

PHUSE SDE Zurich 2023

Evolving SDTM and TFL Programming Using Automation

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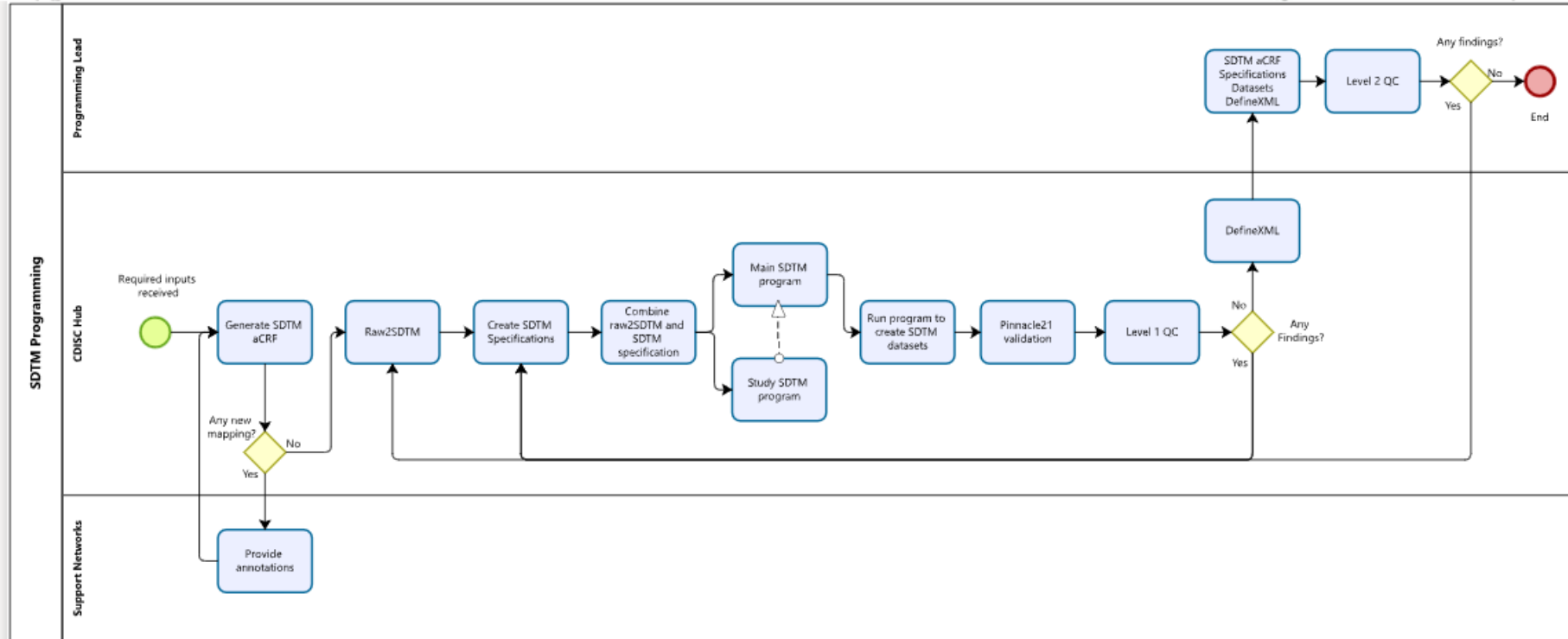


| Introduction and Contents

- Introduction and Contents
- SDTM Automation – What is MAPIT?
- MAPIT Adaptability
- MAPIT Next Steps
- Table Automation – What is REPIT?
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- REPIT Next Steps
- Conclusion
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SDTM Automation – What is MAPIT?



| SDTM Automation – What is MAPIT?



- MAPIT automation tool generates SDTM domain datasets, aCRF, Specifications, SAS code and Define.xml
- Focus on metadata driven processes
- Library repository to re-use metadata from prior studies
- Benefits – standardization, consistency (client and industry standards), improves quality
- aCRF, RAW2SDTM mapping, SDTM Specifications, SDTM Production autocode and define.xml



aCRF



Version_V2.00_14NOV2022: Unique
Form: Medical History (MH)
Generated On: 2022 Nov 14 13:28
Version: XXXXXXXXXX

Has the Subject experienced any past and/or concomitant diseases? No ☐ 2
Yes ☐

Medical history term 3
Start date Fixed Unit: yyyy mon dd 4

End date Fixed Unit: yyyy mon dd 5

Ongoing (at the time of enrollment) No ☐ 6
Yes ☐

Any current medication No ☐ 7
Yes ☐

Version_V2.00_14NOV2022: Unique
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Version: XXXXXXXXXX

Has the Subject experienced any past and/or concomitant diseases? No ☐
Yes ☐

Medical history term
Start date Fixed Unit: yyyy mon dd

End date Fixed Unit: yyyy mon dd

Ongoing (at the time of enrollment) No ☐
Yes ☐

Any current medication No ☐
Yes ☐



aCRF

DESCRIP	MEMNAME	DOMAIN	ANNOT	VERSION
Qualifying Header 3	DISEXOM	MH	MHCAT="ONCOLOGY DISEASE"	
Qualifying Header 3	DISEXT	MH	MHCAT="ONCOLOGY DISEASE"	
Qualifying Header 3	HISDM	MH	MHCAT="DIABETES HISTORY"	
Qualifying Header 3	HISM	MH	MHCAT="GENERAL MEDICAL HISTORY"	
Qualifying Header 3	MH	MH	MHCAT="GENERAL MEDICAL HISTORY"	
Qualifying Header 3	HISS	MH	MHCAT="GENERAL SURGICAL HISTORY"	
Qualifying Header 3	PATHGEN	MH	MHSCAT="FIRST DIAGNOSIS"	
Qualifying Header 4	PATHGEN	MH	MHCAT="DIAGNOSIS OF DISEASE UNDER INVESTIGATION"	

