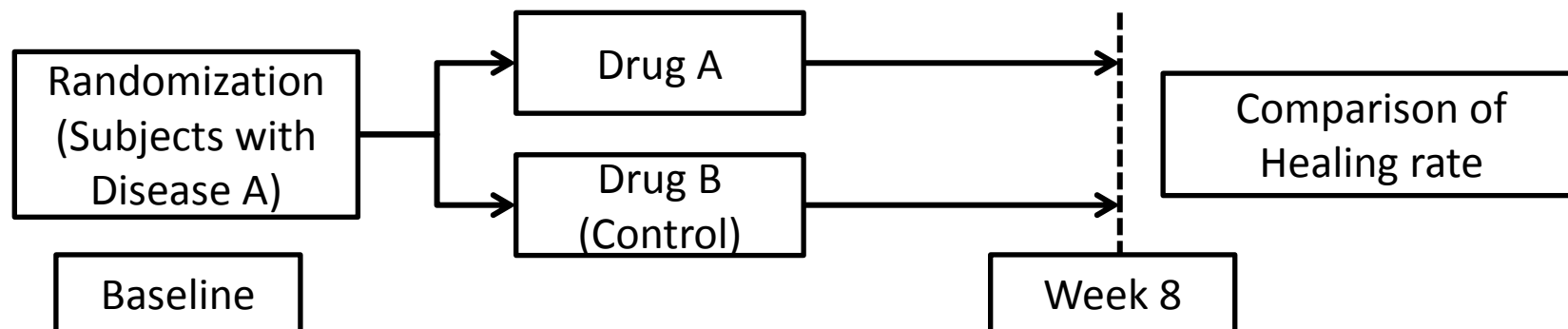
Outline

- Background
 - Circumstances surrounding CDISC
- ADaM Datasets and Metadata
 - ADaM Datasets
 - ADaM Metadata in Excel format
- Approach to Reduction in Workload using SAS and Excel
 - Workflow and Directory Structure
 - Execution of SAS Program with Excel VBA
 - Import of Excel Data with SAS libname excel engine
 - Creation of Define.xml with SAS and VBA
 - Creation of Analysis Reports with SAS and VBA
 - Execution of the OpenCDISC Validator with SAS and VBA

ADaM Datasets and Metadata

➤ Example of clinical trial for ADaM datasets

Item	Contents
Phase	Phase-III trial: PROD-XXX/STUDY-XXX
Target population	Subjects with Disease A
Design	2 arm (Drug A and Drug B (Active control)), parallel, randomized double-blind
Purpose	Comparison of Drug A and Drug B
Primary endpoint	Disease A Healing rate at Week 8
Other endpoint	Adverse Events etc.



ADaM Datasets and Metadata

- ADSL
 - One record per subject

STUDYID	USUBJID	SUBJID	SITEID	AGE	AGEU
PROD-XXX/STUDY-XXX	PROD-XXX/STUDY-XXX/9001001	9001001	9001	70	YEARS
PROD-XXX/STUDY-XXX	PROD-XXX/STUDY-XXX/9001002	9001002	9001	63	YEARS
PROD-XXX/STUDY-XXX	PROD-XXX/STUDY-XXX/9001003	9001003	9001	56	YEARS
PROD-XXX/STUDY-XXX	PROD-XXX/STUDY-XXX/9001004	9001004	9001	62	YEARS
PROD-XXX/STUDY-XXX	PROD-XXX/STUDY-XXX/9001005	9001005	9001	78	YEARS
PROD-XXX/STUDY-XXX	PROD-XXX/STUDY-XXX/9001006	9001006	9001	61	YEARS
PROD-XXX/STUDY-XXX	PROD-XXX/STUDY-XXX/9001007	9001007	9001	38	YEARS
PROD-XXX/STUDY-XXX	PROD-XXX/STUDY-XXX/9001008	9001008	9001	38	YEARS
PROD-XXX/STUDY-XXX	PROD-XXX/STUDY-XXX/9001009	9001009	9001	76	YEARS
PROD-XXX/STUDY-XXX	PROD-XXX/STUDY-XXX/9002001	9002001	9002	67	YEARS
PROD-XXX/STUDY-XXX	PROD-XXX/STUDY-XXX/9002002	9002002	9002	37	YEARS

