



# CDISC SDTM Processing Report

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## Pinnacle21 Report

‘Regulatory Expected variable EPOCH not found’ issue:

- Domains: BE, BS, DD, GF, SM

**Is the EPOCH field needed in these domains or there is another problem?**

- ‘TSVAL value not found in ‘Sex of Participants Response’ non-extensible codelist when TSPARMCD == ‘SEXPOP’ **What are the allowed SEX values for Female, Male, Mixed? Solved!!**
- ‘TSVALCD value not found in ‘Sex of Participants Response Code’ non-extensible codelist when TSPARMCD == ‘SEXPOP’ **What are the allowed SEXCD values for Female, Male, Mixed? Solved!!**
- ‘Invalid TSVAL value for XXX’, where XXX is:
  - AGEMAX
  - AGEMIN
  - LENGTH
  - PLANSUB
  - RANDOM
  - ADDON
  - ADAPT
  - FCNTRY
  - NARMS

**What are the correct formats?**

- ‘Invalid TSVCDREF value for FCNTRY’ **What are the allowed values?**
- ‘TSPARM value not found in ‘Trial Summary Parameter Test Name’ extensible codelist’ **What is the ‘Trial Summary Parameter Test Name’ extensible codelist?**
- ‘TSVAL value not found in ‘Control Type Response’ extensible codelist when TSPARMCD == ‘TCNTRL’ **What is the ‘Control Type Response’ extensible codelist?**
- ‘TSVAL value not found in ‘Trial Blinding Schema Response’ extensible codelist when TSPARMCD == ‘TBLIND’ **What is the ‘Trial Blinding Schema Response’ extensible codelist?**
- ‘TSVAL value not found in ‘Trial Type Response’ extensible codelist when TSPARMCD == ‘TTYPE’ **What is the ‘Trial Type Response’ extensible codelist?**
- ‘TSVALCD value not found in ‘Control Type Response Code’ extensible codelist when TSPARMCD == ‘TCNTRL’ **What is the ‘Control Type Response Code’ extensible codelist?**
- ‘TSVALCD value not found in ‘Trial Phase Response Code’ extensible codelist when TSPARMCD == ‘TPHASE’ **What is the ‘Trial Phase Response Code’ extensible codelist?**

List of domains with ‘wrong’ label (‘SDTM/dataset variable label mismatch’):

- CE, DV, FA, IS, LB, SE, SM, SV, TM, TS

**What are the correct labels for those domains?**

Values not found in —METHOD ('value not found in 'Method' extensible codelist'):

- Domains: FT, MK, OE, QS, RE, RS, SR, UR

**What are the allowed values in 'Method' extensible codelist?**

**Solved for MK, OE, RE, RS, SR, UR!!**

Values not found in —TEST ('value not found in 'xxx' extensible codelist'):

- Domains: CV, DA, DD, EG, IS, LB, MB, MI, MK, NV, OE, PP, RE, RP, RS, SC, SR, SS, TR, TU, UR, VS

**What are the allowed values in 'xxx' extensible codelist for —TEST fields?**

**Solved!!**

Values not found in —TRESC ('value not found in 'xxx' extensible codelist'):

- Domains: RS, SC, TU, VS

**What are the allowed values in 'xxx' extensible codelist for —TRESC fields?**

**Solved!!**

List of fields with 'wrong' values:

- 'value not found in 'Relation to Reference Period (ENRTPT)' non-extensible codelist':
  - AEENRTPT
  - AGENRTPT
  - AGSTRPT
  - CEENRTPT
  - CESTRTPT
  - HOENRTPT
  - HOSTRTPT
  - MHENRTPT
  - PRENRTPT
  - RSENRTPT
  - SUENRTPT

**What are the allowed values?**

**Solved!!**

- 'value not found in 'Unit' extensible codelist':
  - —DOSU
  - —STRESU

**What are the allowed values?**

**Solved!!**

- 'Variable appears in dataset, but is not in SDTM model'
  - 5 in AE
  - 16 in CP
  - 1 in EC
  - 1 in EG
  - 10 in GF

- 4 in IS
- 11 in LB
- 10 in SV
- 1 in VS

Fields we are using in these domains: (See pictures at the end)

**Solved!!**

**What is this issue?**

- ‘GFSPEC value not found in 'Specimen Type' extensible codelist’
- ‘MHEVDTYPE value not found in 'Medical History Event Date Type' extensible codelist’
- ‘RPTESTCD and RPTEST values do not have the same Code in CDISC CT’
- ‘IECAT value not found in 'Category for Inclusion/Exclusion' non-extensible codelist’
- ‘EGLEAD value not found in 'ECG Lead' extensible codelist’
- ‘LBTESTCD value not found in 'Laboratory Test Code' extensible codelist’
- ‘DSDECOD value not found in 'Completion/Reason for Non-Completion' extensible codelist when DSCAT == 'DISPOSITION EVENT’
- ‘EGLEAD value not found in 'ECG Lead' extensible codelist’

**What are the allowed values in each field?**

**Solved some!!**

List of other problems:

- ‘Missing BEDY variable, when BEDTC variable is present’

**Should we have BEDY field in BE domain?**

- ‘Missing value for TUORRES, when TUSTAT or TUDRVFL is not populated’

**Where should be TUDRVFL, TUSTAT?**

**Solved!!**

- ‘Missing value for DDORRES, when DDSTAT or DDDRVFL is not populated’

**Where should be DDSTAT, DDDRVFL?**

**Solved!!**

- ‘Regulatory Expected variable EPOCH not found’
  - Domains: BE, DS, DD, GF, SM

**What is this issue?**

- ‘Permissible variable with missing value for all records’
  - Domains: AE, CE, CM, CO, DA, DD, DM, DS, DV, EC, EG, EX, FA, HO, IE, IS, LB, MB, MH, MI, PC, PE, PP, PR, QS, RP, RS, SC, SE, SR, SS, SU, SV, TI, TR, TS, TU, VS

**What is this issue?**

**Solved!!**

- ‘No Treatment Emergent info for Adverse Event (missing SUPPAE)

**What is SUPPAE?**

- ‘Inconsistent value for AEBDSYCD within AEBODSYS

**What are the allowed values for both fields?**

- ‘Inconsistent value for AEDECOD within AEPTCD



### **What are the allowed values for both fields?**

**Solved!!**

- 'Model permissible variable added into standard domain'
  - Domains: AE, CE, DA, FA, IS, LB, PP, QS, RS, SC, SV

### **What is this problem?**

- 'Inconsistent value for Standard Units'
  - Domains: DA, EG, FA, FT, MK, NV, RP, UR
  - Always in the field –STRESU

### **How can we use the correct units in each case?**

## Open Questions

List of variables in TS domain unknown:

- Number of Groups/Cohorts (**How do you define the Groups/Cohorts?**)
- Planned length of observation for a single subject. (**Every subject has the same duration into the trial?**)
- Data Cutoff Date (**Is always required?**)
- Trial Phase Classification (**What is this?**)

List of domains totally unknown:

- MS
- OI

**How should these domains be filled?**