Best Practices - Assigning VISITNUM to Unscheduled Visits and Assigning EPOCH to Observations

One of the projects within The Optimizing the Use of Data Standards PhUSE CSS Working Group is Best Practices for Standards Implementation. Within this project, a working group was formed to address practices for assigning VISITNUM to unscheduled visits and methods for defining EPOCH and Trial Elements. This document addresses these standards.

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The use of the word 'unscheduled' and 'unplanned' are synonymous in this document. The PhUSE CSS Working Group references unscheduled visits while the SDTMIG[1] references unplanned visits.

Challenges

Assigning VISITNUM values to unscheduled visits across all datasets so they sort chronologically and assigning EPOCH values to observations in a general observation class domain can be especially challenging when scenarios which are not addressed in the SDTMIG[1] are encountered. This document focuses specifically on challenges represented by the use cases given within this document:

Assigning VISITNUM

Scenarios addressed in this document include the following:

- Unscheduled observation dates are partial or missing
- Unscheduled observation date is the same date as the planned visit

Assigning EPOCH

- Use Case 1:
  - Observation date is missing or is a partial date which could be assigned to more than one EPOCH (i.e. either a single treatment or a single non-treatment EPOCH, more than one treatment, or more than one non-treatment EPOCH).
- Use Case 2:
  - Observation date fall during a period of time which is not a planned element in the trial.

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Assigning VISITNUM

Background

Section 4.1.4.5 of the SDTMIG[1] provides two options for populating VISITNUM for unplanned visits. The easiest method of populating VISITNUM for unplanned visits is to assign the same value (e.g., 99) to all unplanned visits, but this method will provide no differentiation between the unplanned visits and does not provide chronological sorting. Methods that provide a one-to-one relationship between visits and values of VISITNUM, that are consistent across domains, and that assign VISITNUM values that sort chronologically require more work and must be applied after all a subject's unplanned visits are known.

This section also specifies that VISIT may be left null or may be populated with a generic value (e.g., "Unplanned") for all unplanned visits, or individual values may be assigned to different unplanned visits.

Section 5.3.2.1 of the SDTMIG[1] specifies that records for unplanned visits should be included in the SV (Subject Visits) domain. For unplanned visits, SVUPDES should be populated with a description of the reason for the unplanned visit.

The scope of this document is limited to actual unplanned visits. Presumably, observations collected out of the schedule defined in the protocol will be assigned to a planned visit number in the data collection system.

Recommendations for Managing Solutions (Assigning VISITNUM)