ADaM Datasets and Metadata

- ADAE
 - One record per subject per each AE recorded in SDTM AE domain

AETERM	AEDECOD	AETCD	AEBODSYS	AEBDSYCD	AELLT
Cystitis acute	Cystitis	10011781	Infections and infestations	10021881	Cystitis acute
Diarrhoea	Diarrhoea	10012785	Gastrointestinal disorders	10017947	Diarrhoea
Alopecia areata	Alopecia areata	10001761	Skin and subcutaneous tissue disorders	10040785	Alopecia areata
Mallory-Weiss syndrome	Mallory-Weiss syndrome	10026712	Gastrointestinal disorders	10017947	Mallory-Weiss syndrome
Common cold	Nasopharyngitis	10028810	Infections and infestations	10021881	Common cold
Acute abdomen	Acute abdomen	10000647	Gastrointestinal disorders	10017947	Acute abdomen
Common cold	Nasopharyngitis	10028810	Infections and infestations	10021881	Common cold
Gastric polyps	Gastric polyps	10017817	Gastrointestinal disorders	10017947	Gastric polyps
Headache	Headache	10019211	Nervous system disorders	10029205	Headache
Constipation	Constipation	10010774	Gastrointestinal disorders	10017947	Constipation
Paronychia	Paronychia	10034016	Infections and infestations	10021881	Paronychia
Epigastric discomfort	Epigastric discomfort	10053155	Gastrointestinal disorders	10017947	Epigastric discomfort
Pharyngeal erosion	Pharyngeal erosion	10062773	Respiratory, thoracic and mediastinal disorders	10038738	Pharyngeal erosion

ADaM Datasets and Metadata

- ADEF
 - One record per subject, parameter

ADY	ADYL	PARAM	PARAMCD	PARAMN	AVAL	AVALC	AVISIT	AVISITN	ANL01FL
13	-16	Healing of Disease A	HEAL	1	2	Unhealed	Week 2	2	Y
30	1	Healing of Disease A	HEAL	1	1	Healed	Week 4	3	Y
30	1	Healing of Disease A	HEAL	1	1	Healed	Week 8	4	Y
16	-13	Healing of Disease A	HEAL	1	2	Unhealed	Week 2	2	Y
30	1	Healing of Disease A	HEAL	1	1	Healed	Week 4	3	Y
30	1	Healing of Disease A	HEAL	1	1	Healed	Week 8	4	Y
14	-14	Healing of Disease A	HEAL	1	2	Unhealed	Week 2	2	Y
29	1	Healing of Disease A	HEAL	1	1	Healed	Week 4	3	Y
29	1	Healing of Disease A	HEAL	1	1	Healed	Week 8	4	Y
15	1	Healing of Disease A	HEAL	1	1	Healed	Week 2	2	Y
15	1	Healing of Disease A	HEAL	1	1	Healed	Week 4	3	Y
15	1	Healing of Disease A	HEAL	1	1	Healed	Week 8	4	Y

ADaM Datasets and Metadata

➤ ADaM Metadata (ADaM V2.1)

Metadata	Definition
Analysis Dataset Metadata	List of Analysis datasets and description
Analysis Variable Metadata	Definition of Variable name, label, derivation rule and codelist for each dataset
Analysis Parameter Value-Level Metadata	Derivation rule and definition for each analysis parameter
Analysis Results Metadata	Description of analysis results

ADaM Datasets and Metadata

- Excel Metadata for creation of ADaM Define.xml (Jack Shostak et al. (2012))
 - Excel file which includes the information in each sheet needed to create Define.xml file
 - The following metadata are included in the file
 - Analysis Dataset Metadata Sheet (List of ADaM datasets)
 - ADSL Sheet (For Analysis Variable Metadata)
 - ADAE Sheet (For Analysis Variable Metadata)
 - ADEF Sheet (For Analysis Variable Metadata)
 - Codelist Sheet (List of Terminology)
 - Value List Sheet (For Parameter Value-Level Metadata)
 - Analysis Results Metadata Sheet

ADaM Datasets and Metadata

- Excel Metadata for creation of ADaM Define.xml (Jack Shostak et al. (2012))
 - Analysis Dataset Metadata Sheet (List of ADaM datasets)

Dataset Name	Dataset Description	Dataset Location	Dataset Structure	Key Variables of Dataset	Class of Dataset	Documentation
ADSL	Subject disposition, demographic, and baseline characteristics	ADSL.xpt	one record per subject	USUBJID	ADSL	SAP, ADSL.sas
ADAE	Adverse Event Analysis Dataset	ADAE.xpt	one record per subject per each AE recorded in SDTM AE domain	USUBJID, AESEQ	ADAE	ADAE.sas Dictionary used is MedDRA VXX.X
ADEF	Analysis Dataset for Target Disease	ADEF.xpt	1 record per subject, parameter	USUBJID, PARAMCD	BDS	SAP, ADEF.sas

