



**What's New:  
SDTM 3.3 vs SDTM 3.4**  
**- SV**  
**- IS/GF/(LB/MB)**

Dagmar Kottig-Roth

Global Data Standards

ICON Biotech Solutions

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# Major Updates to Domains

## Domain Changes

| Change Type | Document            | Domain         | Class                            | Comment                                  |
|-------------|---------------------|----------------|----------------------------------|------------------------------------------|
| Add         | SDTM-IG 3.4         | <b>BE</b>      | Biospecimen Events               | from SDTMIG-PGx                          |
| Add         | SDTM-IG 3.4         | <b>BS</b>      | Biospecimen Findings             | from SDTMIG-PGx                          |
| Add         | SDTM-IG 3.4         | <b>RELSPEC</b> | Related Specimens                | from SDTMIG-PGx                          |
| Add         | SDTM-IG 3.4         | <b>GF</b>      | Genomics Findings                | replaces PF from SDTMIG-PGx              |
| Add         | SDTM-IG 3.4         | <b>CP</b>      | Cell Phenotype Findings          |                                          |
| Add         | Model 2.0           | <b>RELSPEC</b> | Related Specimens                |                                          |
| Add         | Model 1.8 (SEND-IG) | <b>AC</b>      | Challenge Agent Characterization | Only for nonclinical Animal Rule studies |
| Remove      | SDTM-IG 3.4         | <b>MO</b>      | Morphology                       | Domain Decommissioned                    |

## Many other changes, e.g.:

- Label Changes (e.g. DA: Drug Accountability -> Product Accountability)
- Structural Definition Changes
- Variables added, others removed, others with expanded use...

## Sources:

CDISC German UN WIKI: <https://wiki.cdisc.org/pages/viewpage.action?pageId=136094764>

<https://www.pinnacle21.com/blog/exploring-changes-sdtmig-34-adamig-13>

# Subject Visits (SV): Actual vs Planned Visits

## Revision History in SDTM IG v3.4 (Appendix E):

[Subject Visits \(SV\)](#)

**Impact on Date of  
Visit CRF!**



- This domain had been considered for moving to Events, but the decision after public review was to keep it as a Subject Visits domain at this time.
- **Now contains visits that did not occur as well as those that did occur**
- Information was added about contacts with subjects which may not have been designated as "visits" in the protocol
- New variables were added: SVPRESP, SVOCCUR, SVREASOC, SVCNTMOD, SVEPCHGI
  - a. SVPRESP = "Y" identifies rows for planned visits.
  - b. For planned visits, SVOCCUR indicates whether the visit occurred.
  - c. For unplanned visits, SVPRESP and SVOCCUR are null.

Subjects who screen fail, withdraw, die, or otherwise discontinue study participation will not have records for planned visits subsequent to their final disposition event.

# SV New Variables

## New Variables: Based on Regulatory Needs\*

| Variable Name | Variable Label                        | Type | Controlled Terms, Codelist or Format <sup>1</sup> | Role             | CDISC Notes                                                                                | Core |
|---------------|---------------------------------------|------|---------------------------------------------------|------------------|--------------------------------------------------------------------------------------------|------|
| SVCNTMOD      | Contact Mode                          | Char | (CNTMODE)                                         | Record Qualifier | The way in which the visit was conducted. Examples: "IN PERSON", "TELEPHONE CALL", "IVRS". | Perm |
| SVEPCHGI      | Epi/Pandemic Related Change Indicator | Char | (NY)                                              | Record Qualifier | Indicates whether the visit was changed due to an epidemic or pandemic.                    | Perm |

