



Assigning VISITNUM and EPOCH

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Epoch

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Section 1: Unscheduled Visits

Introduction

- ▶ To standardize how visits are numbered and guarantee consistent, chronological display of event in SDTM the PhUSE group created guidance for populating unscheduled visit mapping
- ▶ From this guidance CDASH & SDTM group created a Best Practice document to assist with mapping unscheduled visits in SDTM
- ▶ Best practice is the suggested method from now on but it is not a standard process. Study and/or sponsor requirements may deviate from this guidance

Best Practice – Overview

- ▶ First create TV domain, can also provide guidance to eDC or vendors on how to label visits
- ▶ Then create SV domain, as a “master look-up” table from all observation class data. Use database data and vendor data and include visit dates only
- ▶ Studies in Datalabs can use raw EVENTINFO dataset and studies using Medidata RAVE can use raw VISIT dataset for non-vendor data (first check these datasets are complete and reliable)
- ▶ Sort SV by date order and for each unscheduled visit that occurs after a scheduled visit assign visitnum as the scheduled VISITNUM + 0.01

Rules for assigning unscheduled visits in SV

- ▶ Leave VISIT null for unplanned visits, unless sponsor requests otherwise
- ▶ Do not impute partial or missing dates, assign the chronology based on date parts that are present only
- ▶ If it is not possible to determine chronology of an unplanned visit then assign VISITNUM as 999
- ▶ Use SVUPDES to assign the source(s) of the unplanned visit
- ▶ If unplanned visit falls on same day as a planned visit then assume the planned visit occurs first when assigning VISITNUM – regardless of time
- ▶ For each observation class domain, populated VISIT/VISITNUM by comparing date with SVSTDTC/SVENDTC

Examples

- ▶ The following are slides that display how this best practice will handle different scenarios often found within study data
- ▶ For each example consider the following protocol design and TV dataset:

Protocol					TV	
VISITNUM	Vitals	PE*	ECG	Lab	VISITNUM	VISIT
1	x	x	x	x	1	Screening
2	x	x			2	Week 1
3	x	x		x	3	Week 2
4	x	x	x		4	Week 3
5	x	x		x	5	Week 4
6	x	x			6	Week 5
7		x	x	x	7	Week 6
*Assume PE 1 day later						

Example 1 – Subject without any unplanned events

Subject has no unscheduled visits. SV consists of raw data visits and this is merged on to each SDTM domain by date

Source Data									
Vitals		Physical Exam		Lab Vendor		ECG Vendor			
VISITNUM	VSDTC	VISITNUM	PEDTC	VISITNUM	LBDTC	VISITNUM	EGDTC		
1	2015-04-01	1	2015-04-02	1	2015-04-01	1	2015-04-01		
2	2015-04-08	2	2015-04-09	3	2015-04-15	4	2015-04-22		
3	2015-04-15	3	2015-04-16	5	2015-04-29	7	2015-05-13		
4	2015-04-22	4	2015-04-23	7	2015-05-13				
5	2015-04-29	5	2015-04-30						
6	2015-05-06	6	2015-05-07						
		7	2015-05-13						

Example 2 – Subject with unplanned events, lab only expecting visit 1, 3, 5, 7 and does not know when Visit 2, 4, 6 occur (1)

In this case unplanned visit occurs on same date as planned visit, but from other data.

Sort data chronologically by SVSTDTC and add 0.01 to VISITNUM of the planned visit for unplanned VISITNUM

VISIT is null but can be set to “Unscheduled Week 2.01”, “Unscheduled Week 4.01”, “Unscheduled Week 6.01” if preferred

Source Data									
Vitals		Physical Exam		Lab Vendor		ECG Vendor			
VISITNUM	VSDTC	VISITNUM	PEDTC	VISITNUM	LBDTC	VISITNUM	LBDTC		
1	2015-04-01	1	2015-04-02	1	2015-04-01	1	2015-04-01		
2	2015-04-08	2	2015-04-09	99	2015-04-08	4	2015-04-22		
3	2015-04-15	3	2015-04-16	3	2015-04-15	7	2015-05-13		
4	2015-04-22	4	2015-04-23	99	2015-04-22				
5	2015-04-29	5	2015-04-30	5	2015-04-29				
6	2015-05-06	6	2015-05-07	99	2015-05-06				
		7	2015-05-13	7	2015-05-13				
SDTM	SV	VISITNUM	VISIT	SVSTDTC	SVENDTC	SVUPDES			
		1	Screening	2015-04-01	2015-04-02				
		2	Week 1	2015-04-08	2015-04-09				
		2.01		2015-04-08	2015-04-08	LB			
		3	Week 2	2015-04-15	2015-04-16				
		4	Week 3	2015-04-22	2015-04-23				
		4.01		2015-04-22	2015-04-22	LB			
		5	Week 4	2015-04-29	2015-04-30				
		6	Week 5	2015-05-06	2015-05-07				
		6.01		2015-05-06	2015-05-06	LB			
		7	Week 6	2015-05-13	2015-05-13				
Vitals		Physical Exam		Lab Vendor		ECG Vendor			
VISITNUM	VSDTC	VISITNUM	PEDTC	VISITNUM	LBDTC	VISITNUM	EGDTC		
1	2015-04-01	1	2015-04-02	1	2015-04-01	1	2015-04-01		
2	2015-04-08	2	2015-04-09	2.01	2015-04-08	4	2015-04-22		
3	2015-04-15	3	2015-04-16	3	2015-04-15	7	2015-05-13		
4	2015-04-22	4	2015-04-23	4.01	2015-04-22				
5	2015-04-29	5	2015-04-30	5	2015-04-29				
6	2015-05-06	6	2015-05-07	6.01	2015-05-06				