- ADSL Sheet (For Analysis Variable Metadata)

Dataset Name	Variable Name	Variable Label	Variable Type	Length	Display Format	Codelist / Controlled Terms	Codelist Name	Origin	Source / Derivation
ADSL	STUDYID	Study Identifier	text	40	\$40.			Predecessor	DMSTUDYID
ADSL	USUBJID	Unique Subject Identifier	text	40	\$40.			Predecessor	DMUSUBJID
ADSL	SUBJID	Subject Identifier for the Study	text	20	\$20.			Predecessor	DMSUBJID
ADSL	SITEID	Study Site Identifier	text	20	\$20.			Predecessor	DMSITEID
ADSL	AGE	Age	integer	8	8.0			Predecessor	DMAGE
ADSL	AGEU	Age Units	text	20	\$20.	(AGEU)	AGEU	Predecessor	DMAGEU
ADSL	SEX	Sex	text	1	\$1.	M, F	SEX	Predecessor	DMSEX
ADSL	SEXN	Sex (N)	integer	8	1.0	1=Male, 2=Female	SEXN	Assigned	1 if DMSEX="M", 2 if DMSEX="F"
ADSL	RACE	Race	text	20	\$20.	(RACE)	RACE	Predecessor	DMRACE
ADSL	RACEN	Race (N)	integer	8	1.0		RACEN	Assigned	1, if DMRACE = "ASIAN"
ADSL	ARM	Description of Planned Arm	text	20	\$20.	Drug A, Drug B, Screen Failure	ARM	Predecessor	DMARM
ADSL	TRT01P	Planned Treatment	text	20	\$20.	Drug A, Drug B	TRT	Predecessor	DMARM (missing if DMARM="Screen Failure")
ADSL	TRT01PN	Planned Treatment (N)	integer	8	1.0	1=Drug A, 2=Drug B	TRTN	Assigned	1 if DMARMCD="Drug A", 2 if DMARMCD="Drug B"
ADSL	TRT01A	Actual Treatment	text	20	\$20.	Drug A, Drug B	TRT	Predecessor	DMACTARM (missing if DMACTARM="Screen Failure")
ADSL	TRT01AN	Actual Treatment (N)	integer	8	1.0	1=Drug A, 2=Drug B	TRTN	Assigned	1=Drug A, 2=Drug B

ADaM Datasets and Metadata

- Excel Metadata for creation of ADaM Define.xml (Jack Shostak et al. (2012))
 - Codelist Sheet (List of Codelists)

Name	CodeValue	CodeText	Data Type
SEX	F	Female	text
SEX	M	Male	text
SEXN	1	Male	integer
SEXN	2	Female	integer
AGEU	YEARS		text
ARM	Drug A	Drug A	text
ARM	Drug B	Drug B	text
ARM	Screen Failure	Screen Failure	text
TRT	Drug A	Drug A	text
TRT	Drug B	Drug B	text
TRTN	1	Drug A	integer
TRTN	2	Drug B	integer

- Value List Sheet (For Analysis Parameter Value-Level Metadata)

Name	Dataset Name	Variable Name	Variable Label	Parameter_variable	Comparator	Parameters	Variable Type	Length	Display Format
VL.ADEF.AVAL	ADEF	AVAL	Analysis Value	PARAMCD	IN	HEAL	integer	8	1.0

ADaM Datasets and Metadata

- Excel Metadata for creation of ADaM Define.xml (Jack Shostak et al. (2012))
 - Analysis Results Metadata Sheet

Display Identif	Display Name	Result Identif	PARAMLIST	Parameter	Analysis Variable	Reason	Dataset	Selection Criteria	Documentation	Programming Statements
Table 1	Disease A Healing Rate by Study Visit (FAS)		Healing of Disease A	HEAL	AVAL	Pre-specified in SAP	ADEF	FASFL="Y" and PARAMN = 1 and AVISITN = 4	SAP	<pre>proc format ; value _TRTPF 1 = "Drug A" 2 = "Drug B" ; run ; proc freq data=_ADaM.ADEF ; where FASFL = "Y" and PARAMN = 1 ; table AVISIT*TRTPN*AVALC / riskdiff nocel nope format TRTPN _TRTPF ; run ;</pre>
Table 2	Disease A Healing Rate by Study Visit (PPS)		Healing of Disease A	HEAL	AVAL	Pre-specified in SAP	ADEF	PPROTFL="Y" and PARAMN = 1 and AVISITN = 4	SAP	<pre>proc format ; value _TRTPF 1 = "Drug A" 2 = "Drug B" ; run ; proc freq data=_ADaM.ADEF ; where PPROTFL = "Y" and PARAMN = 1 ; table AVISIT*TRTPN*AVALC / riskdiff nocel nope format TRTPN _TRTPF ; run ;</pre>

