

Mapping of SV

Requirements of SV

- From SDTM IG 3.2
 - The Subject Visits domain consolidates information about the timing of subject visits that is otherwise spread over domains that include the visit variables (VISITNUM and possibly VISIT and/or VISITDY).

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	SV	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
VISITNUM	Visit Number	Num		Topic	1. Clinical encounter number. (Decimal numbering may be useful for inserting unplanned visits.) 2. Numeric version of VISIT, used for sorting.	Req
VISIT	Visit Name	Char		Synonym Qualifier	1. Protocol-defined description of clinical encounter. 2. May be used in addition to VISITNUM and/or VISITDY as a text description of the clinical encounter.	Perm
VISITDY	Planned Study Day of Visit	Num		Timing	Planned study day of the start of the visit based upon RFSTDTC in Demographics.	Perm
SVSTDTC	Start Date/Time of Visit	Char	ISO 8601	Timing	Start date/time for a Visit.	Exp
SVENDTC	End Date/Time of Visit	Char	ISO 8601	Timing	End date/time of a Visit.	Exp
SVSTDY	Study Day of Start of Visit	Num		Timing	Study day of start of visit relative to the sponsor-defined RFSTDTC.	Perm
SVENDY	Study Day of End of Visit	Num		Timing	Study day of end of visit relative to the sponsor-defined RFSTDTC.	Perm
SVUPDES	Description of Unplanned Visit	Char		Synonym Qualifier	Description of what happened to the subject during an unplanned visit.	Perm

Requirements of SV

- For unscheduled visits or measurements, numbers are often assigned values between two protocol-scheduled visits. These numbers should be distinct from other visit numbers but retain the chronological order (e.g. two unscheduled visits between visit 3 and visit 4 might be 3.1 and 3.2). The character form of the visit identifier may be UNSCHEDULED or a similar term.

(Study Data Specifications V2.2

<http://www.fda.gov/downloads/ForIndustry/DataStandards/StudyDataStandards/UCM312964.pdf>)

- Not available in new version of the document

Additions from OpenCDISC for SV

- Expects one to one mapping of VISIT and VISITNUM for **all** visits
 - according to SDTM IG this is only needed for planned visits
- Identifies Unscheduled Visits via the terms „UNSCHEd“, „Unsched“, „UNPLAN“ and „Unplan“

Mapping process of SV

- Visits need to be re-derived centrally for SV
- Process option 1:
 - Derive SV first and output interim data
 - merge interim dataset containing old and new Visit names with visit based datasets during their creation
- Process option 2:
 - Derive SV at the end
 - re-output the new visits in all visit based datasets