Example 3 – Subject with unplanned events, lab only expecting visit 1, 3, 5, 7 and does not know when Visit 2, 4, 6 occur (2)

Similar to previous example but visit occurs on different day to planned visits

Source Data									
Vitals		Physical Exam		Lab Vendor		ECG Vendor			
VISITNUM	VSDTC	VISITNUM	PEDTC		VISITNUM	LBDTC	VISITNUM	LBDTC	
1	2015-04-01	1	2015-04-02		1	2015-04-01	1	2015-04-01	
2	2015-04-08	2	2015-04-09		99	2015-04-10	4	2015-04-22	
3	2015-04-15	3	2015-04-16		3	2015-04-15	7	2015-05-13	
4	2015-04-22	4	2015-04-23		99	2015-04-24			
5	2015-04-29	5	2015-04-30		5	2015-04-29			
6	2015-05-06	6	2015-05-07		99	2015-05-09			
		7	2015-05-13		7	2015-05-13			
SDTM	SV	VISITNUM	VISIT	SVSTDTC	SVENDTC	SVUPDES			
		1	Screening	2015-04-01	2015-04-02				
		2	Week 1	2015-04-08	2015-04-09				
		2.01		2015-04-10	2015-04-10	LB			
		3	Week 2	2015-04-15	2015-04-16				
		4	Week 3	2015-04-22	2015-04-23				
		4.01		2015-04-24	2015-04-24	LB			
		5	Week 4	2015-04-29	2015-04-30				
		6	Week 5	2015-05-06	2015-05-07				
		6.01		2015-05-09	2015-05-09	LB			
		7	Week 6	2015-05-13	2015-05-13				
Vitals		Physical Exam		Lab Vendor		ECG Vendor			
VISITNUM	VSDTC	VISITNUM	PEDTC		VISITNUM	LBDTC	VISITNUM	LBDTC	
1	2015-04-01	1	2015-04-02		1	2015-04-01	1	2015-04-01	
2	2015-04-08	2	2015-04-09		2.01	2015-04-10	4	2015-04-22	
3	2015-04-15	3	2015-04-16		3	2015-04-15	7	2015-05-13	
4	2015-04-22	4	2015-04-23		4.01	2015-04-24			
5	2015-04-29	5	2015-04-30		5	2015-04-29			
6	2015-05-06	6	2015-05-07		6.01	2015-05-09			
		7	2015-05-13		7	2015-05-13			

Example 4 – Subject with unplanned events, lab only expecting visit 1, 3, 5, 7 and does not know when Visit 2, 4, 6 occur. Lab Visit 1 is also done on 4/3/2015

The unplanned PE data on 2015-05-08 and unplanned lab data on 2015-05-09 both occur after VISITNUM=6. Lab data gets assigned VISITNUM=6.02

Source Data									
Vitals		Physical Exam		Lab Vendor		ECG Vendor			
VISITNUM	VSDTC	VISITNUM	PEDTC	VISITNUM	LBDTC	VISITNUM	EGDTC		
1	2015-04-01	1	2015-04-02	1	2015-04-02	1	2015-04-02		
2	2015-04-08	2	2015-04-09	1	2015-04-03	99	2015-04-03		
3	2015-04-15	3	2015-04-16	99	2015-04-09	4	2015-04-21		
4	2015-04-22	4	2015-04-23	3	2015-04-15	7	2015-05-13		
5	2015-04-29	5	2015-04-30	99	2015-04-24				
6	2015-05-06	6	2015-05-07	5	2015-04-29				
99	2015-05-13	99	2015-05-08	99	2015-05-09				
		7	2015-05-13	7	2015-05-13				
SDTM		SV	VISITNUM	VISIT	SVSTDTC	SVENDTC	SVUPDES		
			1	Screening	2015-04-01	2015-04-03			
			1.01		2015-04-02	2015-04-02	EG		
			2	Week 1	2015-04-08	2015-04-09			
			2.01		2015-04-09	2015-04-09	LB		
			3	Week 2	2015-04-15	2015-04-16			
			4	Week 3	2015-04-22	2015-04-23			
			4.01		2015-04-24	2015-04-24	LB		
			5	Week 4	2015-04-29	2015-04-30			
			6	Week 5	2015-05-06	2015-05-07			
			6.01		2015-05-08	2015-05-08	PE		
			6.02		2015-05-09	2015-05-09	LB		
			7	Week 6	2015-05-13	2015-05-13			
			7.01		2015-05-13	2015-05-13	VS		
Vitals		Physical Exam		Lab Vendor		ECG Vendor			
VISITNUM	VSDTC	VISITNUM	PEDTC	VISITNUM	LBDTC	VISITNUM	EGDTC		
1	2015-04-01	1	2015-04-02	1	2015-04-02	1	2015-04-02		
2	2015-04-08	2	2015-04-09	1	2015-04-03	1.01	2015-04-03		
3	2015-04-15	3	2015-04-16	2.01	2015-04-09	4	2015-04-21		
4	2015-04-22	4	2015-04-23	3	2015-04-15	7	2015-05-13		
5	2015-04-29	5	2015-04-30	4.01	2015-04-24				
6	2015-05-06	6	2015-05-07	5	2015-04-29				
7.01	2015-05-13	6.01	2015-05-08	6.02	2015-05-09				
		7	2015-05-13	7	2015-05-13				