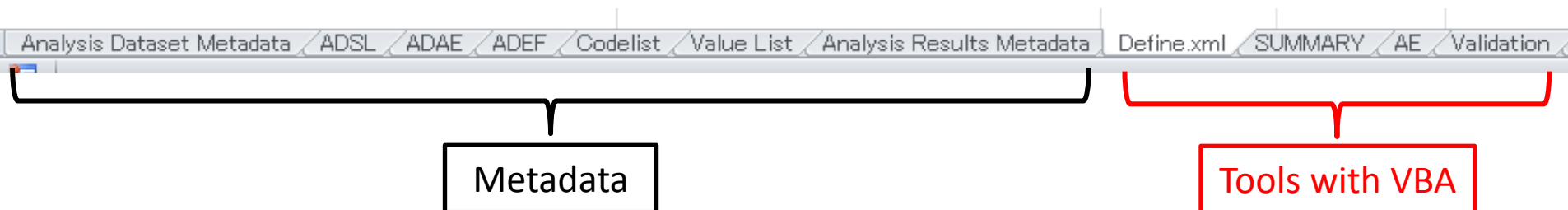
Outline

- Background
 - Circumstances surrounding CDISC
- ADaM Datasets and Metadata
 - ADaM Datasets
 - ADaM Metadata in Excel format
- Approach to Reduction in Workload using SAS and Excel
 - Workflow and Directory Structure
 - Execution of SAS Program with Excel VBA
 - Import of Excel Data with SAS libname excel engine
 - Creation of Define.xml with SAS and VBA
 - Creation of Analysis Reports with SAS and VBA
 - Execution of the OpenCDISC Validator with SAS and VBA

Approach to Reduction in Workload Using SAS and Excel

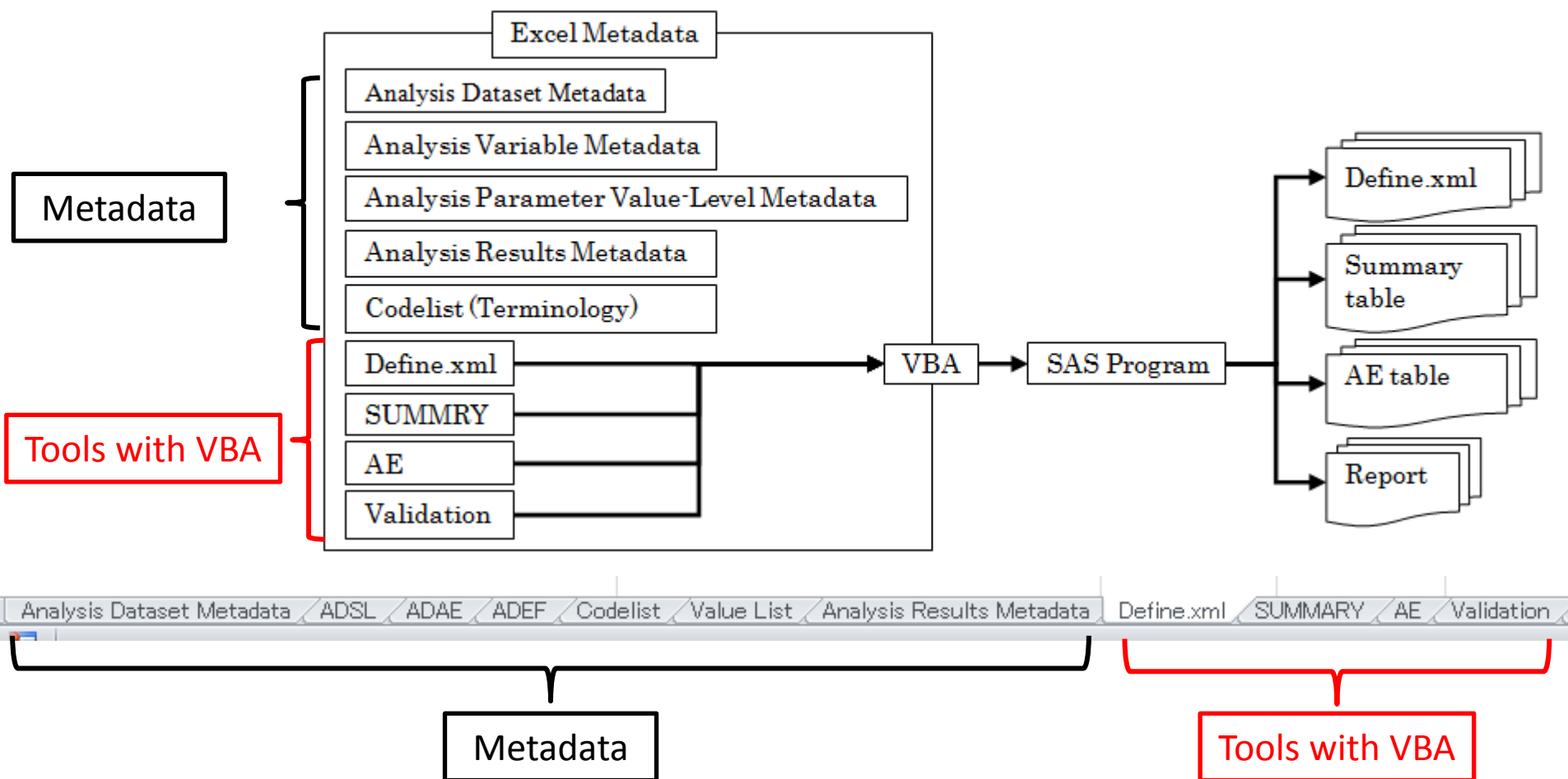
- Adding the following sheets to Excel metadata file for the creation of Define.xml, Analysis Reports and execution of OpenCDISC Validator for the validation of ADaM datasets
- VBA to execute the SAS programs is implemented in each sheet