1. Recommended approach is to assign VISITNUM values to unplanned visits that are consistent across all domains and which will sort chronologically, when possible, across all domains for a subject.
2. The recommended approach of this working group is to leave the VISIT value for unplanned visits as null.
3. Unplanned visits are inserted in chronological order by incrementing the VISITNUM value as the previous visit's VISITNUM + .1 (or + .01, etc. as needed) for that subject.
    1. In order to accomplish this, all VISITNUM/VISIT values and corresponding dates for a subject across all datasets need to be considered. There are various approaches which could be used to accomplish this. Regardless of the approach, the unplanned VISIT/VISITNUM values and dates need to be assembled from all the general observation class domains (e.g., one method might be to create a master look-up table) to be used to re-assign the VISITNUM to the unplanned visits in all datasets. This assembled set may be used as the basis for the creation of the SV (Subject Visits) dataset and the SV dataset could then be used as the master look-up table.
4. No derivation/imputation of partial or missing unplanned observation dates should be performed.
5. For partial unplanned observation dates, the VISITNUM should be assigned based on chronology of known date parts (e.g., 2013-06 is chronologically after 2013-05-17).
6. If it is not possible to determine chronology of a partial unplanned observation date or if the unplanned observation date is completely missing, some generic VISITNUM identifier, such as 999, should be assigned.
7. For unplanned visits with the same date or partial date, or 2 or more unplanned visits with a completely missing observation date, it is recommended that they be assigned the same VISITNUM value. In the SV domain, for the single record representing this unplanned VISITNUM, a description of each of the types of data (e.g., "ECG and Laboratory Test") should be provided in the variable SVUPDES (Description of Unplanned Visit). Otherwise, unplanned visits should not be combined.
8. For multiple unplanned visits which need to be assigned a generic VISITNUM identifier (due to not being able to determine chronology) for a subject, if the date parts are different (e.g., "2012" is different than "2012-01"; "" is different than "2013-05") all VISITNUM values should be incremented (e.g., 999.01, 999.02, etc.). However, if there is only 1 generic VISITNUM identifier assigned for a subject or the date parts are identical, a single VISITNUM should be assigned without incrementing (e.g., 999). The convention for assigning decimal points, for visits which cannot be inserted due to partial dates, should be described in the Reviewer's Guide.
9. For the case when unplanned observation date falls into the same date as a planned visit (i.e. the observation is recorded on an Unscheduled CRF regardless of whether this is a completely unplanned measurement/event or a repetitive test) the sponsor may use one of two approaches:
    1. The unplanned visit VISITNUM may be incremented as the planned visit VISITNUM + .1 (or + .01, etc. as needed). The advantages of this approach are: 1) the data will be presented 'as collected' 2) it will be clearly indicated that the measurement was unplanned since the reason (if collected) can be presented in SVUPDES (Description of Unplanned Visit) in the SV domain. However the disadvantage of this approach is that it may disrupt the chronology if the time of the unscheduled observation falls between the start and end time of the scheduled visit, or if some scheduled measurements have a timestamp past the unscheduled time.
    2. Assign the scheduled VISITNUM/VISIT to the unscheduled observation. This will ensure the undisrupted chronology, while the reason for the unplanned/repetitive measurement (if collected) may be presented in the Comments domain. However, to ensure transparency, it is highly recommended to set an 'Unscheduled' flag for such observations in the supplemental qualifier dataset.

10. Producers of the data should be sure to check the sort order of the final dataset after the unplanned visits are inserted in to be sure it is represented chronologically. In some cases, the example dataset keys specified in the SDTMIG may need to be altered (see SDTMIG section 3.2.1.1 Primary Keys for more information).

Use Case Example (Assigning VISITNUM)

This table represents selected columns and rows from the LB, EG, and SV domains for a single subject in order to illustrate the following:

LB Row	EG Row	SV Row	Explanation	Per Recommendation Number
7		**4**	The unplanned lab date of 2013-05-27 is the same as the Week 2 visit date. In order to differentiate between the planned and unplanned visit, VISITNUM is assigned as 2.01. SVUPDES is populated with descriptive text showing which domain had this visit.	**9**
8		**5**	The unplanned lab date of 2013-05-29 falls between the planned visit dates of Week 2 and Week 3. VISITNUM is assigned as 2.02 because 2.01 has already been assigned. SVUPDES is populated with descriptive text showing which domain had this visit.	**3**
10	**5**	**7**	The unplanned lab and ecg date of 2013-06-03 is the same as the Week 3 visit date. In order to differentiate between the planned and unplanned visit, VISITNUM is assigned as 3.01. SVUPDES is populated with descriptive text showing which domains had this visit.	**7 and 9.1**
12		**6**	The unplanned lab date of 2013-06-10 is the same as the Week 4 visit date. In order to differentiate between the unplanned and planned visit, a record in SUPPLB is necessary to ensure transparency.	**7 and 9.2**
13		**9**	The chronology of the partial unplanned lab date of 2013-07 falls between the planned visit dates of Week 4 and Follow-up. VISITNUM is assigned as 4.01. SVUPDES is populated with descriptive text showing which domain had this visit.	**4 and 5**
1	**1**	**11**	The unplanned lab and ecg dates are missing, and therefore chronology cannot be determined. VISITNUM is assigned a generic value of 999.01*. SVUPDES is populated with descriptive text showing which domains had this visit.	**4, 6, and 8**

2		**12**	The partial unplanned lab date of 2013-05 does not provide enough information to allow chronology to be determined because Screening and Week 2 occurred in the same month. VISITNUM is assigned a generic value of 999.02*. SVUPDES is populated with descriptive text showing which domain had this visit.	**4 and 6**
4		**2**	The unplanned lab date of 2013-05-23 falls within the screening visit start and stop dates. However, in the lab dataset the unplanned visit will sort higher than the scheduled visit.	**9 and 10**

* Note that if there were only one unplanned visit which was re-assigned a generic value for VISITNUM, this value could simply be 999.