Example 5 – Subject with unplanned events, lab only expecting visit 1, 3, 5, 7 and does not know when Visit 2, 4, 6 occur (3)

- VS, PE unplanned visit occurs after VISITNUM=6 and lab unplanned is after VISITNUM=5 but both have same date

- Assigning chronologically in SV puts VISITNUM as 6.01

- SVUPDES would record the fact that visit comes from VS, PE and Laboratory data

Source Data									
Vitals		Physical Exam		Lab Vendor		ECG Vendor			
VISITNUM	VSDTC	VISITNUM	PEDTC		VISITNUM	LBDTC	VISITNUM	EGDTC	
1	2015-04-01	1	2015-04-02		1	2015-04-02	1	2015-04-01	
2	2015-04-08	2	2015-04-09		3	2015-04-15	4	2015-04-22	
3	2015-04-15	3	2015-04-16		5	2015-04-29	7	2015-05-13	
4	2015-04-22	4	2015-04-23		99	2015-05-09			
5	2015-04-29	5	2015-04-30		7	2015-05-13			
6	2015-05-06	6	2015-05-07						
99	2015-05-09	99	2015-05-09						
		7	2015-05-13						

Example 6 – Subject with unplanned events with partial observation dates

- Partial dates not enough to determine VISITNUM so set to 999.01 and 999.02
- VISIT could be set as “Unscheduled” if needed

Source Data									
Vitals		Physical Exam		Lab Vendor		ECG Vendor			
VISITNUM	VSDTC	VISITNUM	PEDTC	VISITNUM	LBDTC	VISITNUM	EGDTC		
1	2015-04-01	1	2015-04-02	1	2015-04-02	1	2015-04-01		
2	2015-04-08	2	2015-04-09	3	2015-04-15	4	2015-04-22		
3	2015-04-15	3	2015-04-16	5	2015-04-29	7	2015-05-13		
4	2015-04-22	4	2015-04-23	99	2015-05	99	2015-04		
5	2015-04-29	5	2015-04-30	7	2015-05-13				
6	2015-05-06	6	2015-05-07						
		7	2015-05-13						
SDTM		SV	SVSTDTC	SVENDTC	SVUPDES				
		1	2015-04-01	2015-04-02					
		2	2015-04-08	2015-04-09					
		3	2015-04-15	2015-04-16					
		4	2015-04-22	2015-04-23					
		5	2015-04-29	2015-04-30					
		6	2015-05-06	2015-05-07					
		7	2015-05-13	2015-05-13					
		999.01	2015-04		EG				
		999.02	2015-05		LB				
Vitals		Physical Exam		Lab Vendor		ECG Vendor			
VISITNUM	VSDTC	VISITNUM	PEDTC	VISITNUM	LBDTC	VISITNUM	EGDTC		
1	2015-04-01	1	2015-04-02	1	2015-04-02	1	2015-04-01		
2	2015-04-08	2	2015-04-09	3	2015-04-15	4	2015-04-22		
3	2015-04-15	3	2015-04-16	5	2015-04-29	7	2015-05-13		
4	2015-04-22	4	2015-04-23	7	2015-05-13	999.01	2015-04		
5	2015-04-29	5	2015-04-30	999.02	2015-05				
6	2015-05-06	6	2015-05-07						
		7	2015-05-13						

Example 7 – Subject with unplanned events with partial/missing observation dates

- Do not impute dates.
- Partial dates not enough to determine VISITNUM so set to 999.01 for missing date and 999.02 for partial date
- VISIT could be set as “Unscheduled” if needed

Source Data									
Vitals		Physical Exam		Lab Vendor		ECG Vendor			
VISITNUM	VSDTC	VISITNUM	PEDTC	VISITNUM	LBDTC	VISITNUM	EGDTC		
1	2015-04-01	1	2015-04-02	1	2015-04-02	1	2015-04-01		
2	2015-04-08	2	2015-04-09	3	2015-04-15	4	2015-04-22		
3	2015-04-15	3	2015-04-16	5	2015-04-29	7	2015-05-13		
4	2015-04-22	4	2015-04-23	7	2015-05-13	99	2015-04		
5	2015-04-29	5	2015-04-30	99		99			
6	2015-05-06	6	2015-05-07						
		7	2015-05-13						
SDTM		SV	SVSTDTC	SVENDTC	SVUPDES				
		1	2015-04-01	2015-04-02					
		2	2015-04-08	2015-04-09					
		3	2015-04-15	2015-04-16					
		4	2015-04-22	2015-04-23					
		5	2015-04-29	2015-04-30					
		6	2015-05-06	2015-05-07					
		7	2015-05-13	2015-05-13					
		999.01			EG, LB				
		999.02	2015-04		EG				
Vitals		Physical Exam		Lab Vendor		ECG Vendor			
VISITNUM	VSDTC	VISITNUM	PEDTC	VISITNUM	LBDTC	VISITNUM	EGDTC		
1	2015-04-01	1	2015-04-02	1	2015-04-02	1	2015-04-01		
2	2015-04-08	2	2015-04-09	3	2015-04-15	4	2015-04-22		
3	2015-04-15	3	2015-04-16	5	2015-04-29	7	2015-05-13		
4	2015-04-22	4	2015-04-23	7	2015-05-13	999.02	2015-04		
5	2015-04-29	5	2015-04-30	999.01		999.01			
6	2015-05-06	6	2015-05-07						
		7	2015-05-13						