Sheet names to be added	Contents
Define.xml	Creation of ADaM Define.xml
SUMMARY	Creation of summary table of demographic data
AE	Creation of Summary report for Adverse Events
Validation	Execution of OpenCDISC Validator



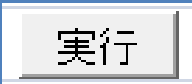
Approach to Reduction in Workload Using SAS and Excel

- Image of whole Excel metadata file and processes of VBA and SAS



Approach to Reduction in Workload Using SAS and Excel

- Run the SAS programs using Excel VBA
 - Implementation of the VBA code to "Run" Button
 - Click on the button and then VBA and SAS codes are executed
 - The following code executes "Mr_Define.sas" program and create the ADaM define.xml file

Run Button	VBA Code
	<pre>Sub SAS_RUN3() Dim sasobj As Object Set sasobj = CreateObject("SAS.application") sasobj.Visible = False sasobj.Submit ("%inc 'C:¥Temp¥SUGI_2014¥Define_xml¥Mr_Define.sas';") sasobj.Submit ("ENDSAS;") End Sub</pre>

Approach to Reduction in Workload Using SAS and Excel

- Import the Excel sheet using the excel engine in the libname statement

*--- Metadata file ;

libname _META excel "C:\temp\SUGI_2014\Metadata\Run_SAS.xlsm" ;

*** Import the Codelist sheet from excel file ;

data _CODELIST ;

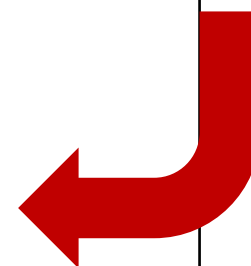
set _META.'Codelist\$'n ;

run ;

_CODELIST dataset

Name	CodeValue	CodeText	Data Type
SEX	F	Female	text
SEX	M	Male	text
SEXN	1	Male	integer
SEXN	2	Female	integer
AGEU	YEARS		text
ARM	Drug A	Drug A	text
ARM	Drug B	Drug B	text
ARM	Screen Failure	Screen Failure	text
TRT	Drug A	Drug A	text
TRT	Drug B	Drug B	text
TRTN	1	Drug A	integer
TRTN	2	Drug B	integer







Name	CodeValue	CodeText	Data Type
SEX	F	Female	text
SEX	M	Male	text
SEXN	1	Male	integer
SEXN	2	Female	integer
AGEU	YEARS		text
ARM	Drug A	Drug A	text
ARM	Drug B	Drug B	text
ARM	Screen Failure	Screen Failure	text
TRT	Drug A	Drug A	text
TRT	Drug B	Drug B	text
TRTN	1	Drug A	integer
TRTN	2	Drug B	integer