DESCRIP	MEMNAME	NAME	DOMAIN	ANNOT	CRF_ORD	VERSION
Parent Variable	MH	HLGTCODE	MH	MHHLGTC		
Parent Variable	MH	HLGTNAME	MH	MHHLGT		
Parent Variable	MH	HLT_CODE	MH	MHHLTCD		
Parent Variable	MH	HLT_NAME	MH	MHHLT		
Parent Variable	MH	LLT_CODE	MH	MHLLTCD		
Parent Variable	MH	LLT_NAME	MH	MHLLT		
Parent Variable	MH	MHCAT	MH	MHCAT		
Parent Variable	MH	MHDAT	MH	MHDT		
Parent Variable	MH	MHENDAT	MH	MHENDT		
Parent Variable	MH	MHONGO	MH	MHENRPT		
Parent Variable	MH	MHSTDAT	MH	MHSTDTC		
Parent Variable	MH	MHTERM	MH	MHTERM		
Parent Variable	MH	MHTERM1	MH	MHTERM		
Parent Variable	MH	MHYN	MH	[NOT SUBMITTED]		
Parent Variable	MH	PT_CODE	MH	MHPTCD		
Parent Variable	MH	PT_NAME	MH	MHDECOD		
Parent Variable	MH	SOC_CODE	MH	MHBDSYCD		
Parent Variable	MH	SOC_NAME	MH	MHBODSYS		
SUPP Variable	MH	MEDDRA_V	MH	SUPPMH.QVAL when QNAM="MEDDRAV"		
SUPP Variable	MH	MHCURM	MH	SUPPMH.QVAL when QNAM="MHCURM"		
SUPP Variable	MH	MHCTRL	MH	SUPPMH.QVAL when QNAM="MHCTRL"		
SUPP Variable	MH	SOC_ABRV	MH	SUPPMH.QVAL when QNAM="SOCABRV"		
Parent Variable	MH	VIS_DAT	MH	MHENTPT		
SUPP Variable	MH	VIS_DAT	MH	SUPPMH.QVAL when QNAM="VISITDTC"		
Parent Variable	MH	Z_NOW	MH	[NOT SUBMITTED]		

```

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139 AnnotSubtype: Link
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MHCAT="GENERAL MEDICAL HISTORY"

MH = Medical History

Version_V2.00_14NOV2022: Unique

Form: Medical History (MH)

Generated On: 2022 Nov 14 13:28 SUPPMH.QVAL when QNAM="MODULE"

Version:

Has the Subject experienced any past and/ [NOT SUBMITTED] No ☐
concomitant diseases? Yes ☐

Medical history term MHTERM

Start date MHSTDTC Fixed Unit: yyyy mon dd

End date MHENDTC Fixed Unit: yyyy mon dd

Ongoing (at the time of enrollment) MHENRTPT No ☐
Yes ☐

Any current medication SUPPMH.QVAL when QNAM="MHCURM" No ☐
Yes ☐

RAW2SDTM Mapping

1	RAW TABLE	RAW COLUMN	RAW FORMAT	RAW COLUMN WHRVALUE	RAW WHRCLAUSE	SDTM TABLE	SDTM COLUMN	SDTM WHRCLAUSE	SDTM ASSIGNED VALUE	MAP COMMENT	SDTM SUPP IDVAR	SDTM SUPP QEVAL	SDTM SUPP QLABEL	SDTM SUPP QORIG
2	AE	AEACN	\$AEACN	"0"		AE	AEACN		"DOSE NOT CHANGED"					
3	AE	AEACN	\$AEACN	"2"		AE	AEACN		"DOSE REDUCED"					
4	AE	AEACN	\$AEACN	"3"		AE	AEACN		"DRUG INTERRUPTED"					
5	AE	AEACN	\$AEACN	"4"		AE	AEACN		"DRUG WITHDRAWN"					
6	AE	AEACN	\$AEACN	"98"		AE	AEACN		"NOT APPLICABLE"					
7	AE	AEACN1	\$AEACN	"0"		AE	AEACN1		"DOSE NOT CHANGED"		AESEQ	"	"Action Taken, Investigational Product 1"	"CRF"
8	AE	AEACN1	\$AEACN	"3"		AE	AEACN1		"DRUG INTERRUPTED"		AESEQ	"	"Action Taken, Investigational Product 1"	"CRF"
9	AE	AEACN1	\$AEACN	"4"		AE	AEACN1		"DRUG WITHDRAWN"		AESEQ	"	"Action Taken, Investigational Product 1"	"CRF"
10	AE	AEACN1	\$AEACN	"98"		AE	AEACN1		"NOT APPLICABLE"		AESEQ	"	"Action Taken, Investigational Product 1"	"CRF"
11	AE	AEACN2	\$AEACN	"0"		AE	AEACN2		"DOSE NOT CHANGED"		AESEQ	"	"Action Taken, Investigational Product 2"	"CRF"
12	AE	AEACN2	\$AEACN	"3"		AE	AEACN2		"DRUG INTERRUPTED"		AESEQ	"	"Action Taken, Investigational Product 2"	"CRF"
13	AE	AEACN2	\$AEACN	"4"		AE	AEACN2		"DRUG WITHDRAWN"		AESEQ	"	"Action Taken, Investigational Product 2"	"CRF"
14	AE	AEACN2	\$AEACN	"98"		AE	AEACN2		"NOT APPLICABLE"		AESEQ	"	"Action Taken, Investigational Product 2"	"CRF"
15	AE	AEACN3	\$AEACN	"0"		AE	AEACN3		"DOSE NOT CHANGED"		AESEQ	"	"Action Taken, Investigational Product 3"	"CRF"
16	AE	AEACN3	\$AEACN	"2"		AE	AEACN3		"DOSE REDUCED"		AESEQ	"	"Action Taken, Investigational Product 3"	"CRF"
17	AE	AEACN3	\$AEACN	"3"		AE	AEACN3		"DRUG INTERRUPTED"		AESEQ	"	"Action Taken, Investigational Product 3"	"CRF"
18	AE	AEACN3	\$AEACN	"4"		AE	AEACN3		"DRUG WITHDRAWN"		AESEQ	"	"Action Taken, Investigational Product 3"	"CRF"
19	AE	AEACN3	\$AEACN	"98"		AE	AEACN3		"NOT APPLICABLE"		AESEQ	"	"Action Taken, Investigational Product 3"	"CRF"
20	AE	AECD1DAT				FA	FADTC	AECD1TOX NE "						
21	AE	AECD1TOX	\$AETOXGR			AE	AECD1TOX							
22	AE	AECD1TOX	\$AETOXGR			FA	FACAT	AECD1TOX NE "	"ADVERSE EVENTS"					
23	AE	AECD1TOX	\$AETOXGR			FA	FAGRPD	AECD1TOX NE "	"2"					
24	AE	AECD1TOX	\$AETOXGR			FA	FASCAT	AECD1TOX NE "	"AE CHANGES"					
25	AE	AECD1TOX	\$AETOXGR			FA	FATEST	AECD1TOX NE "	"Toxicity Grade"					
26	AE	AECD1TOX	\$AETOXGR			FA	FATESTCD	AECD1TOX NE "	"TOXGR"					
27	AE	AECD1TOX	\$AETOXGR	"1"		FA	FAORRES	AECD1TOX NE "	"1"					
28	AE	AECD1TOX	\$AETOXGR	"1"		FA	FASTREC	AECD1TOX NE "	"1"					
29	AE	AECD1TOX	\$AETOXGR	"2"		FA	FAORRES	AECD1TOX NE "	"2"					
30	AE	AECD1TOX	\$AETOXGR	"2"		FA	FASTREC	AECD1TOX NE "	"2"					
31	AE	AECD1TOX	\$AETOXGR	"3"		FA	FAORRES	AECD1TOX NE "	"3"					
32	AE	AECD1TOX	\$AETOXGR	"3"		FA	FASTREC	AECD1TOX NE "	"3"					
33	AE	AECD1TOX	\$AETOXGR	"4"		FA	FAORRES	AECD1TOX NE "	"4"					
34	AE	AECD1TOX	\$AETOXGR	"4"		FA	FASTREC	AECD1TOX NE "	"4"					
35	AE	AECD1TOX	\$AETOXGR	"5"		FA	FAORRES	AECD1TOX NE "	"5"					
36	AE	AECD1TOX	\$AETOXGR	"5"		FA	FASTREC	AECD1TOX NE "	"5"					
37	AE	AECD2DAT				FA	FADTC	AECD2TOX NE "						
38	AE	AECD2TOX	\$AETOXGR			AE	AECD2TOX							

RAW2SDTM Mapping

RAW_TABLE	RAW_COLUMN	RAW_LABEL	RAW_FORMAT	RAW_CODE	RAW_WHERECLAUSE	SDTM_TABLE	SDTM_COLUMN	SDTM_WHERECLAUSE	SDTM_ASSIGNED_VALUE
AE	AEACN	Action Taken, Investigational Pro	\$AEACN.	"0"		AE	AEACN		"DOSE NOT CHANGED"
AE	AEACN	Action Taken, Investigational Pro	\$AEACN.	"2"		AE	AEACN		"DOSE REDUCED"
AE	AEACN	Action Taken, Investigational Pro	\$AEACN.	"3"		AE	AEACN		"DRUG INTERRUPTED"
AE	AEACN	Action Taken, Investigational Pro	\$AEACN.	"4"		AE	AEACN		"DRUG WITHDRAWN"
AE	AEACN	Action Taken, Investigational Pro	\$AEACN.	"98"		AE	AEACN		"NOT APPLICABLE"
AE	AEACN1	Action Taken, Investigational Pro	\$AEACN.	"0"		AE	AEACN1		"DOSE NOT CHANGED"
AE	AEACN1	Action Taken, Investigational Pro	\$AEACN.	"3"		AE	AEACN1		"DRUG INTERRUPTED"
AE	AEACN1	Action Taken, Investigational Pro	\$AEACN.	"4"		AE	AEACN1		"DRUG WITHDRAWN"
AE	AEACN1	Action Taken, Investigational Pro	\$AEACN.	"98"		AE	AEACN1		"NOT APPLICABLE"
AE	AEACN2	Action Taken, Investigational Pro	\$AEACN.	"0"		AE	AEACN2		"DOSE NOT CHANGED"
AE	AEACN2	Action Taken, Investigational Pro	\$AEACN.	"3"		AE	AEACN2		"DRUG INTERRUPTED"
AE	AEACN2	Action Taken, Investigational Pro	\$AEACN.	"4"		AE	AEACN2		"DRUG WITHDRAWN"
AE	AEACN2	Action Taken, Investigational Pro	\$AEACN.	"98"		AE	AEACN2		"NOT APPLICABLE"
AE	AEACN3	Action Taken, Investigational Pro	\$AEACN.	"0"		AE	AEACN3		"DOSE NOT CHANGED"
AE	AEACN3	Action Taken, Investigational Pro	\$AEACN.	"2"		AE	AEACN3		"DOSE REDUCED"
AE	AEACN3	Action Taken, Investigational Pro	\$AEACN.	"3"		AE	AEACN3		"DRUG INTERRUPTED"
AE	AEACN3	Action Taken, Investigational Pro	\$AEACN.	"4"		AE	AEACN3		"DRUG WITHDRAWN"
AE	AEACN3	Action Taken, Investigational Pro	\$AEACN.	"98"		AE	AEACN3		"NOT APPLICABLE"
AE	AEC01DAT	AE Change Date				FA	FADTC	AEC01TOX NE ""	
AE	AEC01TOX	CTCAE Grade	\$AETOXGR.			AE	AEC01TOX		
AE	AEC01TOX	CTCAE Grade	\$AETOXGR.			FA	FACAT	AEC01TOX NE ""	"ADVERSE EVENTS"
AE	AEC01TOX	CTCAE Grade	\$AETOXGR.			FA	FAGRPID	AEC01TOX NE ""	"2"
AE	AEC01TOX	CTCAE Grade	\$AETOXGR.			FA	FASCAT	AEC01TOX NE ""	"AE CHANGES"
AE	AEC01TOX	CTCAE Grade	\$AETOXGR.			FA	FATEST	AEC01TOX NE ""	"Toxicity Grade"
AE	AEC01TOX	CTCAE Grade	\$AETOXGR.			FA	FATESTCD	AEC01TOX NE ""	"TOXGR"
AE	AEC01TOX	CTCAE Grade	\$AETOXGR.	"1"		FA	FAORRES	AEC01TOX NE ""	"1"
AE	AEC01TOX	CTCAE Grade	\$AETOXGR.	"1"		FA	FASTRESC	AEC01TOX NE ""	"1"
AE	AEC01TOX	CTCAE Grade	\$AETOXGR.	"2"		FA	FAORRES	AEC01TOX NE ""	"2"
AE	AEC01TOX	CTCAE Grade	\$AETOXGR.	"2"		FA	FASTRESC	AEC01TOX NE ""	"2"
AE	AEC01TOX	CTCAE Grade	\$AETOXGR.	"3"		FA	FAORRES	AEC01TOX NE ""	"3"
AE	AEC01TOX	CTCAE Grade	\$AETOXGR.	"3"		FA	FASTRESC	AEC01TOX NE ""	"3"
AE	AEC01TOX	CTCAE Grade	\$AETOXGR.	"4"		FA	FAORRES	AEC01TOX NE ""	"4"
AE	AEC01TOX	CTCAE Grade	\$AETOXGR.	"4"		FA	FASTRESC	AEC01TOX NE ""	"4"
AE	AEC01TOX	CTCAE Grade	\$AETOXGR.	"5"		FA	FAORRES	AEC01TOX NE ""	"5"
AE	AEC01TOX	CTCAE Grade	\$AETOXGR.	"5"		FA	FASTRESC	AEC01TOX NE ""	"5"
AE	AEC02DAT	AE Change Date				FA	FADTC	AEC02TOX NE ""	
AE	AEC02TOX	CTCAE Grade	\$AETOXGR.			AE	AEC02TOX		

RAW2SDTM Mapping

RAW_TABLE	RAW_COLUMN	RAW_TYPE	RAW_LENGTH	RAW_LABEL	RAW_FORMAT	RAW_CODE	RAW_WHERECLAUSE	SDTM_TABLE	SDTM_COLUMN	SDTM_WHERECLAUSE
AE	AEC10TOX	C	2	CTCAE Grade	\$AETOXGR.	"3"				
AE	AEC10TOX	C	2	CTCAE Grade	\$AETOXGR.	"4"				
AE	AEC10TOX	C	2	CTCAE Grade	\$AETOXGR.	"5"				
AE	AECAT	C	2	Category for Adverse Events	\$AESPL.		AECATOCC NE "C49488"	AE	AECAT	
AE	AFCAT	C	2	Category for Adverse Events	\$AESPL.	"2"	AECATOCC = "C49488"	AE	AECAT	
