General

Newline characters, i.e., \n, in JSON media type outputs are not present in the XML media type outputs. The textual description about controlled terms are incomplete in ADaM exports, both CSV and Excel format. This affects the Codelist/Controlled Terms column. CDISC is evaluating a fix. Contact CDISC Library Product Inquiry form if you have any concerns.

Note, this limitation does not apply to JSON and XML media types using the CDISC Library API; a similar issue for CDASH, SDTM and SEND exports has been addressed in the 2021-09-28 release.

Data Standards Browser

Refer to Data Standards Browser (Copy) for details.

Controlled Terminology

Currently, the JSON object _links/priorVersion is part of the API response when querying codelists and terms belonging to the earliest CDISC Controlled Terminology package loaded into the metadata repository. CDISC is working to address this so that _links/priorVersion will be removed from the API response in this case.

CDASH

CDASH products contain mapping information to target variables in the SDTM and the SDTMIG. These targets do not always exist in their associated SDTM and SDTMIG product's class or domain specification tables; therefore, these targets are not available in the metadata repository. An example is the CDASHIG variable ECVAMT, where ECVAMT is not present in the SDTMIG v3.2 EC domain specification table. CDISC is working with the standards development teams to identify a resolution.

The Supplemental Qualifier dataset's variable definitions are not instantiated for any general observation class dataset in any of the SDTMIG publications. Therefore, all CDASH variable mappings that involve a domain-specific Supplemental Qualifier target (SUPP--) are generalized. For example, SUPPCM.QVAL is referenced as SUPPQUAL.QVAL. CDISC is working with the standards development teams to identify a resolution.

Variable order (i.e., ordinal) is a numeric property in the metadata repository. In cases where they are not numerical in the published CDASH standard, variables are reassigned a value that preserves their original sequence in the documentation. Example, “10a”, “10b”, “12a”, “12b”, etc. for variables in the CDASH v1.1 AE domain where reassigned values of “10”, “11”, “13”, “14” and so on.

CDISC is working with the standards development teams to identify a resolution.

For CDASHIG v1.1.1, domain and scenario fields do not have the title component in the hypermedia links, i.e., _links/self/title. This is due to the lack of variable label metadata in the original published standard. This metadata gap is resolved in CDASHIG 2.0. For example, an excerpt from CDASH v1.1.1’s CMTRT using /mdr/cdashig/1-1-1/domains/CN/fields/CMTRT:

```
{
  "ordinal": "3",
  "name": "CMTRT",
  "_links": {
    "self": {
      "href": "/mdr/cdashig/1-1-1/domains/CN/fields/CMTRT",
      "type": "Data Collection Field"
    },
    ...
  }
```

In contrast, this is an excerpt from CDASH v2.0’s CMTRT using /mdr/cdashig/2-0/domains/CN/fields/CMTRT, where the title component is present in the hypermedia links.
title is not available within the hypermedia link for CDASH Model v1.1's AP-- domain due to lack of such metadata in the CDASH Model v1.1 publication.

By the same token, label is not available in the response body of this API request: `/mdr/cdash/1-1/domains/AP--`. CDISC Library does not currently differentiate Controlled Terminology Codelist from Subset Controlled Terminology Codelist for variables that have both. For example, EXDOSFRM has (FRM) and (EXDOSFRM) in the CDASHIG. The system exports and displays C66726 and C78426, for (FRM) and (EXDOSFRM) respectively.

**SDTM & SEND**

- **NEW** The design of the Excel and CSV exports for SDTMIG and SENDIG was updated in the 2021-09-29 release to differentiate between CDISC CT codelist codes, described value domains, and value lists.
- **NEW** In SDTM v2.0, for the Events variable --EVDTYP, the qualified variables --ENDTC and --STDTC are missing. CDISC will correct in a subsequent release.
- The Supplemental Qualifier (SUPPQUAL) dataset is not instantiated for any general observation class datasets in any of the SDTMIG publications. In other words, there is only one SUPPQUAL dataset for each version of the SDTMIG and the SENDIG. CDISC is working with the standards development teams to identify a resolution.
- For both SENDIG v3.1 and SENDIG-DART v1.0, the CDISC Library has the described value domain "ISO 21090 NullFlavor enumeration" attached to the TSVALNF variable. It is different from the intention to use a SEND Controlled Terminology codelist due to a typographical error. NULLFLAV is the SEND CT codelist shorthand. However, it is erroneously listed as "(NULLFLAVOR)" in the SENDIG v3.1 publication. CDISC is working to address this with the SEND team.
- For SENDIG v3.1, a portion of the CDISC Notes for the variable MISTRESC is missing in CDISC Library. The missing portion is "Neoplastic findings must be populated using the NEOPLASM controlled list."
- Metadata about described value domain is missing for SENDIG-AR v1.0. Described value domain generally refers to ISO 8601 and other formats and external terminology not found in CDISC Controlled Terminology. These missing values will be added in a future release.

**ADaM & ADaMIG**

- **NEW** New metadata for subclass has been introduced for ADaMIG v1.3, ADaM OCCDS v1.1, and ADaMIG NCA v1.0. Subclass will be added to the Excel and CSV exports, the Diff files, and the API specification in a future release.
- **NEW** Variable --SEV in ADaM OCCDS v1.1 has two allowed codelists, (AESEV) or (SEVRS). At this time, CDISC Library only displays one codelist for each variable. This will be updated in a future release.
- For ADaM TTE v1.0, the response of this API query `/mdr/adam/adam-tte-1-0/datastructures` shows Basic Data Structure for Time to Event Analyses (ADTTE) as a data structure.
In data modeling, ADTTE is a specialized form of the BDS data structure. CDISC is working with the standards development teams to apply this modeling concept into applicable foundational standards.

« Clarifications