Approach to Reduction in Workload Using SAS and Excel

➤ Directory Structure

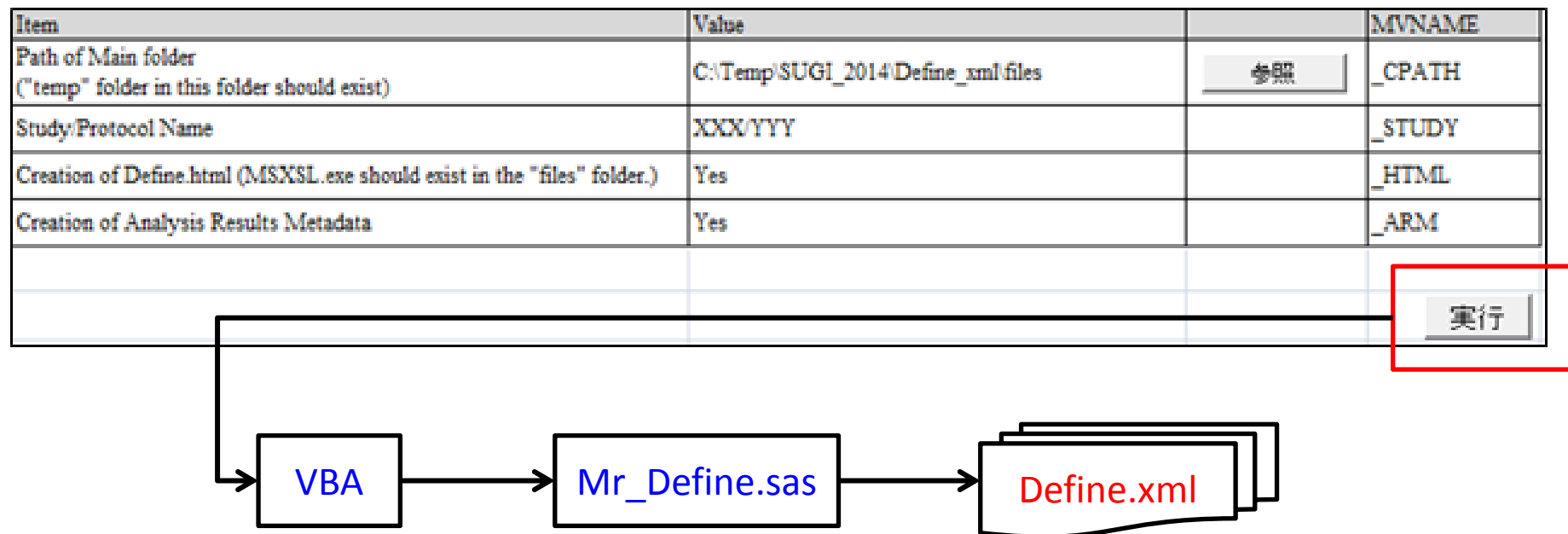
- "c:\temp\SUGI_2014" folder

	Folder	Contents
 Data  Define_xml  Log  Metadata  Output  Programs	Data	ADaM datasets
	Define_xml	Mr_Define.sas and folders for output
	Log	Log and lst files
	Metadata	Excel Metadata
	Output	Results (Tables and report of OpenCDISC Validator
	Programs	SAS programs other than Mr_define.sas

Approach to Reduction in Workload Using SAS and Excel

➤ Creating the ADaM Define.xml

- Input the main folder
- Input the Study name
- Select the creation of HTML file (using MSXSL.exe)
- Select the creation of Analysis Results Metadata