LB (Laboratory Test Results)										
Row	**Raw Visit**	**USUBJID**	**LBTESTCD**	**LBSEQ**	**LBTEST**	**LBORRES**	**LBORRESU**	**VISITNUM**	**VISIT**	**LBDTC**
1	UNPLANNED	001-1002	ALB	13	Albumin	48	g/L	999.01		
2	UNPLANNED	001-1002	ALB	14	Albumin	45	g/L	999.02		2013-05
3	SCREENING	001-1002	ALB	1	Albumin	30	g/L	1	Screening	2013-05-20
4	UNPLANNED	001-1002	ALB	3	Albumin	22	g/L	1.01		2013-05-23
5	SCREENING	001-1002	ALB	2	Albumin	28	g/L	1	Screening	2013-05-25
6	WK2	001-1002	ALB	4	Albumin	52	g/L	2	Week 2	2013-05-27
7	UNPLANNED	001-1002	ALB	5	Albumin	50	g/L	2.01		2013-05-27
8	UNPLANNED	001-1002	ALB	6	Albumin	43	g/L	2.02		2013-05-29
9	WK3	001-1002	ALB	7	Albumin	37	g/L	3	Week 3	2013-06-03
10	UNPLANNED	001-1002	ALB	8	Albumin	27	g/L	3.01		2013-06-03
11	WK4	001-1002	ALB	9	Albumin	31	g/L	4	Week 4	2013-06-10
12	UNPLANNED	001-1002	ALB	10	Albumin	20	g/L	4	Week 4	2013-06-10
13	UNPLANNED	001-1002	ALB	11	Albumin	43	g/L	4.01		2013-07
14	FOLLOW-UP	001-1002	ALB	12	Albumin	55	g/L	20	Follow-up	2013-08-02

SUPPLB (Supplemental Laboratory Test Results)								
Row	**USUBJID**	**IDVAR**	**IDVARVAL**	**QNAM**	**QLABEL**	**QVAL**	**QORIG**	**QEVAL**
1	001-1002	LBSEQ	12	UNSCHEDULED	Unscheduled Lab	Y	eDT	

ECG (ECG Test Results)									
Row	**Raw Visit**	**USUBJID**	**EGTESTCD**	**EGTEST**	**EGORRES**	**EGORRESU**	**VISITNUM**	**VISIT**	**EGDTC**
1	UNPLANNED	001-1002	QTCF	QTcF – Fridericia's Correction Formula	481	msec	999.01		
2	SCREENING	001-1002	QTCF	QTcF – Fridericia's Correction Formula	446	msec	1	Screening	2013-05-21
3	WK2	001-1002	QTCF	QTcF – Fridericia's Correction Formula	498	msec	2	Week 2	2013-05-27
4	WK3	001-1002	QTCF	QTcF – Fridericia's Correction Formula	518	msec	3	Week 3	2013-06-03
5	UNPLANNED	001-1002	QTCF	QTcF – Fridericia's Correction Formula	500	msec	3.01		2013-06-03
6	WK4	001-1002	QTCF	QTcF – Fridericia's Correction Formula	470	msec	4	Week 4	2013-06-10
7	FOLLOW-UP	001-1002	QTCF	QTcF – Fridericia's Correction Formula	470	msec	20	Follow-up	2013-08-01

