



SUPPSV

*SV IN PHASE I
STUDIES*

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SUPPSV

SV IN PHASE I STUDIES

- Part 1: SUPPSV
- CDISC SDTMIG 3.2 definition for SV
- Example 1 / with possible annotations
- Example 2 / with possible annotations
- Questions and Discussion
- Part 2: SV in phase I studies
- Visit Definition / Characteristics
- Continuous Procedures / Unscheduled Measurements
- Collection of visit dates

PART 1

SUPPSV

CDISC SDTMIG 3.2 DEFINITION FOR SV

sv.xpt, Subject Visits — Version 3.2., One record per subject per actual visit.

| 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 |

* Indicates variable may be subject to controlled terminology, (Parenthesis indicates CDISC/NCI codelist code value)

- Variables allowed to add for SV (special purpose domain):
 - Identifiers: --SEQ, --GRPID, --REFID, and --SPID
 - Timing: TAETORD, EPOCH, --DUR, all other seem unnecessary
- Variables not allowed to add (allowed for findings, interventions and events only) : --STAT, --REASND, --CAT

EXAMPLE 1 WITH ANNOTATIONS

To be annotated according to SDTMIG 3.2 and STDM 1.4

SV

Date of Visit

SVSTDTC

Fixed Unit:
DD/MMM/YYYY

Visit performed?

NOT SUBMITTED

Fixed Unit: Not Done

If the visit is not performed please specify the reason.

REASON in SUPPSV

To which record shall REASON in SUPPSV be linked when VISIT has not taken place?

EXAMPLE 1 WITH ANNOTATIONS II

SV DV

Date of Visit

SVSTDTC

Fixed Unit:
DD/MMM/YYYY

Visit performed?

NOT SUBMITTED

Fixed Unit: Not Done

If the visit is not performed please specify the reason.

NOT SUBMITTED

DVTERM

EXAMPLE 2 WITH ANNOTATIONS

SV be annotated according to SDTMIG 3.2 and STDM 1.4

Telephone Visit (TEL)

Visit Conducted by Telephone

1. Was Patient contacted by Telephone

CONTMETH in SUPPSV

**2. Reason, not contacted

REASON in SUPPSV

**3. Date Patient Contacted

SVSTDTC

**4. Did site talk to patient or study partner or both?

CONTPERS in SUPPSV

To which record shall REASON in SUPPSV be linked when VISIT has not taken place?

EXAMPLE 2 WITH ANNOTATIONS II

SV

DV

Telephone Visit (TEL)

Visit Conducted by Telephone

1. Was Patient contacted by Telephone

CONTMETH in SUPPSV

**2. Reason, not contacted

NOT S DVTERM

**3. Date Patient Contacted


SVSTDTC

**4. Did site talk to patient or study partner or both?

NOT SUBMITTED

QUESTIONS AND DISCUSSION

- Information for status / reason of 'Not Done-Visit' needed?
- Contact method / person needed?
- Adaption of electronic Case Report Form: Avoid such design?
- Create in SUPPSV?
- Create in other domains: DV, CO?
- Dismiss information?
- Create 'Unscheduled Visit' with SVUPDES='NOT DONE' to keep the 'Reason not done'?
- Further options?



PART 2

*SV IN PHASE I
STUDIES*

VISIT DEFINITION

- **Visit can be a real ‘clinical’ visit**

➡ One day / one date

- **Visit can reflect data collection at some time point**

➡ Duration of days / multiple dates

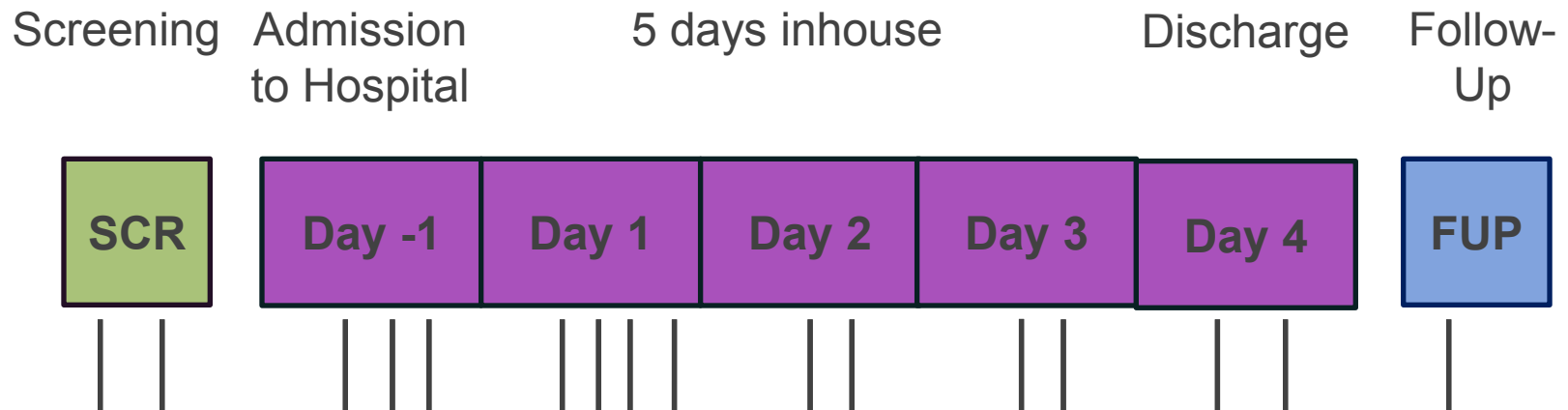
- **Visit Requirements according to CDISC SDTM IG 3.2:**