Approach to Reduction in Workload Using SAS and Excel

➤ Mr_Define.sas (excerpt)

```
***** Header of the Define_ADaM.xml ***** ;
filename _H "&_CPATH.¥temp¥_header.txt" ;
data _HEADER ;
  file _H ;
  _DT = put(datetime(), E8601DT.) ;
  put '<?xml version="1.0" encoding="UTF-8"?>' ;
  put '<?xml-stylesheet type="text/xsl" href="define2-0-0_MOD.xsl"?>' ;
  put '<ODM xmlns="http://www.cdisc.org/ns/odm/v1.3" ;
  xmlns:def="http://www.cdisc.org/ns/def/v2.0" ;
  xmlns:xlink="http://www.w3.org/1999/xlink" ;
  %if &_ARM = 1 %then put '  xmlns:adamref="http://www.cdisc.org/ns/ADaMRes/DRAFT" ;
  put '  ODMVersion="1.3.2" ;
  put '  FileOID=" " &_STUDY-Define-XML_2.0.0 " ' ;
  put '  FileType="Snapshot" ;
  put '  CreationDateTime=" " _DT + (-1) ' ;
  put '  Originator="CDISC ADaM Metadata Team">' ;
  put ' <Study OID=" " &_STUDY " ">' ;
  put '  <GlobalVariables>' ;
  put '    <StudyName> ' &_STUDY " '</StudyName>' ;
  put '    <StudyDescription> ' &_STUDY Data Definition " '</StudyDescription>' ;
  put '    <ProtocolName> ' &_STUDY " '</ProtocolName>' ;
  put '  </GlobalVariables>' ;
  put '  <MetaDataVersion OID="MDV.' &_STUDY " '.ADaMIG.1.0.ADAM.2.1" ;
  put '    Name=" " &_STUDY, Data Definitions " ' ;
  put '    Description=" " &_STUDY, Data Definitions " ' ;
  put '    def:DefineVersion="2.0.0" ;
  put '    def:StandardName="ADaM-IG" ;
  put '    def:StandardVersion="1.0">' ;
run ;
```

Approach to Reduction in Workload Using SAS and Excel

➤ ADaM Define.xml (excerpt)

```
<?xml-stylesheet type="text/xsl" href="define2-0-0_MOD.xsl"?>
<ODM xmlns="http://www.cdisc.org/ns/odm/v1.3"
  xmlns:def="http://www.cdisc.org/ns/def/v2.0"
  xmlns:xlink="http://www.w3.org/1999/xlink"
  xmlns:adamref="http://www.cdisc.org/ns/ADaMRes/DRAFT"
  ODMVersion="1.3.2"
  FileOID="XXX/YYY-Define-XML_2.0.0"
  FileType="Snapshot"
  CreationDateTime="2014-06-23T11:40:16"
  Originator="CDISC ADaM Metadata Team">
<Study OID="XXX/YYY">
  <GlobalVariables>
    <StudyName>XXX/YYY</StudyName>
    <StudyDescription>XXX/YYY Data Definition</StudyDescription>
    <ProtocolName>XXX/YYY</ProtocolName>
  </GlobalVariables>
  <MetaDataVersion OID="MDV.XXX/YYY.ADaMIG.1.0.ADaM.2.1"
    Name="XXX/YYY, Data Definitions"
    Description="XXX/YYY, Data Definitions"
    def:DefineVersion="2.0.0"
    def:StandardName="ADaM-IG"
    def:StandardVersion="1.0">
```

Approach to Reduction in Workload Using SAS and Excel

- Creation of analysis reports (demographic data)
- "SUMMARY" sheet ("AE" sheet creates AE summary table)

Item	Dataset	Variable	Label	Display Format	Codelist	Value	MVNAME			
Treatment Group	ADSL	TRT01PN	Planned Treatment (N)	1.0	TRTN		TRT			
Selection Criteria 1	ADSL	FASFL	Full Analysis Set Population Flag	\$10.	NY	"Y"	SELECT1			
Selection Criteria 2							SELECT2			
Selection Criteria 3							SELECT3			
Analysis variable 1	ADSL	AGE	Age	3.0			VAR1			
Analysis variable 2	ADSL	SEX	Sex	\$1.	SEX		VAR2			
Analysis variable 3	ADSL	RACEN	Race (N)	1.0	RACEN		VAR3			
Analysis variable 4							VAR4			
Analysis variable 5							VAR5			
Summary Statistics						N MEAN STDDEV MIN MEDIAN MAX	STAT			
Title 1						Table 1.1	TITLE1			
Title 2						Demographic and Baseline Characteristics	TITLE2			
Title 3							TITLE3			
								TRUE	<input checked="" type="checkbox"/> N	N
								TRUE	<input checked="" type="checkbox"/> Mean	MEAN
								TRUE	<input checked="" type="checkbox"/> SD	STDDEV
								TRUE	<input checked="" type="checkbox"/> Min	MIN
								FALSE	<input type="checkbox"/> Q1	
								TRUE	<input checked="" type="checkbox"/> Median	MEDIAN
								FALSE	<input type="checkbox"/> Q3	
								TRUE	<input checked="" type="checkbox"/> Max	MAX