## Example from SDTM IG

| Row | STUDYID | DOMAIN | USUBJID | VISITNUM | VISIT     | SVPRESP | SVOCCUR | SVREASOC                         | SVCNTMOD           | SVEPCHGI | VISITDY | SVSTDTDC   | SVENDTC    | SVSTDY | SVENDY | SVUPDES          |
|-----|---------|--------|---------|----------|-----------|---------|---------|----------------------------------|--------------------|----------|---------|------------|------------|--------|--------|------------------|
| 9   | 123456  | SV     | 85      | 8        | FOLLOW-UP | Y       | Y       |                                  | IN PERSON          |          |         | 2020-02-27 | 2020-02-27 | 72     | 72     |                  |
| 10  | 123456  | SV     | 101     | 1        | SCREEN    | Y       | Y       |                                  | IN PERSON          |          |         | 2020-02-13 | 2020-02-18 | -6     | -1     |                  |
| 11  | 123456  | SV     | 101     | 2        | DAY 1     | Y       | Y       |                                  | IN PERSON          |          | 1       | 2020-02-19 | 2020-02-19 | 1      | 1      |                  |
| 12  | 123456  | SV     | 101     | 3        | WEEK 1    | Y       | Y       |                                  | IN PERSON          |          | 8       | 2020-02-25 | 2020-02-25 | 7      | 7      |                  |
| 13  | 123456  | SV     | 101     | 4        | WEEK 2    | Y       | N       | CLINIC CLOSED DUE TO BAD WEATHER |                    |          | 15      |            |            |        |        |                  |
| 14  | 123456  | SV     | 101     | 4.1      |           |         |         |                                  | REMOTE AUDIO VIDEO | Y        |         | 2020-03-07 | 2020-03-07 | 18     | 18     | EVALUATION OF AE |
| 15  | 123456  | SV     | 101     | 8        | FOLLOW-UP | Y       | Y       |                                  | TELEPHONE CALL     | Y        |         | 2020-03-16 | 2020-03-16 | 26     | 26     |                  |

\* **FDA Technical Conformance Guide:** It is the current preference of the Agency that for all clinical studies, not limited to those impacted by COVID-19, subject visit data for scheduled (whether or not they occurred), and unscheduled visits be submitted in one single dataset structured as the current CDISC Subject Visits (SV) domain. It is also Agency preference that three non-standard variables (NSVs) for missed visits, --REASOC (Reason for Occur Value), --EPCHGI (Epi/Pandemic Related Change Indicator), and --CNTMOD (Contact Mode), outlined in the CDISC document "Guidance for Ongoing Studies Disrupted by COVID-19 Pandemic" be included within the SV domain and not within the supplemental SUPPSV domain or in other SDTM datasets. Submitting subject visits information in one single structured dataset allows both the human and technology consumer of this information to operate efficiently and with confidence that all visit data are considered during regulatory review.

# News for IS

## [Immunogenicity Specimen Assessments \(IS\)](#)

- The domain definition has been updated. Note, however, that the definition will be finalized through the Controlled Terminology process, and the final definition may change from that shown here.
- Added 6 new variables: ISBDAGNT, ISMSCBCE, ISTSTOPO, ISTSTCND, ISCNDA GT, and NHOID.
- Added permissible variables that were previously not included in the IS domain specification.
- Replaced assumptions from SDTMIG v3.3.
- Examples 1 and 2 replaced with new content; Examples 3-11 added.

**More, and more specific variables**

## Change in Scope of Use:

- Previous: assessments that describe whether a **therapy** provoked/caused/induced an immune response
- v3.4: immune response upon an **antigen** stimulation or encounter (incl. Anti-Drug-Antibody Data/ADA Data)

| USUBJID | ISSEQ | ISREFID | ISGRPID | ISTESTCD | ISTEST                    | ISBDAGNT    | ISTSTOPO | ISCAT               | ISSCAT           | ISORRES  | ISORRESU | ISSTRESC |
|---------|-------|---------|---------|----------|---------------------------|-------------|----------|---------------------|------------------|----------|----------|----------|
| ABC-002 | 1     | V555    | 1       | ADA_BAB  | Binding Antidrug Antibody | DRUG AZ-007 | SCREEN   | ANTIDRUG ANTIBODIES | HUMORAL IMMUNITY | POSITIVE |          | POSITIVE |
| ABC-002 | 2     | V555    | 1       | ADA_BAB  | Binding Antidrug Antibody | DRUG AZ-007 | CONFIRM  | ANTIDRUG ANTIBODIES | HUMORAL IMMUNITY | POSITIVE |          | POSITIVE |
| ABC-002 | 3     | V555    | 1       | ADA_BAB  | Binding Antidrug Antibody | DRUG AZ-007 | QUANTIFY | ANTIDRUG ANTIBODIES | HUMORAL IMMUNITY | 50       | titer    | 50       |

