

LET’S VISIT – “THE VISITS”: SCHEDULED/UNSCHEDULED, WINDOWING & CLINICAL ENCOUNTERS



To expect the unexpected, a hallmark of modern thinking, requires us to plan for deviations in study protocol compliance. Trial subjects are rarely 100% compliant in following the requirements outlined in the protocol. We see that the protocol clearly defines the expected visits for a study but what do we do with the unexpected visits we find in the data? Recognizing these unplanned visits and having a plan for how they fit among the scheduled visits is vital to the success of reporting the data. Telephone visits, diaries, and unscheduled encounters should be named and placed among scheduled visits based on the analysis requirements for studies. There are two common approaches to how to handle these unplanned visits: **windowing** and **clinical encounters**. This poster will explore both the visit windowing and clinical encounters methods for handling ‘Unscheduled’ visits along with the pros and cons of these different methods.

Windowing & Clinical Encounters:

Generally, visit windows are derived in ADaM but they are also done in SDTM in cases where beginning and end of each visit are not collected. In such cases visits can be derived in SDTM.

Forward Windowing:

Collected visit date will be the start of the visit and the visit end date will be the day before the next visit’s start date or the discontinuation date.

Backward Windowing:

Collected visit will be the visit end date and start date will be the day after the previous visit’s end date.

Clinical Encounters:

Migrating visits as is – No derivation!! No Hassle!!

Understanding With An Example:

The 3 raw datasets below are used to map visits in SV in 3 different methods (Forward/backward windowing and clinical encounters)

Raw Data: VIS

SITE	SUBJECT	VISNUM	VISDT
100	1234	1	2011-04-29
100	1234	2	2011-05-07
100	1234	3	2011-05-21
100	1234	4	2011-06-18
100	1234	5	2011-08-21
100	1234	6	2011-11-19
100	1234	7	2012-02-19
100	1234	8	2012-05-14
100	1234	9	2012-09-09

Raw Data: LABS

SITE	SUBJECT	VISNUM	VISTYP	SAMPCOLLDT	LABCAT	LABTESTCD	LABRESULT
100	1234	7	U	2012-03-03	CHEM	AST	33
100	1234	7	U	2012-03-03	CHEM	ALT	57
100	1234	9	S	2012-09-09	CHEM	AST	19
100	1234	9	S	2012-09-09	CHEM	ALT	36

Raw Data: SCAN

SITE	SUBJECT	VISNUM	VISTYP	SCANDT	RES1
100	1234	2	S	2011-05-14	18.5
100	1234	4	S	2011-06-18	18.4
100	1234	5	S	2011-08-27	20.1
100	1234	6	S	2011-11-19	18.9
100	1234	8	S	2012-05-12	17.1
100	1234	9	S	2012-09-08	22.1

Forward Windowing:

(Preferred In Oncology studies where the visits are conducted in alignment w/ the treatment)

STUDYID	DOMAIN	USUBJID	VISITNUM	VISIT	EPOCH	SVSTDTCT	SVENDTCT
ABC-DEF	SV	ABC-DEF-100-1234	1	VISIT 1	SCREENING	2011-04-29	2011-05-13
ABC-DEF	SV	ABC-DEF-100-1234	2	VISIT 2	RUN-IN	2011-05-14	2011-05-20
ABC-DEF	SV	ABC-DEF-100-1234	3	VISIT 3	TREATMENT	2011-05-21	2011-06-17
ABC-DEF	SV	ABC-DEF-100-1234	4	VISIT 4	TREATMENT	2011-06-18	2011-08-26
ABC-DEF	SV	ABC-DEF-100-1234	5	VISIT 5	TREATMENT	2011-08-27	2011-11-18
ABC-DEF	SV	ABC-DEF-100-1234	6	VISIT 6	TREATMENT	2011-11-19	2012-02-18
ABC-DEF	SV	ABC-DEF-100-1234	7	VISIT 7	TREATMENT	2012-02-19	2012-05-13
ABC-DEF	SV	ABC-DEF-100-1234	7.01	UNSCHEDULED 7.01	TREATMENT	2012-03-03	2012-03-03
ABC-DEF	SV	ABC-DEF-100-1234	8	VISIT 8	TREATMENT	2012-05-14	2012-09-08
ABC-DEF	SV	ABC-DEF-100-1234	9	FOLLOW-UP 1	FOLLOW-UP	2012-09-09	2012-09-09

SVSTDTCT: The first visit date collected on the CRF is mapped to SVSTDTCT.

SVENDTCT: The SVENDTCT is mapped from the next visit’s start date minus one.