VBA

demog_table.sas

Table 1.1
Demographic and Baseline Characteristics

Variable		Statistics /Categories	Drug A		Drug B		Total
Age	N		145		133		278
	Mean		58.5		56.7		57.6
	SD		13.5		12.9		13.2
	Min		22		28		22
	Median		59.0		58.0		59.0
	Max		88		84		88
Sex	Female		44 (30.3)		42 (31.6)		86 (30.9)
	Male		101 (69.7)		91 (68.4)		192 (69.1)
Race (N)		ASIAN	145 (100.0)		133 (100.0)		278 (100.0)

Approach to Reduction in Workload Using SAS and Excel

- Execution of OpenCDISC Validator
- "Validation" sheet
 - Run the SAS program which executes the OpenCDISC Validator

Item	Value		MVNAME
Source data path	C:\Temp\SUGI_2014\Data	参照	_SOURCE
OpenCDISC path	C:\Temp\SUGI_2014\OpenCDISC\1.5\opencdisc-validator	参照	_OPENCDISCPATH
jar file name	C:\Temp\SUGI_2014\OpenCDISC\1.5\opencdisc-validator\lib\validator-cli-1.5.jar	参照	_JAR
data files	*.xpt		_FILES
Config file	C:\Temp\SUGI_2014\OpenCDISC\1.5\opencdisc-validator\config\config-adam-1.0.xml	参照	_CONFIG
Define-XML	Y		_DEFINE

実行

VBA

demog_table.sas

OpenCDISC Validator Report							
Configuration: C:\Temp\SUGI_2014\OpenCDISC\1.5\opencdisc-validator\config\config-adam-1.0.xml							
Define.xml: Not provided							
Generated: 2014-06-23T19:08:33							
Engine Version: 1.5							
Processed Sources							
Domain	Label	Class	Source	Records	Errors	Warnings	Notices
GLOBAL	Global Metadata	--	--	--	0	0	0
ADAE	Basic Data Structure	Basic Data Structure	adae.xpt	55	3	1	2
		Basic Data Structure	adef.xpt	852	0	0	1
ADSL	Subject-Level Analysis	Subject-Level Analysis	adsl.xpt	300	4	0	8
Total				1207	7	1	11
Unprocessed Sources							
Domain	Label	Class	Reason		Errors	Warnings	Notices
Total					0	0	0
Grand Total					1207	7	11

DEMO
If time permitted..

Summary

- Submission of electronic data from clinical trials will be mandatory in 2016FY in Japan.
- Pharmaceutical companies will need to create and submit the CDISC compliant data (SDTM, ADaM and their Define.xml etc.) to PMDA for NDA.
- In order to manage the ADaM datasets efficiently, using Excel Metadata is one of the good solution.
- With basic functionalities of SAS and Excel VBA, the workload of ADaM standard such as creation of Define.xml and analysis reports and validation of ADaM datasets can be reduced.

References

- FDA Study Data Standards Resources
<http://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm>
- FDA (2014). STUDY DATA TECHNICAL CONFORMANCE GUIDE (DRAFT)
<http://www.fda.gov/downloads/ForIndustry/DataStandards/StudyDataStandards/UCM384744.pdf>
- PMDA 次世代審査・相談体制について(申請時電子データ提出)
<http://www.pmda.go.jp/operations/shonin/info/iyaku/jisedai.html>
- PMDA(2014)薬食審査発第0620第6号通知「承認申請時の電子データ提出に関する基本的考え方について」
<http://www.pmda.go.jp/operations/shonin/info/iyaku/jisedai/file/140620-tsuchi.pdf>
- CDISC <http://www.cdisc.org/>
- Chris Holland, Jack Shostak (2012). Implementing CDISC Using SAS: An End-to-End Guide. Sas Inst
- 高浪 洋平(2013). Simple Tool for Creating ADaM Define.xml for Statisticians in Pharmaceutical Companies Using SAS and HTML Application with Excel Metadata File. CDISC 2013 Japan Interchange
- 森岡 裕(2013)「ライブラリ参照と名前定義を利用してEXCELファイルへの柔軟な入出力を実現する方法と応用例の提案—解析結果のレポートティングからセルオートマトンまで—」SASユーザー総会2013
- 高浪 洋平, 舟尾 暢男(2012)「統計解析ソフト『SAS』」工学社
- OpenCDISC Validator <http://www.opencdisc.org/>

Thank you for your attention