AE	AECATOCC	C	6	AE Category Occurrence	\$NY.	"C49487"				
AE	AECATOCC	C	6	AE Category Occurrence	\$NY.	"C49488"				
AE	AECAT	C	2	Category for Adverse Events	\$AESPL.	"3"	AECATOCC = "C49488"	AE	AECAT	
AE	AECAT	C	2	Category for Adverse Events	\$AESPL.	"4"	AECATOCC = "C49488"	AE	AECAT	
AE	AECAT	C	2	Category for Adverse Events	\$AESPL.	"5"	AECATOCC = "C49488"	AE	AECAT	
AE	AECAT	C	2	Category for Adverse Events	\$AESPL.	"6"	AECATOCC = "C49488"	AE	AECAT	
AE	AECAT	C	2	Category for Adverse Events	\$AESPL.	"7"	AECATOCC = "C49488"	AE	AECAT	
AE	AECAT	C	2	Category for Adverse Events	\$AESPL.	"9"	AECATOCC = "C49488"	AE	AECAT	
AE	AECAT	C	2	Category for Adverse Events	\$AESPL.	"10"	AECATOCC = "C49488"	AE	AECAT	
AE	AECAT	C	2	Category for Adverse Events	\$AESPL.	"11"	AECATOCC = "C49488"	AE	AECAT	
AE	AECAT	C	2	Category for Adverse Events	\$AESPL.	"12"	AECATOCC = "C49488"	AE	AECAT	
AE	AECAT	C	2	Category for Adverse Events	\$AESPL.	"16"	AECATOCC = "C49488"	AE	AECAT	
AE	AECAT	C	2	Category for Adverse Events	\$AESPL.	"17"	AECATOCC = "C49488"	AE	AECAT	
AE	AECAT	C	2	Category for Adverse Events	\$AESPL.	"19"	AECATOCC = "C49488"	AE	AECAT	
AE	AECAT	C	2	Category for Adverse Events	\$AESPL.	"20"	AECATOCC = "C49488"	AE	AECAT	
AE	AECAT	C	2	Category for Adverse Events	\$AESPL.	"99"	AECATOCC = "C49488"	AE	AECAT	
AE	AECONTRT	C	6	Concomitant or Additional Trtmt	\$NY.	"C49487"		AE	AECONTRT	
AE	AECONTRT	C	6	Concomitant or Additional Trtmt	\$NY.	"C49488"		AE	AECONTRT	
AE	AEENDAT	C		Adverse Event End Date				AE	AEENDTC	
AE	AENO	N	8	AE Number				AE	AESPID	
AE	AENO	N	8	AE Number				FA	FASPID	AEC01TOX NE ""
AE	AENO	N	8	AE Number				FA	FASPID	AEC02TOX NE ""
AE	AENO	N	8	AE Number				FA	FASPID	AEC01TOX NE "" AND AETOXGR NE ""
AE	AEOUT	C	6	Outcome of Adverse Event	\$OUT.	"C48275"		AE	AEOUT	
AE	AEOUT	C	6	Outcome of Adverse Event	\$OUT.	"C49494"		AE	AEOUT	

SDTM Specifications

1	AE	Adverse Events	STUDYID,USUBJID,AESTDTC,AEDECOD, AESPID	One record per adverse event per subject					
2	Variable	Label	Data Type	Length	Controlled Terms or Format	Origin	CRF Pages	Derivation	Comment
3	STUDYID	Study Identifier	text	21		Protocol			
4	DOMAIN	Domain Abbreviation	text	8	AE DOMAIN	Assigned			
5	USUBJID	Unique Subject Identifier	text	30		Derived		USUBJID	
6	AESQ	Sequence Number	integer	8		Derived		SEQ	
7	AESPID	Sponsor-Defined Identifier	text	40		CRF	430 444		
8	AETERM	Reported Term for the Adverse Event	text	200		CRF	430 444		
9	AELLT	Lowest Level Term	text	200	MedDRA	CRF			
10	AELLTCD	Lowest Level Term Code	integer	8	MedDRA	CRF			
11	AEDECOD	Dictionary-Derived Term	text	200	MEDDRA	Assigned			
12	AEPTCD	Preferred Term Code	integer	8	MedDRA	CRF			
13	AEHLT	High Level Term	text	200	MedDRA	CRF			
14	AEHLTCD	High Level Term Code	integer	8	MedDRA	CRF			
15	AEHLGT	High Level Group Term	text	200	MedDRA	CRF			
16	AEHLGTCD	High Level Group Term Code	integer	8	MedDRA	CRF			
17	AECAT	Category for Adverse Event	text	200	AECAT	CRF			
18	AEBODSYS	Body System or Organ Class	text	200		CRF			
19	AEBDSYCD	Body System or Organ Class Code	integer	8	MedDRA	CRF			
20	AESOC	Primary System Organ Class	text	200	MedDRA	CRF			
21	AESOCDD	Primary System Organ Class Code	integer	8	MedDRA	CRF			
22	AESER	Serious Event	text	1	NY	CRF	430		

Variables

Variables_SUPP

ValueLevel

Codelists

Derivations

Comments



SDTM Specifications

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O
1	Order	Dataset	Variable	Where	Comparator	Value	Label	Data Type	Length	Controlled Terms or Format	Origin	CRF Pages	Derivation	Value Level Comment	Join Comment
2	1	SUPPAE	QVAL	QNAM	EQ	AEACN1	Action Taken, Investigational Product 1	text	200	AEACN1	CRF	430			
3	2	SUPPAE	QVAL	QNAM	EQ	AEACN2	Action Taken, Investigational Product 2	text	200	AEACN1	CRF	431			
4	3	SUPPAE	QVAL	QNAM	EQ	AEACN3	Action Taken, Investigational Product 3	text	200	AEACN	CRF	431			
5	4	SUPPAE	QVAL	QNAM	EQ	AEDESC01	AE Description 01	text	200		CRF	445			
6	5	SUPPAE	QVAL	QNAM	EQ	AEDESC02	AE Description 02	text	200		CRF	445			
7	6	SUPPAE	QVAL	QNAM	EQ	AEDESC03	AE Description 03	text	200		CRF	445			
8	7	SUPPAE	QVAL	QNAM	EQ	AEDESC04	AE Description 04	text	200		CRF	445			
9	8	SUPPAE	QVAL	QNAM	EQ	AEDESC05	AE Description 05	text	200		CRF	445			
10	9	SUPPAE	QVAL	QNAM	EQ	AEDESC06	AE Description 06	text	200		CRF	445			
11	10	SUPPAE	QVAL	QNAM	EQ	AEDESC07	AE Description 07	text	200		CRF	445			
12	11	SUPPAE	QVAL	QNAM	EQ	AEDESC08	AE Description 08	text	200		CRF	445			
13	12	SUPPAE	QVAL	QNAM	EQ	AEDESC09	AE Description 09	text	200		CRF	445			
14	13	SUPPAE	QVAL	QNAM	EQ	AEDESC10	AE Description 10	text	200		CRF	445			
15	14	SUPPAE	QVAL	QNAM	EQ	AEREL1	Causality to IP 1	text	200		CRF	431			
16	15	SUPPAE	QVAL	QNAM	EQ	AEREL2	Causality to IP 2	text	200		CRF	431			
17	16	SUPPAE	QVAL	QNAM	EQ	AEREL3	Causality to IP 3	text	200		CRF	431			
18	17	SUPPAE	QVAL	QNAM	EQ	AESMED	Other Medication	text	200		CRF	445			
19	18	SUPPAE	QVAL	QNAM	EQ	AETRTEM	Treatment Emergent Flag	text	1	NY	Derived		AETRTEM		
20	19	SUPPAE	QVAL	QNAM	EQ	CTC	CTC Version	text	200		CRF	430			
21	20	SUPPAE	QVAL	QNAM	EQ	IP	Investigational Product	text	200		CRF	430			
22	21	SUPPAE	QVAL	QNAM	EQ	IP1	Investigational Product 1	text	200		CRF	430			
23	22	SUPPAE	QVAL	QNAM	EQ	IP2	Investigational Product 2	text	200		CRF	431			
24	23	SUPPAE	QVAL	QNAM	EQ	IP3	Investigational Product 3	text	200		CRF	431			
25	24	SUPPAE	QVAL	QNAM	EQ	MEDDRAV	MedDRA Version	text	200		eDT				
26	25	SUPPAE	QVAL	QNAM	EQ	MODULE	Source Module Short Name	text	200		CRF	430 431			
27	26	SUPPAE	QVAL	QNAM	EQ	SAECAUSP	SAE Caused by Study Procedure(s)	text	1	NY	CRF	445			
28	27	SUPPAE	QVAL	QNAM	EQ	SAEDIDTC	Date of Discharge	datetime			CRF	444			
29	28	SUPPAE	QVAL	QNAM	EQ	SAEDTC	Date/Time AE Met Criteria for Serious AE	datetime			CRF	444			
30	29	SUPPAE	QVAL	QNAM	EQ	SAEHODTC	Date of Hospitalization	datetime			CRF	444			
31	30	SUPPAE	QVAL	QNAM	EQ	SAEIANTC	Date Investigator Aware of Serious AE	datetime			CRF	444			

SDTM Specifications



	A	B	C	D	E	F	G	H
	ID	Name	NCI Codelist Code	Data Type	Order	Term	NCI Term Code	Decoded Value
2	AEACN	Action Taken with Study Treatment	C66767	text	1	DOSE NOT CHANGED	C49504	
3	AEACN	Action Taken with Study Treatment	C66767	text	2	DOSE REDUCED	C49505	
4	AEACN	Action Taken with Study Treatment	C66767	text	3	DRUG INTERRUPTED	C49501	
5	AEACN	Action Taken with Study Treatment	C66767	text	4	DRUG WITHDRAWN	C49502	
6	AEACN	Action Taken with Study Treatment	C66767	text	5	NOT APPLICABLE	C48660	
7	AEACN1	Action Taken with Study Treatment	C66767	text	1	DOSE NOT CHANGED	C49504	
8	AEACN1	Action Taken with Study Treatment	C66767	text	2	DRUG INTERRUPTED	C49501	
9	AEACN1	Action Taken with Study Treatment	C66767	text	3	DRUG WITHDRAWN	C49502	
10	AEACN1	Action Taken with Study Treatment	C66767	text	4	NOT APPLICABLE	C48660	
11	AEACN2	Action Taken with Study Treatment	C66767	text	1	DOSE NOT CHANGED	C49504	
12	AEACN2	Action Taken with Study Treatment	C66767	text	2	DRUG INTERRUPTED	C49501	
13	AEACN2	Action Taken with Study Treatment	C66767	text	3	DRUG WITHDRAWN	C49502	
14	AEACN2	Action Taken with Study Treatment	C66767	text	4	NOT APPLICABLE	C48660	
15	AEACN3	Action Taken with Study Treatment	C66767	text	1	DOSE NOT CHANGED	C49504	
16	AEACN3	Action Taken with Study Treatment	C66767	text	2	DOSE REDUCED	C49505	
17	AEACN3	Action Taken with Study Treatment	C66767	text	3	DRUG INTERRUPTED	C49501	
18	AEACN3	Action Taken with Study Treatment	C66767	text	4	DRUG WITHDRAWN	C49502	
19	AEACN3	Action Taken with Study Treatment	C66767	text	5	NOT APPLICABLE	C48660	
20	AEOUT	Outcome of Event	C66768	text	1	FATAL	C48275	
21	AEOUT	Outcome of Event	C66768	text	2	NOT RECOVERED/NOT RESOLVED	C49494	
22	AEOUT	Outcome of Event	C66768	text	3	RECOVERED/RESOLVED WITH SEQUELAE	C49495	
23	AEOUT	Outcome of Event	C66768	text	4	RECOVERING/RESOLVING	C49496	
24	AEOUT	Outcome of Event	C66768	text	5	RECOVERED/RESOLVED	C49498	
25	AEREL	Causality		text	1	UNLIKELY AE CAUSED BY IP		
26	AEREL	Causality		text	2	REASONABLE POSSIBILITY AE CAUSED BY IP		
27	AEREL1	Causality		text	1	UNLIKELY AE CAUSED BY IP 1		
28	AEREL1	Causality		text	2	REASONABLE POSSIBILITY AE CAUSED BY IP 1		
29	AEREL2	Causality		text	1	UNLIKELY AE CAUSED BY IP 2		
30	AEREL2	Causality		text	2	REASONABLE POSSIBILITY AE CAUSED BY IP 2		
31	AEREL3	Causality		text	1	UNLIKELY AE CAUSED BY IP 3		

Variables Variables_SUPP ValueLevel **Codlists** Derivations Comments +



SDTM Production Autocode