Example 8 – Subject missing a planned event, but has unplanned visits

- Subject has no Visit 2 so can't determine if unplanned visit on 2015-04-14 should be VISITNUM=1.01 or 2.01
- Special care needed when visits are missing in determining elements and EPOCH

Source Data									
Vitals		Physical Exam		Lab Vendor		ECG Vendor			
VISITNUM	VSDTC	VISITNUM	PEDTC		VISITNUM	LBDTC	VISITNUM	LBDTC	
1	2015-04-01	1	2015-04-02		1	2015-04-01	1	2015-04-01	
					99	2015-04-14	4	2015-04-22	
3	2015-04-15	3	2015-04-16		3	2015-04-15	7	2015-05-13	
4	2015-04-22	4	2015-04-23		99	2015-04-22			
5	2015-04-29	5	2015-04-30		5	2015-04-29			
6	2015-05-06	6	2015-05-07		99	2015-05-06			
		7	2015-05-13		7	2015-05-13			
SDTM		SV	VISITNUM	VISIT	SVSTDTC	SVENDTC	SVUPDES		
			1	Screening	2015-04-01	2015-04-02			
								No Record for VISITNUM=2	
			1.01		2015-04-14	2015-04-14	LB		
			3	Week 2	2015-04-15	2015-04-16			
			4	Week 3	2015-04-22	2015-04-23			
			4.01		2015-04-22	2015-04-22	LB		
			5	Week 4	2015-04-29	2015-04-30			
			6	Week 5	2015-05-06	2015-05-07			
			6.01		2015-05-06	2015-05-06	LB		
			7	Week 6	2015-05-13	2015-05-13			

Example 9 – Subject where the chronology of visits is out of order

Even though
unplanned Lab
visit is within
Screening range
it is considered
an unplanned
event

Source Data									
Vitals		Physical Exam		Lab Vendor		ECG Vendor			
VISITNUM	VSDTC	VISITNUM	PEDTC	VISITNUM	LBDTC	VISITNUM	EGDTC		
1	2015-04-01	1	2015-04-03	1	2015-04-01	1	2015-04-01		
2	2015-04-08	2	2015-04-09	99	2015-04-02	4	2015-04-22		
3	2015-04-15	3	2015-04-16	3	2015-04-15	7	2015-05-13		
4	2015-04-22	4	2015-04-23	5	2015-04-29				
5	2015-04-29	5	2015-04-30	7	2015-05-13				
6	2015-05-06	6	2015-05-07						
		7	2015-05-13						
SDTM	SV	VISITNUM	VISIT	SVSTDTC	SVENDTC	SVUPDES			
		1	Screening	2015-04-01	2015-04-03				
		1.01		2015-04-02	2015-04-02	LB			
		2	Week 1	2015-04-08	2015-04-09				
		3	Week 2	2015-04-15	2015-04-16				
		4	Week 3	2015-04-22	2015-04-23				
		5	Week 4	2015-04-29	2015-04-30				
		6	Week 5	2015-05-06	2015-05-07				
		7	Week 6	2015-05-13	2015-05-13				
Vitals		Physical Exam		Lab Vendor		ECG Vendor			
VISITNUM	VSDTC	VISITNUM	PEDTC	VISITNUM	LBDTC	VISITNUM	EGDTC		
1	2015-04-01	1	2015-04-02	1	2015-04-01	1	2015-04-01		
2	2015-04-08	2	2015-04-09	1.01	2015-04-02	4	2015-04-22		
3	2015-04-15	3	2015-04-16	3	2015-04-15	7	2015-05-13		
4	2015-04-22	4	2015-04-23	5	2015-04-29				
5	2015-04-29	5	2015-04-30	7	2015-05-13				
6	2015-05-06	6	2015-05-07						
		7	2015-05-13						

Section 2: EPOCH variable

Introduction

- ▶ FDA requested EPOCH in clinical subject-level observations to help review easily determine which phase of the trial the observation occurred
- ▶ Based on PhUSE guidance CDASH&SDTM team created best practice for populating EPOCH

Best Practice – Overview

- ▶ Create TE, TA and TV SDTM domains first
- ▶ Then create SE domain, there should be no gaps between Elements – SEENDTC will be same as SESTDTC for the next Element
- ▶ Compare date of observation with SESTDTC and SEENDTC to determine EPOCH