- Visit numbers should be consistent across domains
- Visit numbers should be chronological
- Visit number for planned events
- Visit number for actual events
- Visit number and Visit should have a one-to-one relationship

VISIT CHARACTERISTICS IN EARLY PHASE

• Characteristics:

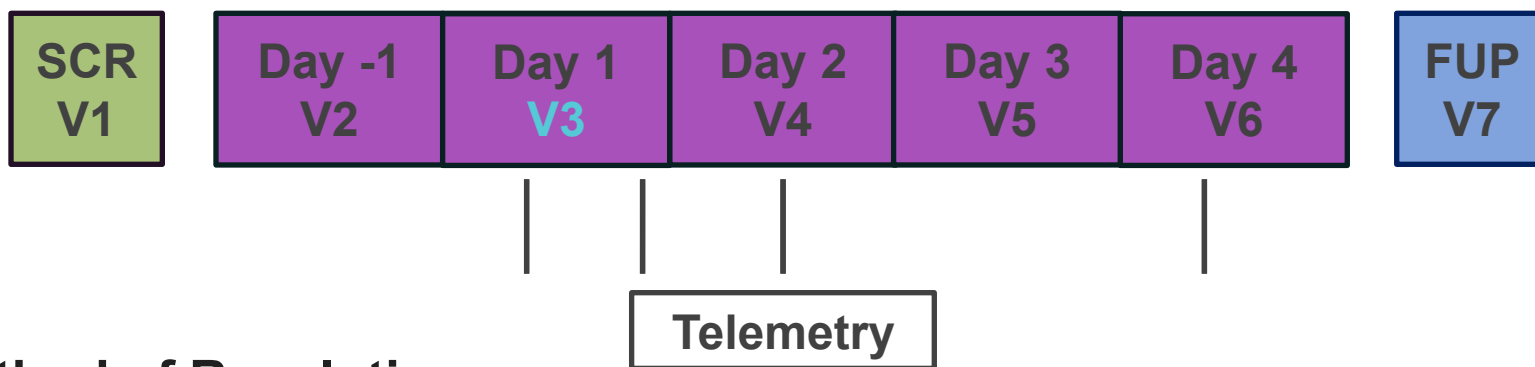
- Phase I to IIa
- Shorter than late phase trials
- Whole study period in hospital
- No resting period between trial days
- Subjects tightly monitored
- Numerous safety procedures during the day



CONTINUOUS PROCEDURES

• Challenge

- Procedures running through several visits starting in one visit, stopping in another visit
- Appropriate visit numbering algorithm...
 - ...in order to sort procedures chronologically
 - ...in order to fill SV domain with consistent start and stop dates



• Method of Resolution

- Procedure assigned to **one** visit number
- Start date will be in visit 3 / end date will not be reflected and part of visit 6

UNSCHEDULED MEASUREMENTS

• Challenge

- More than one unscheduled measurement per day for one procedure
- Unscheduled measurements performed on days with scheduled visits
- How to find appropriate visit numbers for unscheduled measurements...
- ...to distinguish all unscheduled measurements performed the same day
- ...to fill SV domain with consistent values for visit and date

• Method of Resolution

- **Use TPTNUM**

- Timepoints not summarized in SV

| Procedure | Timepoint | Date | Time | VISITNUM | TPTNUM |
|------------|--------------------|-------------------|--------------|----------|-------------|
| ECG | Predose | 2012-02-04 | 07:30 | 3 | 0 |
| ECG | 2H post | 2012-02-04 | 10:05 | 3 | 2 |
| Vitals | 2H post | 2012-02-04 | 10:07 | 3 | 2 |
| ECG | 4H post | 2012-02-04 | 11:59 | 3 | 4 |
| ECG | Unscheduled | 2012-02-04 | 13:01 | 3 | 4.01 |
| ECG | Unscheduled | 2012-02-04 | 17:25 | 3 | 4.02 |
| ECG | 12H post | 2012-02-04 | 20:12 | 3 | 12 |