```
*****;  
** Create empty template dataset to set attributes of the variables. **;  
** Information coming from spec. **;  
*****;  
  
data templ_AE;  
  attrib  
    s __STUDYID length=$21 label="Study Identifier"  
    s __DOMAIN length=$8 label="Domain Abbreviation"  
    s __USUBJID length=$30 label="Unique Subject Identifier"  
    s __AESEQ length=8 label="Sequence Number"  
    s __AESPID length=$40 label="Sponsor-Defined Identifier"  
    s __AETERM length=$200 label="Reported Term for the Adverse Event"  
    s __AELLT length=$200 label="Lowest Level Term"  
    s __AELLTCD length=8 label="Lowest Level Term Code"  
    s __AEDECOD length=$200 label="Dictionary-Derived Term"  
    s __AEPTCD length=8 label="Preferred Term Code"  
    s __AEHLT length=$200 label="High Level Term"  
    s __AEHLTCD length=8 label="High Level Term Code"  
    s __AEHLGT length=$200 label="High Level Group Term"  
    s __AEHLGTCD length=8 label="High Level Group Term Code"  
    s __AECAT length=$200 label="Category for Adverse Event"  
    s __AEBODSYS length=$200 label="Body System or Organ Class"  
    s __AEBDSYCD length=8 label="Body System or Organ Class Code"  
    s __AESOC length=$200 label="Primary System Organ Class"
```

SDTM Production Autocode