Rules for assigning EPOCH

- ▶ Since SEENDTC of an Element will equal next Elements SESTDTC assign EPOCH where observation –_DTC/--STDTC is greater than or equal to SESTDTC and less than SEENDTC (except for subject's last Element). Study specific logic can also be added
- ▶ If observation date is missing EPOCH should be null, unless –ENDTC indicates a particular EPOCH
- ▶ For partial dates assign based on chronology of known parts – do not impute date or time
- ▶ If EPOCH can't be determined then use most conservation approach and document in reviewers guide. Assign to Treatment over Non-Treatment
- ▶ For Observation's outside of planned Elements add a record to SE with TAETORD null and SEUPDES populated and use this to assign EPOCH
- ▶ If chronology can't be determined use VISIT/VISITNUM by determining which EPOCHs would correspond to each visit as per protocol
- ▶ VISIT/VISITNUM should only be used if reflect actual time in study the observation was collected

Examples

- ▶ The following slides are examples of how assigning EPOCH using the guidance will handle different scenarios
- ▶ For each example consider the following:

Protocol						
ARMCD	ARM	ETCD	ELEMENT	EPOCH	VISITNUM	VISIT
A	DRUGA	RI	Run In	RUN-IN	1	Run-In
A	DRUGA	SCR	Screening	SCREENING	2	Screening
A	DRUGA	F	Fasted	PERIOD 1	3	Period 1 Day 1
A	DRUGA	F	Fasted	PERIOD 1	4	Period 1 Day 7
A	DRUGA	WO	Wash Out	WASHOUT	5	Period 1 Day 14
A	DRUGA	NF	Non-Fasted	PERIOD 2	6	Period 2 Day 1
A	DRUGA	NF	Non-Fasted	PERIOD 2	7	Period 2 Day 7
A	DRUGA	NF	Non-Fasted	PERIOD 2	8	Period 2 Day 14
A	DRUGA	FU	Follow-Up	FOLLOW-UP	9	Follow-Up

TE	
ETCD	ELEMENT
RI	Run In
SCR	Screening
F	Fasted
WO	Wash Out
NF	Non-Fasted
FU	Follow-Up

TA					
ARMCD	ARM	TAETORD	ETCD	ELEMENT	EPOCH*
A	DRUGA	1	RI	Run In	RUN-IN
A	DRUGA	2	SCR	Screening	SCREENING
A	DRUGA	3	F	Fasted	PERIOD 1
A	DRUGA	4	WO	Wash Out	WASHOUT
A	DRUGA	5	NF	Non-Fasted	PERIOD 2
A	DRUGA	6	FU	Follow-Up	FOLLOW-UP

EPOCH*
RUN-IN
SCREENING
PERIOD 1
PERIOD 1
WASHOUT
PERIOD 2
PERIOD 2
PERIOD 2
FOLLOW-UP

*EPOCH is NOT part of TV domain

TV			
VISITNUM	VISIT	ARMCD	ARM
1	Run-In	A	DRUGA
2	Screening	A	DRUGA
3	Period 1 Day 1	A	DRUGA
4	Period 1 Day 7	A	DRUGA
5	Period 1 Day 14	A	DRUGA
6	Period 2 Day 1	A	DRUGA
7	Period 2 Day 7	A	DRUGA
8	Period 2 Day 14	A	DRUGA
9	Follow-Up	A	DRUGA

Example 1 – As expected without issues

Subject's dates are all present and full and match up with SE

Source Data						
Subject Visits			Exposure			
VISITNUM	VISIT	SVSTDC	EXTRT	EXSTDC	EXENDTC	
1	Run-In	2013-04-01	DRUG A	2013-05-01	2013-05-01	
2	Screening	2013-04-30	DRUG A	2013-05-29	2013-05-29	
3	Period 1 Day 1	2013-05-01				
4	Period 1 Day 7	2013-05-08				
5	Period 1 Day 14	2013-05-15				
6	Period 2 Day 1	2013-05-29				
7	Period 2 Day 7	2013-06-05				
8	Period 2 Day 14	2013-06-12				
9	Follow up	2013-06-14				
SOTM						
Subject Elements						
ETCD	ELEMENT	SESTDC	SEENDTC	EPOCH		
RI	Run In	2013-04-01	2013-04-30	RUN-IN		
SCR	Screening	2013-04-30	2013-05-01	SCREENING		
F	Fasted	2013-05-01	2013-05-15	PERIOD 1		
WO	Wash Out	2013-05-15	2013-05-29	WASHOUT		
NF	Non-Fasted	2013-05-29	2013-06-14	PERIOD 2		
FU	Follow-Up	2013-06-14	2013-06-14	FOLLOW-UP		
Vital Signs			Adverse Events			
VISITNUM	VISIT	VSDTC	EPOCH	AETERM	AESTDC	EPOCH
1	Run-In	2013-04-01	RUN-IN	HEADACHE	2013-04-02	RUN-IN
2	Screening	2013-04-30	SCREENING	VOMITING	2013-05-01	PERIOD 1
3	Period 1 Day 1	2013-05-01	PERIOD 1	NAUSEA	2013-05-02	PERIOD 1
4	Period 1 Day 7	2013-05-08	PERIOD 1	HEAD PAIN	2013-06-07	PERIOD 2
5	Period 1 Day 14	2013-05-15	WASHOUT			
6	Period 2 Day 1	2013-05-29	PERIOD 2			
7	Period 2 Day 7	2013-06-05	PERIOD 2			
8	Period 2 Day 14	2013-06-12	PERIOD 2			
9	Follow up	2013-06-14	FOLLOW-UP			

