

SEND Implementation FAQ - Known Issues



This page was recently migrated; its contents are under review.



phuse.global

Nonclinical Topics

Known Issues

SENDIG 3.0 Known Issues

The following are known issues in the SEND 3.0 Implementation Guide that may affect the creation of a SEND dataset. These were corrected in SEND 3.1 or deferred.

CO (Comments) Domain

POOLID is missing from this domain description table. If comments associated with a pool need to be reported in a SEND dataset, one option is to include POOLID in the CO domain anyway, and provide explanation for the error that the validator will raise.

This has been corrected in 3.1.

EX (Exposure) Domain

The CDISC notes in the domain description table for EXDOSU should indicate that these are units for both EXDOSE and EXDOSTXT, not just EXDOSE.

This has been corrected in 3.1.

CL (Clinical Observations) Domain

The variable label for CLDTC should be "Date/Time of Observation" not "Start Date/Time of Observation".

This has been corrected in 3.1.

EG (ECG Test Results) Domain

The variable label for EGLEAD should be "Lead Used for Measurement" not "Location Used for Measurement".

This has been corrected in 3.1.

The variable label for EGDTC should be "Date/Time of ECG Collection" not "Date/Time of ECG".

This has been corrected in 3.1.

FW (Food and Water Consumption) Domain

FW Example 4, description of Row 2, should say, ".. since one animal died *at the end of* the first week", rather than during the first week. Note: This is still an issue with 3.1.

This has been clarified in 3.1 by way of further description in comments.

LB (Laboratory Test Results) Domain

LBORNRL0 and LBORNRLHI should be type Char, not Num.

This has been corrected in 3.1.

The CDISC notes in the domain description table for LBSTRESU currently includes a notation "Preferably SI units". Assumption 2a also includes a statement that values should be reported in SI units when possible. These are incorrect; there is no preference for SI units in SEND.

This has been corrected in 3.1.

OM (Organ Measurements) Domain

The bolded portion of this statement in the implementation guide is incorrect: "Organ measurement ratios within a single study should either be **pure ratios with no units** specified or percentages with unit shown as %". There is a term "RATIO" in the controlled terminology UNIT codelist.

Therefore organ-to-brain and organ-to-organ ratios should use RATIO (not blank) or % as the unit.

This has been corrected in 3.1.

PM (Palpable Masses) Domain

The variable label for PMDTC should be "Date/Time of Observation" not "Start Date/Time of Observation".

This has been corrected in 3.1.

PC (Pharmacokinetics Concentrations) Domain

The variable label for VISITDY should be "Planned Study Day of Collection", not "Visit Day", consistent with other domains.

This has been corrected in 3.1.

TF (Tumor Findings) Domain

The variable shown as TSTFNAM should be TFNAM.

This has been corrected in 3.1.

The variable label for TFSPID should be "Mass Identifier", not "Mass Number".

This has been corrected in 3.1.

VS (Vital Signs) Domain

The "Controlled Terms, Codelist, or Format" in the domain description table for DOMAIN should be "VS" and for VSDRVFL it should be "(NY)".

This has been corrected in 3.1.

SENDIG 3.1 Known Issues

The following are known issues in the SEND 3.1 Implementation Guide that may affect the creation of a SEND dataset. These were corrected in SEND 3.1 or deferred.