```
data AE_AE(keep=s__);
  set AE_AE_set;

  *** RAW column =AEACN ***;
  if AEACN= "0" then do;
    S__AEACN = "DOSE NOT CHANGED";
  end;
  if AEACN= "2" then do;
    S__AEACN = "DOSE REDUCED";
  end;
  if AEACN= "3" then do;
    S__AEACN = "DRUG INTERRUPTED";
  end;
  if AEACN= "4" then do;
    S__AEACN = "DRUG WITHDRAWN";
  end;
  if AEACN= "98" then do;
    S__AEACN = "NOT APPLICABLE";
  end;

  *** RAW column =AEACN1 ***;
  if AEACN1= "0" then do;
    length S__AEACN1 $200;
    S__AEACN1 = "DOSE NOT CHANGED";
  end;
  if AEACN1= "3" then do;
    S__AEACN1 = "DRUG INTERRUPTED";
```

RAW_COLUMN	RAW_LABEL	RAW_FORMAT	RAW_COLUMN
AEACN	Action Taken, Investigational Pro	\$AEACN.	"0"
AEACN	Action Taken, Investigational Pro	\$AEACN.	"2"
AEACN	Action Taken, Investigational Pro	\$AEACN.	"3"
AEACN	Action Taken, Investigational Pro	\$AEACN.	"4"
AEACN	Action Taken, Investigational Pro	\$AEACN.	"98"
AEACN1	Action Taken, Investigational Pro	\$AEACN.	"0"
AEACN1	Action Taken, Investigational Pro	\$AEACN.	"3"
AEACN1	Action Taken, Investigational Pro	\$AEACN.	"4"
AEACN1	Action Taken, Investigational Pro	\$AEACN.	"98"
AEACN2	Action Taken, Investigational Pro	\$AEACN.	"0"
AEACN2	Action Taken, Investigational Pro	\$AEACN.	"3"
AEACN2	Action Taken, Investigational Pro	\$AEACN.	"4"
AEACN2	Action Taken, Investigational Pro	\$AEACN.	"98"
AEACN3	Action Taken, Investigational Pro	\$AEACN.	"0"
AEACN3	Action Taken, Investigational Pro	\$AEACN.	"2"
AEACN3	Action Taken, Investigational Pro	\$AEACN.	"3"
AEACN3	Action Taken, Investigational Pro	\$AEACN.	"4"
AEACN3	Action Taken, Investigational Pro	\$AEACN.	"98"

SDTM_TABLE	SDTM_COLUMN	SDTM_WHERECLAUSE	SDTM_ASSIGNED_VALUE
AE	AEACN		"DOSE NOT CHANGED"
AE	AEACN		"DOSE REDUCED"
AE	AEACN		"DRUG INTERRUPTED"
AE	AEACN		"DRUG WITHDRAWN"
AE	AEACN		"NOT APPLICABLE"
AE	AEACN1		"DOSE NOT CHANGED"
AE	AEACN1		"DRUG INTERRUPTED"
AE	AEACN1		"DRUG WITHDRAWN"
AE	AEACN1		"NOT APPLICABLE"
AE	AEACN2		"DOSE NOT CHANGED"
AE	AEACN2		"DRUG INTERRUPTED"
AE	AEACN2		"DRUG WITHDRAWN"
AE	AEACN2		"NOT APPLICABLE"
AE	AEACN3		"DOSE NOT CHANGED"
AE	AEACN3		"DOSE REDUCED"
AE	AEACN3		"DRUG INTERRUPTED"
AE	AEACN3		"DRUG WITHDRAWN"
EA	EADTC	AEAC01TOX NE ""	"NOT APPLICABLE"

SDTM Production Autocode

```

*** RAW column =AECAT ***;
if AECATOCC = "C49488" and AECAT= "2" then do;
  S__AECAT = "POTENTIAL ENDOCRINOPATHIES";
end;
if AECATOCC = "C49488" and AECAT= "3" then do;
  S__AECAT = "POTENTIAL HEPATIC EVENTS";
end;
if AECATOCC = "C49488" and AECAT= "4" then do;
  S__AECAT = "POTENTIAL NEPHRITIS OR RENAL DYSFUNCTION";
end;
if AECATOCC = "C49488" and AECAT= "5" then do;
  S__AECAT = "POTENTIAL NEUROPATHY/NEURO-MUSCULAR TOXICITY";
end;
if AECATOCC = "C49488" and AECAT= "6" then do;
  S__AECAT = "POTENTIAL PANCREATITIS";
end;
if AECATOCC = "C49488" and AECAT= "7" then do;
  S__AECAT = "POTENTIAL RASH OR DERMATITIS";
end;
if AECATOCC = "C49488" and AECAT= "9" then do;
  S__AECAT = "POTENTIAL GI TOXICITY";
end;
if AECATOCC = "C49488" and AECAT= "10" then do;
  S__AECAT = "POTENTIAL MYOSITIS/POLYMYOSITIS";
end;
if AECATOCC = "C49488" and AECAT= "11" then do;
  S__AECAT = "POTENTIAL MYOCARDITIS";
end;

```

Category for Adverse Events	SAESPI	AE	AECATOCC = "C49488"	AE	AECAT
AE Category Occurrence	\$NY.	"C49487"			
AE Category Occurrence	\$NY.	"C49488"			
Category for Adverse Events	\$AESPI.	"3"	AECATOCC = "C49488"	AE	AECAT
Category for Adverse Events	\$AESPI.	"4"	AECATOCC = "C49488"	AE	AECAT
Category for Adverse Events	\$AESPI.	"5"	AECATOCC = "C49488"	AE	AECAT
Category for Adverse Events	\$AESPI.	"6"	AECATOCC = "C49488"	AE	AECAT
Category for Adverse Events	\$AESPI.	"7"	AECATOCC = "C49488"	AE	AECAT
Category for Adverse Events	\$AESPI.	"9"	AECATOCC = "C49488"	AE	AECAT
Category for Adverse Events	\$AESPI.	"10"	AECATOCC = "C49488"	AE	AECAT
Category for Adverse Events	\$AESPI.	"11"	AECATOCC = "C49488"	AE	AECAT
Category for Adverse Events	\$AESPI.	"12"	AECATOCC = "C49488"	AE	AECAT
Category for Adverse Events	\$AESPI.	"16"	AECATOCC = "C49488"	AE	AECAT
Category for Adverse Events	\$AESPI.	"17"	AECATOCC = "C49488"	AE	AECAT
Category for Adverse Events	\$AESPI.	"19"	AECATOCC = "C49488"	AE	AECAT
Category for Adverse Events	\$AESPI.	"20"	AECATOCC = "C49488"	AE	AECAT
Category for Adverse Events	\$AESPI.	"99"	AECATOCC = "C49488"	AE	AECAT

SDTM Production Autocode