Example 2 – When the observation date is not available use the VISITNUM/VISIT to assign

EPOCH can be
assigned as
PERIOD 1 using
VISIT=“Period 1
Day 7”

Source Data			Exposure		
Subject Visits					
VISITNUM	VISIT	SVSTDTC	EXTRT	EXSTDTC	EXENDTC
1	Run-In	2013-04-01	DRUG A	2013-05-01	2013-05-01
2	Screening	2013-04-30	DRUG A	2013-05-29	2013-05-29
3	Period 1 Day 1	2013-05-01			
4	Period 1 Day 7	2013-05-08			
5	Period 1 Day 14	2013-05-15			
6	Period 2 Day 1	2013-05-29			
7	Period 2 Day 7	2013-06-05			
8	Period 2 Day 14	2013-06-12			
9	Follow up	2013-06-14			
SDTM					
Subject Elements					
ETCD	ELEMENT	SESTDTC	SEENDTC	EPOCH	
RI	Run In	2013-04-01	2013-04-30	RUN-IN	
SCR	Screening	2013-04-30	2013-05-01	SCREENING	
F	Fasted	2013-05-01	2013-05-15	PERIOD 1	
WO	Wash Out	2013-05-15	2013-05-29	WASHOUT	
NF	Non-Fasted	2013-05-29	2013-06-14	PERIOD 2	
FU	Follow-Up	2013-06-14	2013-06-14	FOLLOW-UP	
Vital Signs					
VISITNUM	VISIT	VSDTC	EPOCH	Adverse Events	
1	Run-In	2013-04-01	RUN-IN	AETERM	AESTDTC
2	Screening	2013-04-30	SCREENING	HEADACHE	2013-04-02
3	Period 1 Day 1	2013-05-01	PERIOD 1	VOMITING	2013-05-01
4	Period 1 Day 7		PERIOD 1	NAUSEA	2013-05-02
5	Period 1 Day 14	2013-05-15	WASHOUT	HEAD PAIN	2013-06-07
6	Period 2 Day 1	2013-05-29	PERIOD 2		PERIOD 2
7	Period 2 Day 7	2013-06-05	PERIOD 2		
8	Period 2 Day 14	2013-06-12	PERIOD 2		
9	Follow up	2013-06-14	FOLLOW-UP		

Example 3 – Date is missing

Unclear when
adverse event
started so
EPOCH can't
be assigned

Source Data									
Subject Visits			Exposure						
VISITNUM	VISIT	SVSTDTC		EXTRT	EXSTDTC	EXENDTC			
1	Run-In	2013-04-01		DRUG A	2013-05-01	2013-05-01			
2	Screening	2013-04-30		DRUG A	2013-05-29	2013-05-29			
3	Period 1 Day 1	2013-05-01							
4	Period 1 Day 7	2013-05-08							
5	Period 1 Day 14	2013-05-15							
6	Period 2 Day 1	2013-05-29							
7	Period 2 Day 7	2013-06-05							
8	Period 2 Day 14	2013-06-12							
9	Follow up	2013-06-14							
SDTM									
Subject Elements									
ETCD	ELEMENT	SESTDTC	SEENDTC	EPOCH					
RI	Run In	2013-04-01	2013-04-30	RUN-IN					
SCR	Screening	2013-04-30	2013-05-01	SCREENING					
F	Fasted	2013-05-01	2013-05-15	PERIOD 1					
WO	Wash Out	2013-05-15	2013-05-29	WASHOUT					
NF	Non-Fasted	2013-05-29	2013-06-14	PERIOD 2					
FU	Follow-Up	2013-06-14	2013-06-14	FOLLOW-UP					
Vital Signs			Adverse Events						
VISITNUM	VISIT	SVSTDTC	EPOCH	AETERM	AESTDTC	AEENDTC	EPOCH		
1	Run-In	2013-04-01	RUN-IN	HEADACHE	2013-04-02	2013-04-02	RUN-IN		
2	Screening	2013-04-30	SCREENING	VOMITING	2013-05-01	2013-05-01	PERIOD 1		
3	Period 1 Day 1	2013-05-01	PERIOD 1	NAUSEA		2013-05-02			
4	Period 1 Day 7	2013-05-08	PERIOD 1	HEAD PAIN	2013-06-07	2013-06-07	PERIOD 2		
5	Period 1 Day 14	2013-05-15	WASHOUT						
6	Period 2 Day 1	2013-05-29	PERIOD 2						
7	Period 2 Day 7	2013-06-05	PERIOD 2						
8	Period 2 Day 14	2013-06-12	PERIOD 2						
9	Follow up	2013-06-14	FOLLOW-UP						