SV (Subject Visits)						
Row	**USUBJID**	**VISITNUM**	**VISIT**	**SVSTDTC**	**SVENDTC**	**SVUPDES**
1	001-1002	1	Screening	2013-05-20	2013-05-25	
2	001-1002	1.01		2013-05-23	2013-05-23	Lab Test
3	001-1002	2	Week 2	2013-05-27	2013-05-27	
4	001-1002	2.01		2013-05-27	2013-05-27	Lab Test
5	001-1002	2.02		2013-05-29	2013-05-29	Lab Test
6	001-1002	3	Week 3	2013-06-03	2013-06-03	
7	001-1002	3.01		2013-06-03	2013-06-03	ECG Test and Lab Test
8	001-1002	4	Week 4	2013-06-10	2013-06-10	
9	001-1002	4.01		2013-07	2013-07	Lab Test
10	001-1002	20	Follow-Up	2013-08-01	2013-08-02	
11	001-1002	999.01				ECG Test and Lab Test
12	001-1002	999.02		2013-05	2013-05	Lab Test

Assigning EPOCH

Background

When submitting datasets to the FDA, sponsors can find guidance from FDA[2,3] which states the following:

- The variable EPOCH should be included for every clinical subject-level observation (e.g., adverse events, laboratory, concomitant medications, exposure, vital signs). This will allow the reviewer to easily determine during which phase of the trial the observation occurred (e.g., screening, on-therapy, follow-up), as well as the actual intervention the subject experienced during that phase. Inclusion of ELEMENT and ETCD (element code) is desired as well, to help reviewers understand timing of events whose durations span multiple epochs. However, because of implementation challenges associated with this request, CDER is not yet requiring these for submission of SDTM data.
- Please include the variables EPOCH for every clinical subject-level observation (e.g., adverse events, laboratory, concomitant medications, exposure, vital signs). This will allow the reviewer to easily determine during which phase of the trial the observation occurred (e.g., screening, on-therapy, follow-up), as well as actual intervention the subject experienced during that phase.

EPOCH could be assigned using either one of two methods:

1. VISIT and/or VISITNUM
    a. This would be accomplished by comparison of the VISIT and/or VISITNUM values to protocol defined epochs corresponding to those visits.
    b. This method should only be used when the VISIT and/or VISITNUM reflects the point in time when the observation was collected (for findings) or started (for interventions and events).
    c. For unplanned visits, VISITNUM would need to be assigned prior to using this method.
2. --DTC(for findings)/--STDTC(for interventions and events)
    a. The --DTC/--STDTC would be compared to the SE (Subject Elements) domain SESTDTC and SEENDTC.
    b. Therefore, the SE domain must be created prior to using this method.

c. Per section 5 of the SDTMIG, since there are, by definition, no gaps between Elements, the value of SEENDTC for one Element will always be the same as the value of SESTDTC for the next Element. Therefore an observation should be assigned to an EPOCH if the –DTC/--STDTC is greater than or equal to the SESTDTC and less than the SEENDTC for that element (except for the last element for a subject where the date may equal the SEENDTC).

Section 5 of the SDTMIG specifies that if the sponsor decides that the subject's experience for a particular period of time cannot be represented with one of the planned Elements, then that period of time should be represented as an unplanned Element. In the SE domain, the value SEUPDES should be populated with a description of the unplanned Element and, if TAETORD is included, it should be null for unplanned elements. It also specifies that the sponsor will have to decide what value, if any, of EPOCH to assign SE records for unplanned Elements and in other cases where the subject's actual Elements deviate from the plan.

Please note that for historical data, such as medical history, where all of the observation dates are assumed to have occurred prior to the start of the study, it is recommended to exclude EPOCH from the domain.

Recommendations for Managing Solutions (Assigning EPOCH)

1. The preferred way of assigning EPOCH should always be by inserting the observation date into a relevant reference period. However, when chronology cannot be determined due to a missing or partial observation date, the VISIT and/or VISITNUM as defined by the protocol can be used as an alternative method of assigning the EPOCH in that domain. If that fails, the sponsor may use approaches described below. Any non-conventional approach to assigning EPOCH should be described in the Reviewer's Guide.