```
proc sort data=sdtm.dm out=dm (keep=studyid usubjid rfstdtc);  
  by studyid usubjid;  
run;
```

```
proc sort data=AE_AE_1;  
  by studyid usubjid;  
run;
```

```
data AE_AE_2;  
  merge AE_AE_1 (in=one) dm;  
  by studyid usubjid;  
  if one;  
  domain="AE";  
  if length(rfstdtc) >= 10 then do;  
    rfstdtn=input(substr(rfstdtc,1,10), yymmdd10.);  
    ** Code to generate study day from DTC variable **;  
    if length(AEENDTC) >= 10 then do;  
      AEENDTCN=input(substr(AEENDTC,1,10), yymmdd10.);  
      AEENDY=AEENDTCN - rfstdtn + (AEENDTCN >= rfstdtn);  
    end;  
    ** Code to generate study day from DTC variable **;  
    if length(AESTDTC) >= 10 then do;  
      AESTDTCN=input(substr(AESTDTC,1,10), yymmdd10.);  
      AESTDY=AESTDTCN - rfstdtn + (AESTDTCN >= rfstdtn);  
    end;  
  end;  
run;
```

```
*****;  
** Create derived variables that can be created. **;  
*****;
```

```
data AE_AE_1;  
  set AE_AE_ren;  
  usubjid=strip(studyid) || "/" || strip(subjid);  
run;
```

```
*****;  
** P21 call. **;  
*****;  
  
%p21_validate(study=&proj., model=SDTM, domain=ae, print_details=Y);  
  
*****;  
** Log Check code. **;  
*****;  
  
%checklog;
```

SDTM Production Autocode

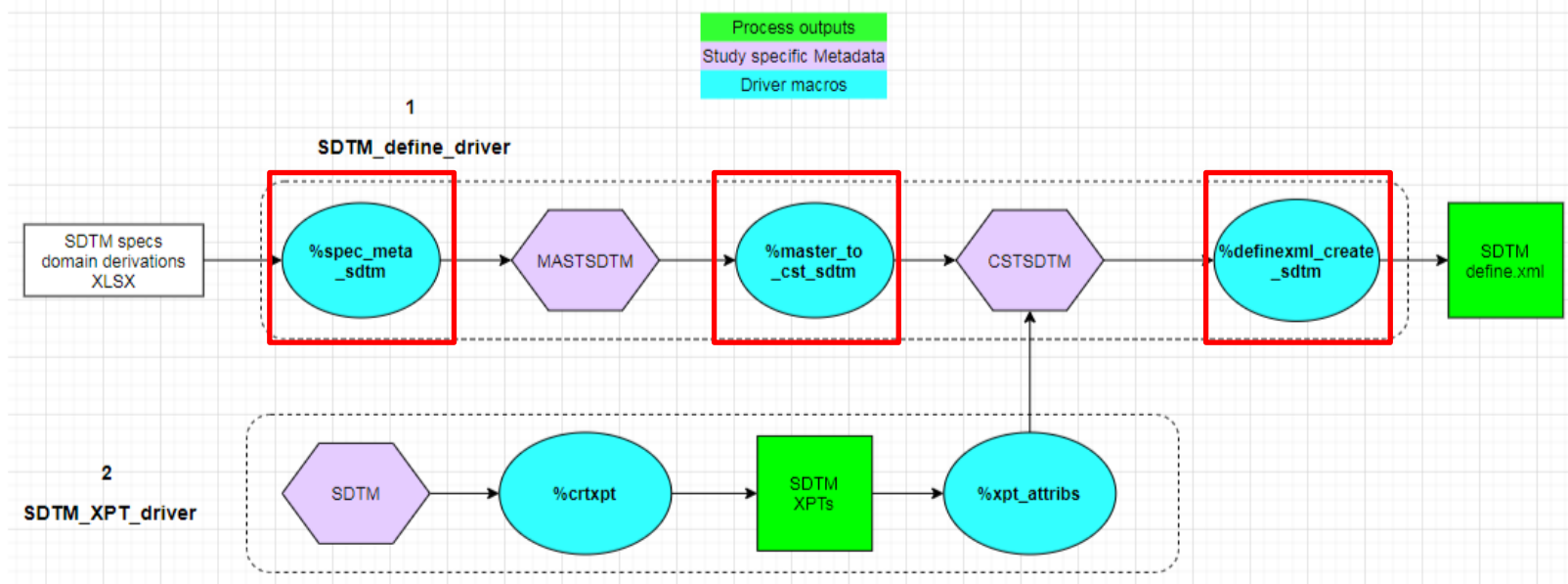
User Code



```
  ** Merging SERAE variables onto AE variables **;  
proc sort data=ae_ae_addvars;  
  by usubjid aespids;  
run;  
  
proc sort data=ae_serae_addvars;  
  by usubjid aespids;  
run;  
  
data ae_all_addvars;  
  merge ae_ae_addvars(in=one) ae_serae_addvars;  
  by usubjid aespids;  
  if one;  
run;  
  