Example 4 – Partial Date 1

Partial date is enough to determine EPOCH in this case

Source Data						
Subject Visits			Exposure			
VISITNUM	VISIT	SVSTDTC	EXTRT	EXSTDTC	EXENDTC	
1	Run-In	2013-04-01	DRUG A	2013-05-01	2013-05-01	
2	Screening	2013-04-30	DRUG A	2013-05-29	2013-05-29	
3	Period 1 Day 1	2013-05-01				
4	Period 1 Day 7	2013-05-08				
5	Period 1 Day 14	2013-05-15				
6	Period 2 Day 1	2013-05-29				
7	Period 2 Day 7	2013-06-05				
8	Period 2 Day 14	2013-06-12				
9	Follow up	2013-06-14				
SDTM						
Subject Elements						
ETCD	ELEMENT	SESTDTC	SEENDTC	EPOCH		
RI	Run In	2013-04-01	2013-04-30	RUN-IN		
SCR	Screening	2013-04-30	2013-05-01	SCREENING		
F	Fasted	2013-05-01	2013-05-15	PERIOD 1		
WO	Wash Out	2013-05-15	2013-05-29	WASHOUT		
NF	Non-Fasted	2013-05-29	2013-06-14	PERIOD 2		
FU	Follow-Up	2013-06-14	2013-06-14	FOLLOW-UP		
Vital Signs			Adverse Events			
VISITNUM	VISIT	VSTDTC	EPOCH	AETERM	AESTDTC	EPOCH
1	Run-In	2013-04-01	RUN-IN	HEADACHE	2013-04	RUN-IN
2	Screening	2013-04-30	SCREENING	VOMITING	2013-05-01	PERIOD 1
3	Period 1 Day 1	2013-05-01	PERIOD 1	NAUSEA	2013-05-02	PERIOD 1
4	Period 1 Day 7	2013-05-08	PERIOD 1	HEAD PAIN	2013-06-07	PERIOD 2
5	Period 1 Day 14	2013-05-15	WASHOUT			
6	Period 2 Day 1	2013-05-29	PERIOD 2			
7	Period 2 Day 7	2013-06-05	PERIOD 2			
8	Period 2 Day 14	2013-06-12	PERIOD 2			
9	Follow up	2013-06-14	FOLLOW-UP			

Example 5 – Partial Date 2

Partial date used to determine EPOCH by using conservative approach that they were on Treatment in PERIOD 1 & 2

Document in Reviewer's guide and consult with review division on best way to approach

Source Data						
Subject Visits			Exposure			
VISITNUM	VISIT	SVSTDTC	EXTRT	EXSTDTC	EXENDTC	
1	Run-In	2013-04-01	DRUG A	2013-05-01	2013-05-01	
2	Screening	2013-04-30	DRUG A	2013-05-29	2013-05-29	
3	Period 1 Day 1	2013-05-01				
4	Period 1 Day 7	2013-05-08				
5	Period 1 Day 14	2013-05-15				
6	Period 2 Day 1	2013-05-29				
7	Period 2 Day 7	2013-06-05				
8	Period 2 Day 14	2013-06-12				
9	Follow up	2013-06-14				
SDTM						
Subject Elements						
ETCD	ELEMENT	SESTDTC	SEENDTC	EPOCH		
RI	Run In	2013-04-01	2013-04-30	RUN-IN		
SCR	Screening	2013-04-30	2013-05-01	SCREENING		
F	Fasted	2013-05-01	2013-05-15	PERIOD 1		
WO	Wash Out	2013-05-15	2013-05-29	WASHOUT		
NF	Non-Fasted	2013-05-29	2013-06-14	PERIOD 2		
FU	Follow-Up	2013-06-14	2013-06-14	FOLLOW-UP		
Vital Signs			Adverse Events			
VISITNUM	VISIT	VSTDTC	EPOCH	AETERM	AESTDTC	EPOCH
1	Run-In	2013-04-01	RUN-IN	HEADACHE	2013-04-02	RUN-IN
2	Screening	2013-04-30	SCREENING	VOMITING	2013-05-01	PERIOD 1
3	Period 1 Day 1	2013-05-01	PERIOD 1	NAUSEA	2013-05	PERIOD 1
4	Period 1 Day 7	2013-05-08	PERIOD 1	HEAD PAIN	2013-06	PERIOD 2
5	Period 1 Day 14	2013-05-15	WASHOUT			
6	Period 2 Day 1	2013-05-29	PERIOD 2			
7	Period 2 Day 7	2013-06-05	PERIOD 2			
8	Period 2 Day 14	2013-06-12	PERIOD 2			
9	Follow up	2013-06-14	FOLLOW-UP			

Example 6 – Observation outside of planned event

SE updated so record added with Element null to assign EPOCH to record outside of planned events