Backward Windowing:

(Preferred in **diabetes** studies where the subjects will start the dosing after the finish of the visit)

STUDYID	DOMAIN	USUBJID	VISITNUM	VISIT	EPOCH	SVSTDTCT	SVENDTCT
ABC-DEF	SV	ABC-DEF-100-1234	1	VISIT 1	SCREENING	2011-04-29	2011-04-29
ABC-DEF	SV	ABC-DEF-100-1234	2	VISIT 2	RUN-IN	2011-04-30	2011-05-14
ABC-DEF	SV	ABC-DEF-100-1234	3	VISIT 3	TREATMENT	2011-05-15	2011-05-21
ABC-DEF	SV	ABC-DEF-100-1234	4	VISIT 4	TREATMENT	2011-05-22	2011-06-18
ABC-DEF	SV	ABC-DEF-100-1234	5	VISIT 5	TREATMENT	2011-06-19	2011-08-27
ABC-DEF	SV	ABC-DEF-100-1234	6	VISIT 6	TREATMENT	2011-08-28	2011-11-19
ABC-DEF	SV	ABC-DEF-100-1234	7	VISIT 7	TREATMENT	2011-11-20	2012-02-19
ABC-DEF	SV	ABC-DEF-100-1234	7.01	UNSCHEDULED 7.01	TREATMENT	2012-03-03	2012-03-03
ABC-DEF	SV	ABC-DEF-100-1234	8	VISIT 8	TREATMENT	2012-02-20	2012-05-14
ABC-DEF	SV	ABC-DEF-100-1234	9	FOLLOW-UP 1	FOLLOW-UP	2012-05-15	2012-09-09

SVSTDTCT: The first visit date collected on the CRF is mapped to SVSTDTCT. If the CRF date for first visit is not collected then informed consent date is mapped. For second visit onwards, SVSTDTCT is set equal to the value in SVENDTCT of the prior visit plus one.

SVENDTCT: The end date is collected from the CRF visit date for that particular visit.

Comparison: Pros/Cons

Windowing	Clinical encounters
No concept of Unscheduled visits. Unscheduled visits are mapped in to scheduled windows.	Reports exact data. Unscheduled visits are exposed.
Though the scheduled and unscheduled are collected on the same day it can be assigned to the same window.	If scheduled and unscheduled are collected on the same day it is difficult to interpret.
Windowing does not allow for any gaps between the visits.	Gaps may be present between the visits as per the data collected.
It will be tedious to map the unscheduled visits separately, if required in analysis at a later point of time.	Identifying the unscheduled visits and naming them to fit with the scheduled visits will aid in good reporting of the data.

Clinical Encounters:

STUDYID	DOMAIN	USUBJID	VISITNUM	VISIT	EPOCH	SVSTDTCT	SVENDTCT
ABC-DEF	SV	ABC-DEF-100-1234	1	VISIT 1	SCREENING	2011-04-29	2011-04-29
ABC-DEF	SV	ABC-DEF-100-1234	2	VISIT 2	RUN-IN	2011-05-07	2011-05-14
ABC-DEF	SV	ABC-DEF-100-1234	3	VISIT 3	TREATMENT	2011-05-21	2011-05-21
ABC-DEF	SV	ABC-DEF-100-1234	4	VISIT 4	TREATMENT	2011-06-18	2011-06-18
ABC-DEF	SV	ABC-DEF-100-1234	5	VISIT 5	TREATMENT	2011-08-21	2011-08-27
ABC-DEF	SV	ABC-DEF-100-1234	6	VISIT 6	TREATMENT	2011-11-19	2011-11-19
ABC-DEF	SV	ABC-DEF-100-1234	7	VISIT 7	TREATMENT	2012-02-19	2012-02-19
ABC-DEF	SV	ABC-DEF-100-1234	7.01	UNSCHEDULED 7.01	TREATMENT	2012-03-03	2012-03-03
ABC-DEF	SV	ABC-DEF-100-1234	8	VISIT 8	TREATMENT	2012-05-12	2012-05-14
ABC-DEF	SV	ABC-DEF-100-1234	9	FOLLOW-UP 1	FOLLOW-UP	2012-09-08	2012-09-09

SVSTDTCT: Get all the scheduled visit dates from CRF and non-CRF findings and map the minimum date to start date for the first visit. Get all the unscheduled visits from CRF and non-CRF findings per subject by visit number and date to create sequence number for each record within the same visit number and set to SVSTDTCT. Arrange them according to the date and visit number and assign the unscheduled visit number with a decimal position.

SVENDTCT: Get all the scheduled visit dates from CRF and non-CRF findings and map the maximum date.

A Note On Unscheduled Numbering:

Easiest – Assign VISITNUM 99 to all unplanned visits and VISIT may be left null or assign a generic value (as “Unscheduled”) or individual values (may cause warning in Open CDISC report).

Ideal/Preferred - Add “0.01” to the previous scheduled VISITNUM so as to facilitate chronological sorting.

If there’s an unscheduled visit after Day 1 where VISITNUM is “1”, the unscheduled visit has a VISITNUM of “1.01”

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

Conclusion:

Visit windowing and clinical encounters can both be useful methods for handling scheduled and unscheduled visits. The nature of the clinical study and the needs of statistical analysis determine the suitability of one approach over the other. Visit windowing may suffice if a quick and easily reportable grouping of visits is desired but clinical encounters will have better traceability in SDTM and preserve the dataset for additional manipulation.

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