** EPOCH **;  
%study_epoch(dsin=ae_all_addvars, dtc=aestdtc, dsout=ae_addvars, pre=Y, tim=);
```



Define.xml



MAPIT Adaptability



- Automation and innovation – critical data driven automation is essential component and which significantly improves quality, efficiency, consistency and reusability across the SDTM Production process for the full eCRT package
- Can work on a variety of different databases
- Using MAPIT we can create a full package (aCRF, SDTM specifications, SDTM Datasets and define.xml) saving on time, costs and improves quality
- Programming can begin with the database documents and does not require live study data



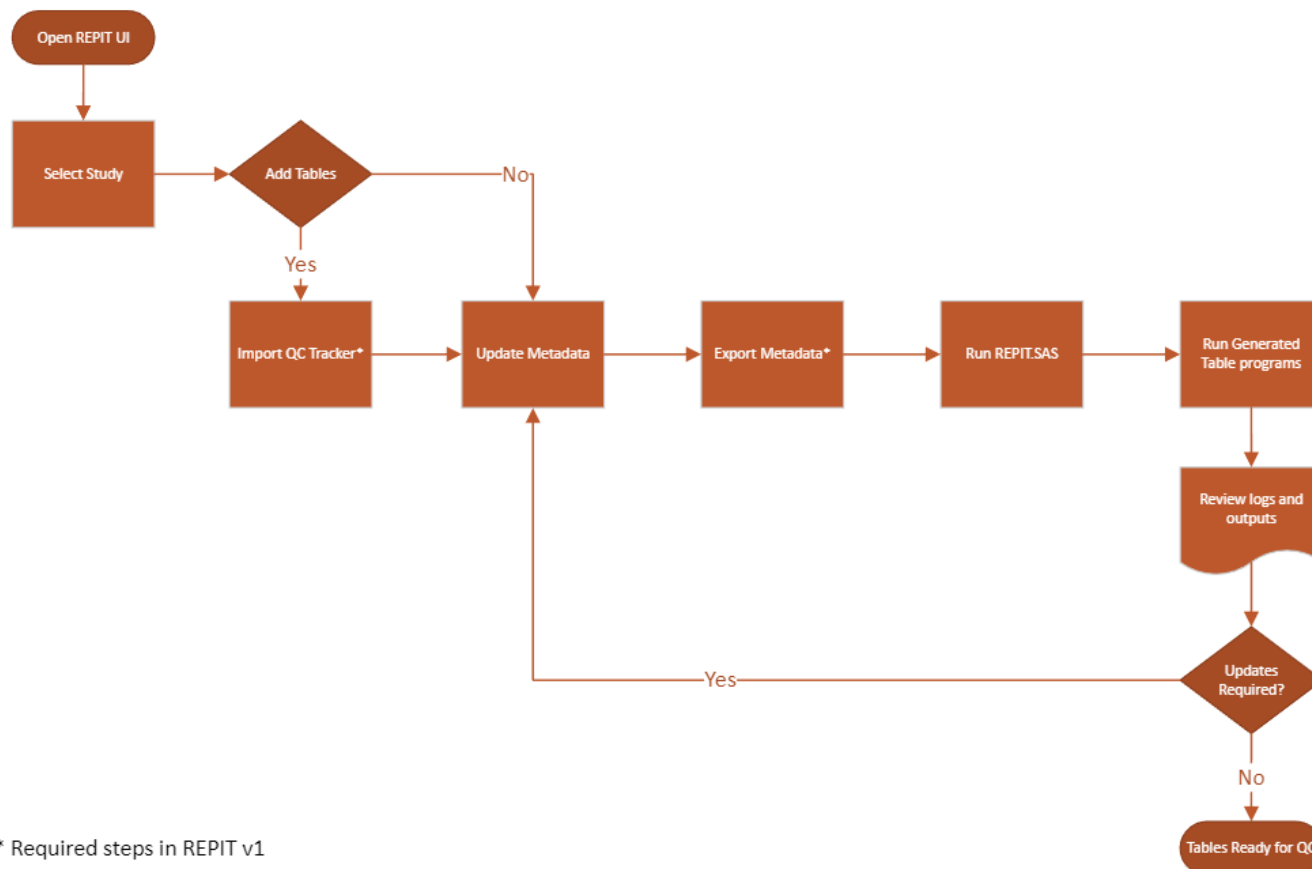
MAPIT Next Steps



- User Interface is being developed for the RAW2SDTM spreadsheet mappings to help improve quality, usability, efficiency, and adaptability
- Automated R-code is being developed, allowing SDTMs to be generated using SAS or R within the MAPIT automation tool



Table Automation – What is REPIT?



* Required steps in REPIT v1

Table Automation – What is REPIT?



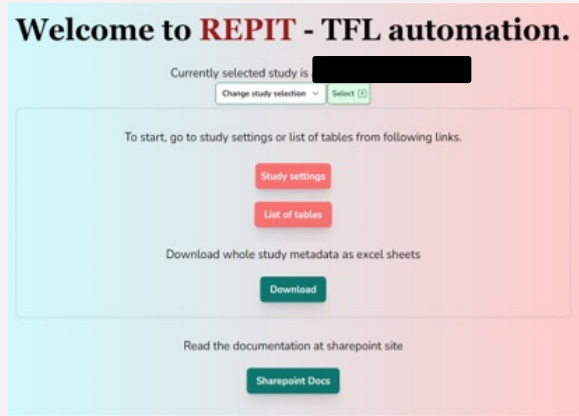
- REPIT is PHASTAR's TFL automation tool
- REPIT approach aligns with the CDISC 360 proof of concept with a modern web application
- User Interface (UI) provide ultimate flexibility for building TFLs
- Library within the system metadata for existing studies can be used to quickly produce the first draft of the metadata for a new study
- Benefits – standardization, consistency (client and industry standards), improves quality



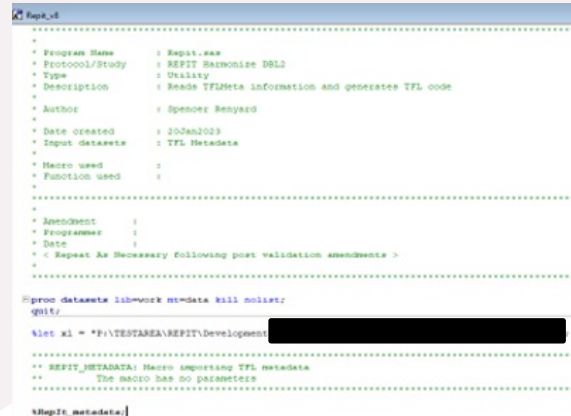
- TFL Shells, User Interface and Table Production Autocode



Table Automation – What is REPIT?



User Interface



REPIT SAS Program

A screenshot of a file explorer showing a list of files generated by the REPIT program. The files are named 'm200' through 'm214' and 'm200'. They are all SAS System Programs, created on 02/03/2023 at 14:01. The sizes range from 8 KB to 10 KB. The files are located in the path 'Phastar Shared Folders (P) > TESTAREA > REPIT > Development'.

Name	Date modified	Type	Size
m200	02/03/2023 14:02	Windows Batch File	1 KB
m201	02/03/2023 14:04	Windows Batch File	2 KB
m202	02/03/2023 14:01	SAS System Program	8 KB
m203	02/03/2023 14:01	SAS System Program	10 KB
m204	02/03/2023 14:01	SAS System Program	10 KB
m205	02/03/2023 14:01	SAS System Program	12 KB
m206	02/03/2023 14:01	SAS System Program	12 KB
m207	02/03/2023 14:01	SAS System Program	13 KB
m208	02/03/2023 14:01	SAS System Program	13 KB
m209	02/03/2023 14:01	SAS System Program	13 KB
m210	02/03/2023 14:01	SAS System Program	13 KB
m211	02/03/2023 14:01	SAS System Program	13 KB
m212	02/03/2023 14:01	SAS System Program	13 KB
m213	02/03/2023 14:01	SAS System Program	13 KB
m214	02/03/2023 14:01	SAS System Program	13 KB
m215	02/03/2023 14:01	SAS System Program	13 KB
m216	02/03/2023 14:01	SAS System Program	13 KB
m217	02/03/2023 14:01	SAS System Program	13 KB
m218	02/03/2023 14:01	SAS System Program	13 KB
m219	02/03/2023 14:01	SAS System Program	13 KB
m220	02/03/2023 14:01	SAS System Program	13 KB

Output Program Created



TFL Shells and QC Tracker



Output Type	Output Number	Title	Output Name	Dependencies	Population	Shell	REPI Template Category	REPI Unique Template ID
Demographic, Baseline, Concomitant Medication, and Other Subject-Specific Characteristics								
Table	14.1.1	Disposition	ds200	ADSL	FASFL	TSP01	SUMMARY TYPE 3	PHSP01
Table	14.1.2	Recruitment per <<region>>, country and site	ds201	ADSL	ENRFL	TSP02	EVENTS3	PHSP02
Table	14.1.3	Stratification factors at randomisation	ds202	ADSL	FASFL	TSP03	EVENTSUM	PHSP03
Table	14.1.4	Disposition due to global/country situation	ds203	ADSL	FASFL	TSP04	SUMMARY TYPE 3	PHSP04
Table	14.1.5	Global/country situation study disruptions	ds204	ADSL	FASFL	TSP05	EVENTSUM	PHSP05
Table	14.1.6	Important Protocol deviations	dv200	ADSL	FASFL	TSP06	EVENTSUM	PHSP06
Table	14.1.7	Analysis sets	ds206	ADSL		TSP07	SUMMARY TYPE 3	PHSP07
Table	14.1.8	Demographics	dm202	ADSL	FASFL	TSP08	SUMMARY TYPE 2	PHSP08
Table	14.1.9	Baseline characteristics	ds208	ADSL	FASFL	TSP09	SUMMARY TYPE 2	PHSP09
Table	14.1.10	<<Disease background>> characteristics (categorical and continuous variables)	dm200	ADSL	FASFL	TSP10	SUMMARY TYPE 2	PHSP10
Table	14.1.11	<<Disease background>> characteristics (categorical variables only)	dm201	ADSL	FASFL	TSP11	SUMMARY TYPE 3	PHSP11
Table	14.1.12	<<Disease background>> characteristics (continuous variables only)	dm202	ADSL	FASFL	TSP12	SUMMARY TYPE 1	PHSP12
Table	14.1.13	[[Medical/Surgical]] history by system organ class and preferred term	mh200	ADSL, ADMH	FASFL	TSP13	EVENTS2	PHSP13
Table	14.1.14	Prior medication by ATC classification and generic drug name	cm200	ADSL, ADCM	FASFL	TSP14	EVENTS2	PHSP14
Table	14.1.15	Concomitant medication by ATC classification and generic drug name	cm201	ADSL, ADCM	FASFL	TSP15	EVENTS2	PHSP15
Table	14.1.16	Disallowed concomitant medication by ATC classification and generic drug name	cm202	ADSL, ADCM	FASFL	TSP16	EVENTS2	PHSP16
Table	14.1.17	Study treatment compliance	ex200	ADSL, ADEXSUM	FASFL	TSP17	SUMMARY TYPE 2	PHSP17



User Interface



Welcome to **REPIT** - TFL automation.

Currently selected study is [REDACTED]

Change study selection ▾

Save ↱

To start, go to study settings or list of tables from following links.

Study settings

List of tables

Download whole study metadata as excel sheets

Download

Read the documentation at sharepoint site

Sharepoint Docs



User Interface



List of tables Upload QC tracker Filter Export Metadata

SL ↑	Type ↓	Output Name ↓	Title ↑	Template ↑	Status ↓	
1	TABLE	DS200	Table 14.1.1 Disposition	PHSP01	Not Started	1d ⋮
2	TABLE	DS201	Table 14.1.2 Recruitment per <<region>>, country and site	PHSP02	Not Started	19h ⋮
3	TABLE	DS203	Table 14.1.4 Disposition due to global/country situation	PHSP04	Not Started	1d ⋮
4	TABLE	DS204	Table 14.1.5 Global/country situation study disruptions	PHSP05	Not Started	1d ⋮
5	TABLE	DV200	Table 14.1.6 Important Protocol deviations	PHSP06	Not Started	1d ⋮
6	TABLE	DS206	Table 14.1.7 Analysis sets	PHSP07	Not Started	1d ⋮
7	TABLE	DS207	Table 14.1.8 Demographics	PHSP08	Not Started	1d ⋮
8	TABLE	DS208	Table 14.1.9 Baseline characteristics	PHSP09	Not Started	1d ⋮
9	TABLE	DM201	Table 14.1.11 <<Disease background>> characteristics (categorical variables only)	PHSP11	Not Started	1d ⋮
10	TABLE	DM202	Table 14.1.12 <<Disease background>> characteristics (continuous variables only)	PHSP12	Not Started	1d ⋮
11	TABLE	MH200	Table 14.1.13 [[Medical/Surgical]] history by system organ class and preferred term	PHSP13	Not Started	1d ⋮
12	TABLE	CM200	Table 14.1.14 Prior medication by ATC classification and generic drug name	PHSP14	Not Started	1d ⋮
13	TABLE	CM201	Table 14.1.15 Concomitant medication by ATC classification and generic drug name	PHSP15	Not Started	1d ⋮
14	TABLE	CM202	Table 14.1.16 Disallowed concomitant medication by ATC classification and generic drug name	PHSP16	Not Started	1d ⋮



User Interface



Group Label - Randomized

Population = **RANDFL**

Order	Treatment Label	Where Clause		
1	Drug 1^n<<low dose>>	TRT01AN=1	☒	☐
2	Drug 2^n<<high dose>>	TRT01AN=3	☒	☐
3	Total	TRT01PN in (1 3)	☒	☐

Group Label - Safety

Population = **SAFFL**

Order	Treatment Label	Where Clause		
1	Drug 1^n<<low dose>>	TRT01AN=1	☒	☐
2	Drug 2^n<<high dose>>	TRT01AN=3	☒	☐

Group Label - Safety With Total

Population = **SAFFL**

Order	Treatment Label	Where Clause		
1	Drug 1^n<<low dose>>	TRT01AN=1	☒	☐
2	Drug 2^n<<high dose>>	TRT01AN=3	☒	☐
3	Total	TRT01PN in (1 3)	☒	☐

Save all changes

User Interface

Study Settings

List of tables

Back to output details

Header & Footer

Column

Row block

Row block

DM201C

Table 14.1.5c Demographics (Full analysis set)

←

→

Blocks

Add

Block Level	Block Order	Indent	Block title	Source Table	Source Column	Block Filter	Format	Decimal	Sort By		
1	1	0	Age (years) [a]	ADSL	AGE		SUMSTAT_:	0		✓	✗
2	1	0	Age group (years)	ADS	AGE		AGECAT_1A			✓	✗

Copy to...

Save all changes

User Interface

Format = SUMSTAT_1A

Add new label +

Order	Label	Source condition	Statistics	Actions
1	n		N	☒ ☐
2	Mean		MEAN	☒ ☐
3	SD		STD	☒ ☐
4	Median		MEDIAN	☒ ☐
5	Min		MIN	☒ ☐
6	Max		MAX	☒ ☐

Format = AGECAT_1A

Add new label +

Order	Label	Source condition	Statistics	Actions
1	< 65	AGE <65	NSubj COL%	☒ ☐
3	>= 65	AGE >=65	NSubj COL%	☒ ☐

Table Production Autocode