   When using the --DTC(for findings)/--STDTC(for interventions and events) method to assign EPOCH:

2. No derivation/imputation of partial or missing observation dates should be performed.
3. If the observation date is completely missing, EPOCH should be assigned as null.
4. For partial observation dates, the EPOCH should be assigned based on chronology of known date parts (e.g., 2013-06 is chronologically after 2013-05-17).
5. If based on the chronology of a partial observation date it is possible that it occurred in either a treatment or non-treatment epoch (but it cannot be determined which), the most conservative approach could be taken to assign EPOCH to the treatment phase. However, it is best to consult with the review division on how to handle this situation. The approach taken should be described in the Reviewer's Guide.
6. If based on the chronology of a partial observation date it is possible that it occurred in multiple treatment or multiple non-treatment epochs, the most conservative approach could be taken to assign EPOCH to the treatment phase. However, it is best to consult with the review division on how to handle this situation.
7. If an observation date falls into a period of time which is not a planned element in the trial (e.g., after treatment discontinuation/withdrawal of consent with no follow-up visits; or after the last follow-up visit) the TAETORD variable could be included in both the affected general observation class domain and the SE domain.
   a. The unplanned element could be added to the SE domain with SEUPDES populated to describe this unplanned element, and TAETORD could be populated for all SE records except the unplanned element record (as per SDTMIG TAETORD rules).
   b. In the affected general observation class domains any observation occurring during this unplanned time period could be assigned to the corresponding EPOCH in SE (for that unplanned ELEMENT) and TAETORD could be populated for all records in that domain except the unplanned element record. This will serve to highlight that the general observation class observation occurred during an unplanned element.

Use Case Examples (Assigning EPOCH)

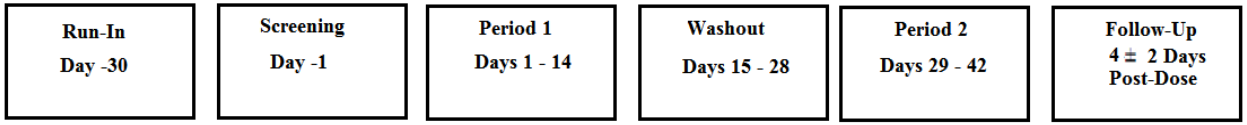
EPOCH Use Case 1:

- Observation date is missing or is a partial date which could not be assigned to one single EPOCH (i.e., could be assigned to more than one EPOCH).

The table below represents selected columns and rows from the VS, AE, and SE domains for a single subject in order to illustrate the following:

VS Row	AE Row	SE Row(s) to Which Compared	Explanation	Per Recommendation Number
2			The vital sign date is missing. However, EPOCH can be assigned based on VISIT since the protocol defines the PERIOD 1 EPOCH as Days 1 – 14.	**1**
10			The unplanned vital sign date is completely missing. Neither the date nor the visit can be used to assign EPOCH. Therefore, EPOCH will be assigned as null	**2 and 3**
	1	**1**	The chronology of the partial AE start date falls in the RUN-IN EPOCH.	**2 and 4**
	3	**1, 2, 3, 4, and 5**	The chronology of the partial AE start date indicates that the observation could be associated with multiple epochs. Therefore, EPOCH could be assigned to a treatment EPOCH to be most conservative. However, it is important to consult with the review division to determine the best way to approach this situation.	**2 and 5**
	4	**5 and 6**	The chronology of the partial AE start date indicates that the observation could be associated with either a treatment or follow-up EPOCH. Therefore, EPOCH could be assigned to the treatment phase to be most conservative. However, it is important to consult with the review division to determine the best way to approach this situation.	**2 and 6**