Source Data			Exposure		
Subject Visits					
VISITNUM	VISIT	SVSTDTC	EXTRT	EXSTDTC	EXENDTC
1	Run-In	2013-04-01	DRUG A	2013-05-01	2013-05-01
2	Screening	2013-04-30	DRUG A	2013-05-29	2013-05-29
3	Period 1 Day 1	2013-05-01			
4	Period 1 Day 7	2013-05-08			
5	Period 1 Day 14	2013-05-15			
6	Period 2 Day 1	2013-05-29			
7	Period 2 Day 7	2013-06-05			
8	Period 2 Day 14	2013-06-12			
9	Follow up	2013-06-14			
SDTM					
Subject Elements					
ETCD	ELEMENT	SESTDTC	SEENDTC	EPOCH	
RI	Run In	2013-04-01	2013-04-30	RUN-IN	
SCR	Screening	2013-04-30	2013-05-01	SCREENING	
F	Fasted	2013-05-01	2013-05-15	PERIOD 1	
WO	Wash Out	2013-05-15	2013-05-29	WASHOUT	
NF	Non-Fasted	2013-05-29	2013-06-14	PERIOD 2	
FU	Follow-Up	2013-06-14	2013-06-14	FOLLOW-UP	
Vital Signs					
VISITNUM	VISIT	VSTDTC	EPOCH	Adverse Events	
1	Run-In	2013-04-01	RUN-IN	AETERM	AESTDTC
2	Screening	2013-04-30	SCREENING	HEADACHE	2013-04-02
3	Period 1 Day 1	2013-05-01	PERIOD 1	VOMITING	2013-05-01
4	Period 1 Day 7	2013-05-08	PERIOD 1	NAUSEA	2013-05-02
5	Period 1 Day 14	2013-05-15	WASHOUT	HEAD PAIN	2013-07-15
6	Period 2 Day 1	2013-05-29	PERIOD 2		POST FOLLOW-UP
7	Period 2 Day 7	2013-06-05	PERIOD 2		
8	Period 2 Day 14	2013-06-12	PERIOD 2		
9	Follow up	2013-06-14	FOLLOW-UP		

Subject Elements					
ETCD	ELEMENT	SESTDTC	SEENDTC	EPOCH	SVUPDES
RI	Run In	2013-04-01	2013-04-30	RUN-IN	
SCR	Screening	2013-04-30	2013-05-01	SCREENING	
F	Fasted	2013-05-01	2013-05-15	PERIOD 1	
WO	Wash Out	2013-05-15	2013-05-29	WASHOUT	
NF	Non-Fasted	2013-05-29	2013-06-14	PERIOD 2	
FU	Follow-Up	2013-06-14	2013-06-14	FOLLOW-UP	
UNPLAN		2013-06-14	2013-07-15	POST FOLLOW-UP	After Study discontinuation

Example 7 – Considering Exposure Data

May need to use Exposure data. In this case first dose is after Period 1 Day 1 so this changes the Elements and Epoch

Source Data						
Subject Visits			Exposure			
VISITNUM	VISIT	SVSTDTC	EXTRT	EXSTDTC	EXENDTC	
1	Run-In	2013-04-01	DRUG A	2013-05-02	2013-05-02	
2	Screening	2013-04-30	DRUG A	2013-05-30	2013-05-29	
3	Period 1 Day 1	2013-05-01				
4	Period 1 Day 7	2013-05-08				
5	Period 1 Day 14	2013-05-15				
6	Period 2 Day 1	2013-05-29				
7	Period 2 Day 7	2013-06-05				
8	Period 2 Day 14	2013-06-12				
9	Follow-up	2013-06-14				
SDTM						
Subject Elements						
ETCD	ELEMENT	SESTDTC	SEENDTC	EPOCH		
RI	Run In	2013-04-01	2013-04-30	RUN-IN		
SCR	Screening	2013-04-30	2013-05-02	SCREENING		
F	Fasted	2013-05-02	2013-05-15	PERIOD 1		
WO	Wash Out	2013-05-15	2013-05-30	WASHOUT		
NF	Non-Fasted	2013-05-30	2013-06-14	PERIOD 2		
FU	Follow-Up	2013-06-14	2013-06-14	FOLLOW-UP		
Vital Signs			Adverse Events			
VISITNUM	VISIT	VSDTC	EPOCH	AETERM	AESTDTC	EPOCH
1	Run-In	2013-04-01	RUN-IN	HEADACHE	2013-04-02	RUN-IN
2	Screening	2013-04-30	SCREENING	VOMITING	2013-05-01	SCREENING
3	Period 1 Day 1	2013-05-01	SCREENING	NAUSEA	2013-05-02	PERIOD 1
4	Period 1 Day 7	2013-05-08	PERIOD 1	HEAD PAIN	2013-06-07	PERIOD 2
5	Period 1 Day 14	2013-05-15	WASHOUT			
6	Period 2 Day 1	2013-05-29	PERIOD 2			
7	Period 2 Day 7	2013-06-05	PERIOD 2			
8	Period 2 Day 14	2013-06-12	PERIOD 2			
9	Follow-up	2013-06-14	FOLLOW-UP			

Recap of both best practices

VISITNUM for unscheduled visits

- ▶ Create TV and SV first
- ▶ Sort SV data chronologically and add 0.01 to VISITNUM of previous planned visit for each unplanned visit that occurs next
- ▶ Using the dates assign VISIT/VISITNUM to necessary SDTM data by comparing dates

Epoch variable

- ▶ Create TA, TE, TV and SE first
- ▶ In clinical observation level data use -STDTC/--DTC to compare with SESTDTC/SEENDTC in SE and assign EPOCH from SE
- ▶ Do not impute date or time when assigning EPOCH

Links

- ▶ PhUSE White Paper

http://www.phusewiki.org/wiki/index.php?title=VISITNUM_and_EPOCH

- ▶ Study Data Technical Conformance Guide

<http://www.fda.gov/downloads/ForIndustry/DataStandards/StudyDataStandards/UCM384744.pdf>

Thank you!

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