```
*****;  
** CODE_BIGN **;  
*****;  
  
** Create count of subjects from ADSL based on column and table where clauses **;  
  
data colsubj (keep=usubjid colidl);  
  set adam.adsl;  
  colidl=1;  
  if SAFFL="Y" and TRT01AN=1 then output;  
  colidl=2;  
  if SAFFL="Y" and TRT01AN=2 then output;  
  colidl=3;  
  if SAFFL="Y" and TRT01AN=3 then output;  
run;  
  
proc sql;  
  create table colbigNs as  
  select colidl, count(distinct usubjid) as bigN  
  from colsubj  
  group by colidl;  
quit;  
  
** Output BigNs as macro variables for use in column titles **;
```

Table Production Autocode

```
** Proc report to generate output **;

%rstart(pdfoptions=uniform);
ods escapechar='^';

%if &_repit_nobs > 0 %then %do;
proc report data = tab_l4_3_6_1 missing spanrows split='~'
  style(report)=[asis=on protectspecialchars=off cellspacing=0]
  style(column)=[asis=on protectspecialchars=off]
  style(header column)=[asis=off protectspecialchars=off rules=none fontsize=9pt];

  column rowblk rowidl rowtitle1 col01 col02 col03;
  define rowblk / order order=internal noprint;
  define rowidl / order order=internal noprint;
  define rowtitle1 / group id "Specific adverse event of interest" style(header column)=[just=1] style(column)=[just=1]
  define col01 / display style(column)=[just=1 asis=on cellwidth=20% pretext=""] flow style(header)=[asis=on];
  define col02 / display style(column)=[just=1 asis=on cellwidth=20% pretext=""] flow style(header)=[asis=on];
  define col03 / display style(column)=[just=1 asis=on cellwidth=20% pretext=""] flow style(header)=[asis=on];
  compute after rowblk;
    line ' ';
  endcomp;
run;
%end;

%if &_repit_nobs = 0 %then %do;
proc report data = tab_l4_3_6_1 nowd missing spanrows split='~'
  style(report)=[asis=on protectspecialchars=off cellspacing=0]
  style(column)=[asis=on protectspecialchars=off]
  style(header column)=[asis=off protectspecialchars=off rules=none fontsize=9pt];

  column rowtitle1;
  define rowtitle1 / '' order order=internal style={just=center asis=off};
run;
```

Table Production Autocode - Output



Demographic characteristic	Stat	Drug 1 (N=362)	Drug 2 (N=365)	Total (N=727)
Age (years) [a]	n	362	365	727
	Mean	55.0	55.3	55.2
	SD	11.00	11.72	11.36
	Median	55.0	55.0	55.0
	Min	29	28	28
	Max	86	86	86
Age group (years) [a]	< 65	287 (79.3)	277 (75.9)	564 (77.6)
	>= 65	75 (20.7)	88 (24.1)	163 (22.4)

REPIT Adaptability



- REPIT is a super fast way to produce tables, ensuring quality and efficiency
- Smart metadata management with web application that can start programming without live data
- Standard and often repetitive tables can be produced very quickly, meaning more time can be spent on the more complex tables
- We can 'build tables' within REPIT via generic templates but also have the option of loading specific templates that align with standard shells



REPIT Adaptability



- Ease of making updates to outputs once loaded in the UI, especially global updates. Benefits include
 - Changing a treatment group label, order or even adding or removing a treatment group is done in one place
 - Similar to above, stats for inclusion in univariate, categories to be used in race counts can easily be switched via preloaded system formats
 - Easy to customise reporting requirements between clients with modular metadata management
- Increase ADaM Quality and integrate more fully with ADaM standard of 'One Proc Away'



REPIT Next Steps



- REPIT is a work in progress, more templates are being added
- Development of Listings
- With TFL metadata broken into logical modules, this dramatically increases the flexibility in the workflow, going as far as the programming language of choice for the TFL programs, moving REPIT to also produce different code outputs – for example R code



Conclusion

The automation of SDTMs and Outputs greatly increases quality and consistency for study reporting whilst reducing cost and timelines

Phastar is dedicated to automating our process, and innovating new developmental tools to improve reporting, data quality and subject safety



Any Questions?

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