** Planned EPOCHs for this Use Case are:



VS (Vital Signs)									
Row	**USUBJID**	**VSTESTCD**	**VSTEST**	**VSORRES**	**VSORRESU**	**VISITNUM**	**VISIT**	**VSDTC**	**EPOCH**
1	001-1002	TEMP	Temperature	34.7	C	1	Screening	2013-05-01	SCREENING
2	001-1002	TEMP	Temperature	36.2	C	2	Period 1 Day 1		PERIOD 1
3	001-1002	TEMP	Temperature	35.3	C	3	Period 1 Day 7	2013-05-08	PERIOD 1
4	001-1002	TEMP	Temperature	34.6	C	4	Period 1 Day 14	2013-05-16	PERIOD 1
5	001-1002	TEMP	Temperature	36.2	C	5	Period 2 Day 1	2013-05-29	PERIOD 2
6	001-1002	TEMP	Temperature	37.8	C	5.01		2013-05-30	PERIOD 2
7	001-1002	TEMP	Temperature	35.3	C	6	Period 2 Day 7	2013-06-07	PERIOD 2
8	001-1002	TEMP	Temperature	34.6	C	7	Period 2 Day 14	2013-06-13	PERIOD 2
9	001-1002	TEMP	Temperature	35.1	C	8	Follow up	2013-06-14	FOLLOW-UP
10	001-1002	TEMP	Temperature	34	C	999			

AE (Adverse Events)								
Row	**USUBJID**	**AESEQ**	**AETERM**	**AEDECOD**	**AESTDTC**	**AEENDTC**	**AEENRF**	**EPOCH**
1	001-1002	1	HEADACHE	Headache	2013-04	2013-04		RUNIN
2	001-1002	2	VOMITING	Vomiting	2013-05-19	2013-05-23		WASHOUT
3	001-1002	3	NAUSEA	Nausea	2013-05		ONGOING	PERIOD 1
4	001-1002	4	HEAD PAIN	Headache	2013-06		ONGOING	PERIOD 2

SE (Subject Elements)							
Row	**USUBJID**	**ECTD**	**ELEMENT**	**SESTDTC**	**SEENDTC**	**SEUPDES**	**EPOCH**
1	001-1002	RI	Run In	2013-04-01	2013-05-01		RUN-IN
2	001-1002	SCR	Screening	2013-05-01	2013-05-02		SCREENING
3	001-1002	F	Fasted	2013-05-02	2013-05-16		PERIOD 1
4	001-1002	WO	Wash Out	2013-05-16	2013-05-29		WASHOUT
5	001-1002	NF	Non-Fasted	2013-05-29	2013-06-14		PERIOD 2
6	001-1002	FU	Follow Up	2013-06-14	2013-06-14		FOLLOW-UP

EPOCH Use Case 2:

- Observation date falls during a period of time which is not a planned element in the trial.

Example 1:
Observation date falls during a treatment delay for which there is subsequent treatment discontinuation.

The table below represents selected columns and rows from the SE, LB, SV and DS for a single subject in order to illustrate the following:

The subject has 2 cycles and the last treatment date (TRTDTC) was 2014-02-01.
Cycle 3 would have started on 2014-02-21, but the subject had an AE, and therefore treatment was delayed.
Since the AE did not resolve after 14 days, a Lab visit was performed. Subsequently, the physician decided to discontinue treatment on 2014-03-14. The subject withdrew consent and did not continue to any FU visit.

LB Row	SV Row	DS Row	SE Row	Explanation	Per Recommendation Number
2	**3**	**2,3**	**3**	Additional unplanned element "Treatment delay" added. During treatment delay the subject was considered by the investigator to be on treatment (no treatment termination pages were completed and all data collected during treatment delay period are collected within the treatment visit CRF pages). The Unplanned Element can be associated with the treatment epoch. Both visit numbers were included as collected on the CRF, when in theory they might be re-assigned to FU and End of Study. However re-assigning would have a data traceability issue and is therefore not recommended.	**7**

LB (Laboratory Test Results)										
Row	**USUBJID**	**LBTESTCD**	**LBTEST**	**LBORRES**	**LBORRESU**	**EPOCH**	**VISITNUM**	**VISIT**	**LBDTC**	**TAETORD**
1	001-1002	HGB	Hemoglobin	10	g/dL	Treatment	2	Cycle 2	2014-02-01	2
2	001-1002	HGB	Hemoglobin	6	g/dL	Treatment	3	Cycle 3	2014-03-07	

