

# SEND Implementation FAQ - Known Issues

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## 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

LBORNRLO and LBORNRHI 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.