# News for GF (1/2)

## Previous PGx IG v1.0 deprecated with SDTM IG v3.4

- **GF Domain:** Genomics Findings (GF)
  - Many specific variables for representing genomics data
- **BE Domain:** Biospecimen Events (BE)
  - Specimen Tracking Data
- **BS Domain:** Biospecimen Findings (BS)
  - Data related to specimen handling
  - BSSPEC depends on the type of sample:
    - For genetic samples, use GENSMP codelist
    - For non-genetic samples, use SPECTYPE codelist

BE, BS, and RELSPEC domain specifications, assumptions, and examples were copied and minimally updated from the provisional SDTMIG-PGx, published 2015-05-26. This was done in preparation for the retirement of the SDTMIG-PGx upon publication of SDTMIG v3.4. These domains are currently under extensive revision for inclusion in a future SDTMIG publication, after v3.4.

# News for GF (2/2)

## – Example GF Domain

| GFTSTCD | GFTST                       | GFTSTDTL                    | GFORRES | GFORRESU | GFSTRESC | GFSTRESN | GFSTRESU | GFINHRT           | GFGENREF  | GFCHROM | GFSYM |
|---------|-----------------------------|-----------------------------|---------|----------|----------|----------|----------|-------------------|-----------|---------|-------|
| SNV     | Single Nucleotide Variation | PREDICTED AMINO ACID CHANGE | D1853N  |          | D1853N   |          |          | SOMATIC VARIATION | GRCh37.75 | 11      | ATM   |

| GFSYMTYP                  | GFGENLOC  | GFSEQID           | GFPVRID   | GFXFN                                                                                                                    | GFNAM               | GFSPEC | GFMETHOD                   |
|---------------------------|-----------|-------------------|-----------|--------------------------------------------------------------------------------------------------------------------------|---------------------|--------|----------------------------|
| GENE WITH PROTEIN PRODUCT | 108175462 | ENST00000278616.4 | COSM41596 | /comptbio/analysis/120718_SN855_0084_AD13D5ACXX_LCNL-361/sampleAnalysis/sample18.TRF001338.01/TF001338.01.vars.final.xml | ACME SEQUENCING LLC | DNA    | TARGETED GENOME SEQUENCING |

## – Example BE Domain

| USUBJID | SPDEVID  | BESEQ | BEREFID  | BETERM         | BEDECOD        | BEPARTY | BEPRTYID | BECAT       |
|---------|----------|-------|----------|----------------|----------------|---------|----------|-------------|
| 43871   | TS409871 | 1     | 1148.267 | Collecting     | COLLECTING     | SITE    | 01       | COLLECTION  |
| 43871   |          | 2     | 1148.267 | Flash Freezing | FLASH FREEZING | SITE    | 01       | PREPARATION |
| 43871   | 309827   | 3     | 1148.267 | Storing        | STORING        | SITE    | 01       | STORING     |

## – Example BS Domain

| BSTESTCD | BSTEST    | BSCAT           | BSORRES | BSSTRESC | BSSTRESN | BSXFN                         | BSNAM               | BSSPEC | BSMETHOD          |
|----------|-----------|-----------------|---------|----------|----------|-------------------------------|---------------------|--------|-------------------|
| A260A230 | A260/A230 | QUALITY CONTROL | 2.05    | 2.05     | 2.05     | 2.16.090.1.135764.3.4:7280912 | Deluxe Central Labs | rRNA   | SPECTROPHOTOMETRY |