SV (Subject Visits)							
Row	**USUBJID**	**EPOCH**	**VISITNUM**	**VISIT**	**SVSTDTC**	**SVENDTC**	**TAETORD**
1	001-1002	Screening	1	Screening	2014-01-01	2014-01-01	1
2	001-1002	Treatment	2	Cycle 2	2014-02-01	2014-02-01	2
3	001-1002	Treatment	3	Cycle 3	2014-02-21	2014-02-21	
4	001-1002	Treatment	99	End of Treatment	2014-03-14	2014-03-14	2

DS (Subject Disposition)							
Row	**USUBJID**	**DSCAT**	**DSSCAT**	**DSDECOD**	**EPOCH**	**DSSTDTC**	**TAETORD**
1	001-1002	PROTOCOL MILESTONE		RANDOMIZATION	Screening	2013-11-11	1
2	001-1002	DISPOSITION EVENT	END OF TREATMENT	AE	Treatment	2014-02-01	2
3	001-1002	DISPOSITION EVENT	END OF STUDY	CONSENT WITHDRAWAL	Treatment	2014-03-14	

SE (Subject Elements)								
Row	**USUBJID**	**ECTD**	**ELEMENT**	**SESTDTC**	**SEENDTC**	**TAETORD**	**EPOCH**	**SEUPDES**
1	001-1002	SCR	Screening	2014-01-01	2014-01-10	1	Screening	
2	001-1002	TRT	Treatment	2014-01-10	2014-02-21	2	Treatment	
3	001-1002	UNPLAN		2014-02-21	2014-03-14		Treatment	Treatment Delay

Example 2:

Observation date falls after treatment discontinuation (e.g., after treatment discontinuation/withdrawal of consent after which there were no follow-up visits; or after the last follow-up visit).

The table below represents selected columns and rows from the SE, LB, SV and DS for a single subject in order to illustrate the following:

AE Row	SV Row	SE Row	Explanation	Per Recommendation Number
1	**4**	**4**	Additional unplanned element "After study discontinuation" added.	**7**

AE (Adverse Events)								
Row	**USUBJID**	**AESEQ**	**AETERM**	**AEDECOD**	**AESTDTC**	**AEENDTC**	**AEENRF**	**EPOCH**
1	001-1002	1	Rash	Rash	2013-04-01		Ongoing	Post Follow Up

SV (Subject Visits)							
Row	**USUBJID**	**VISIT NUM**	**VISIT**	**EPOCH**	**SVSTDTC**	**SVENDTC**	**SVUPDES**
1	001-1002	1	Screening	Screening	2014-01-01	2014-01-01	
2	001-1002	2	Cycle 1	Treatment	2014-01-10	2014-01-10	
3	001-1002	801	Follow Up	Follow-Up	2014-03-14	2014-03-14	
4	001-1002	999			2013-04-01	2013-04-01	After study discontinuation

SE (Subject Elements)							
Row	**USUBJID**	**ECTD**	**ELEMENT**	**SESTDTC**	**SEENDTC**	**SEUPDES**	**EPOCH**
1	001-1002	SCR	Screening	2014-01-01	2014-01-10		Screening
2	001-1002	TRT	Treatment	2014-01-10	2014-03-14		Treatment
3	001-1002	FU	Follow Up	2014-03-14	2014-03-14		Follow Up
4	001-1002	UNPLAN	Unplanned	2014-03-14	2013-04-01	After study discontinuation	Post Follow Up

[1] SDTM Implementation Guide v3.2 [http://www.cdisc.org/system/files/all/standard_category/application/pdf/sdtmig_20v3.2_20noportfolio.pdf]

[2] Draft Study Data Technical Conformance Guide [http://www.fda.gov/downloads/ForIndustry/DataStandards/StudyDataStandards/UCM384744.pdf]

[3] CDER Common Data Standards Issues Document (Version 1.1/December 2011)
[http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/UCM254113.pdf]