UNSCHEDULED MEASUREMENTS II

• Challenge and Method of resolution

- Visit not done on day of a planned visit
- **Increment visit number**

| Procedure | Timepoint | Date | Time | VISITNUM | TPTNUM |
|------------|--------------------|-------------------|--------------|-------------|-------------|
| ECG | Predose | 2012-02-04 | 07:30 | 3 | 0 |
| Vitals | Predose | 2012-02-04 | 07:41 | 3 | 0 |
| ECG | 2H post | 2012-02-04 | 10:05 | 3 | 2 |
| Vitals | 2H post | 2012-02-04 | 10:07 | 3 | 2 |
| ECG | 4H post | 2012-02-04 | 11:59 | 3 | 4 |
| ECG | Unscheduled | 2012-02-04 | 13:01 | 3 | 4.01 |
| ECG | 12H post | 2012-02-04 | 20:12 | 3 | 12 |
| ECG | Unscheduled | 2012-02-05 | 17:24 | 4.01 | |

COLLECTION OF VISIT DATES

• Challenge

- Not all visit dates are kept as such in eCRF

• Method of resolution (for unscheduled procedures)

- Use assessment dates

electronic data:

| PATNO | LBTP | LBDTCD | LBTESTN |
|-------|------|------------|---------|
| 042-A | 904 | 2012-02-07 | 481 |
| 042-A | 904 | 2012-02-07 | 482 |
| 042-A | 904 | 2012-02-07 | 484 |
| 042-A | 903 | 2011-10-18 | 481 |
| 042-A | 903 | 2011-10-18 | 482 |
| 042-A | 903 | 2011-10-18 | 484 |
| 042-A | 902 | 2011-09-20 | 481 |
| 042-A | 902 | 2011-09-20 | 484 |
| 042-A | 901 | 2011-07-05 | 403 |
| 042-A | 901 | 2011-07-05 | 427 |

| Source | Source |
|--|---|
| Variable | Variable |
| LB | LB |
| where LBTP = 91 | where LBTP > 900 |
| "SV" | "SV" |
| 10.0n where n is the number of follow up - screening. | compare the dates to the respective SVSTDC in SV and do following: "VISITNUM.0n" where n is nr of Follow Up Visits |
| "VISIT", UNSCHEDULED n (where n is the number of Follow Up Screenings) | compare the dates to the respective SVSTDC in SV and do following: If LBTP = 901 then "VISIT, UNSCHEDULED 1" If LBTP = 902 then "VISIT, UNSCHEDULED 2" If LBTP = 903 then "VISIT, UNSCHEDULED 3" If LBTP = 904 then "VISIT, UNSCHEDULED 4" list the visits (if duplicates) only once |
| Compare dates with the respective SVSTDC in SV and assign the respective visit | |
| LBDTCD | LBDTCD |
| LBDTCD | LBDTCD |
| use | use COMPMETHOD.DY |
| use | use COMPMETHOD.DY |

COLLECTION OF VISIT DATES II

CRF: **[PSI]** **DOMAIN=YP** **DOMAIN=YA** **YPCAT = PSI**

| | | | | | |
|---|---------------------------------|---------------------------------|---------------------------------|---------------------------------|---------------------------------------|
| Start Day of treatment (day of randomization) | Week 1 | Week 2 | Week 4 | Week 6 | Week 8/ Day of discontinuation |
| 201_(year) (month) (day) | 201_(year)____ (month) (day) | 201_(year)____ (month) (day) | 201_(year)____ (month) (day) | 201_(year)____ (month) (day) | 201_(year)____ (month) (day) |

YPDTC
YADTC

- Method of resolution (for scheduled procedures)

mapping specification

| Source | Source | Source | Source | Source |
|-------------------|-------------------|-------------------|-------------------|-------------------|
| Variable | Variable | Variable | Variable | Variable |
| PSIDEGCO | PSIDEGCO | PSIDEGCO | PSIDEGCO | PSIDEGCO |
| where PSIPINT = 1 | where PSIPINT = 2 | where PSIPINT = 4 | where PSIPINT = 6 | where PSIPINT = 8 |
| "SV" | "SV" | "SV" | "SV" | "SV" |

VISITNUM
VISIT

| | | | | |
|---------------|---------------|---------------|---------------|---------------------------------|
| "40" | "50" | "60" | "70" | "80" |
| WEEK 1 | WEEK 2 | WEEK 4 | WEEK 6 | WEEK 8 - DISCONTINUATION |
| | | | | |
| PSEVDAY | PSEVDAY | PSEVDAY | PSEVDAY | PSEVDAY |
| PSEVDAY | PSEVDAY | PSEVDAY | PSEVDAY | PSEVDAY |

THANK YOU