

News and updates



- 2021-03-30: Hyperlink in SDTMIG v3.4 draft content
- 2020-11-20: Document a bug related ADaM v2.1 exports
- 2020-11-11: Document revision with new and updated information
- 2020-08-03: Document a bug related to search
- 2020-07-07: Document revision with new and updated information
- 2020-02-14: CDASH documentation wording adjustments
- 2019-11-18: Document revision with new and updated information
- 2019-09-13: Document revision with new and updated information
- 2019-09-16: Added a section for ADaM & ADaMIG
- 2019-07-18: Removed issues addressed in the release
- 2019-04-10: Document revision with new and updated information
- 2019-02-15: Initial version

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 CDASH, SDTM, SEND, and ADaM exports, both CSV and Excel format. The affected columns are listed below. 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.

Foundational Standard	Column Name
ADaMIG	Codelist/Controlled Terms
CDASH Model, CDASHIG	Controlled Terminology Codelist Name
SDTM, SDTMIG, SENDIG	Controlled Terms, Codelist or Format

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/CM/fields/CMTRT`:

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

In contrast, this is an excerpt from CDASH v2.0's CMTRT using `/mdr/cdashig/2-0/domains/CM/fields/CMTRT`, where the `title` component is present in the hypermedia links:

```

{
  "ordinal": "8",
  "name": "CMTRT",
  "label": "Concomitant Medication Name",
  ...
  "_links": {
    "self": {
      "href": "/mdr/cdashig/2-0/domains/CM/fields/CMTRT",
      "title": "Concomitant Medication Name",
      "type": "Data Collection Field"
    },
    ...
  }
}

```

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.

/mdr/cdash/1-1/domains

```

{
  "name": "CDASH Model v1.1",
  ...
  "_links": {
    ...
    "domains": [
      ...
      {
        "href": "/mdr/cdash/1-1/domains/AP--",
        "type": "CDASH Domain"
      }
    ]
  }
}

```

By the same token, label is not available in the response body of this API request: </mdr/cdash/1-1/domains/AP-->.

SDTM & SEND

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 shortname. 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.

NEW

A hyperlink to SDTM v2.0 is included in the API response for SDTMIG v3.4. This hyperlink is currently not functional. This will be remediated when SDTM v2.0 draft content is added to CDISC Library.

ADaM & ADaMIG

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.

```

{
  ...
  "dataStructures": [
    {
      "href": "/mdr/adam/adam-tte-1-0/datastructures/ADTTE",
      "title": "Basic Data Structure for Time to Event Analyses",
      "type": "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. For ADaM v2.1, making an Excel or a CSV export will result in an error. Note, this does not impact JSON and XML outputs. CDISC will investigate and address this in a future release.

Example API calls

```
curl -X GET \  
  https://library.cdisc.org/api/mdr/adam/adam-2-1 \  
  -H 'Accept: text/csv'  
  
curl -X GET \  
  https://library.cdisc.org/api/mdr/adam/adam-2-1 \  
  -H 'Accept: application/vnd.ms-excel'
```

Example response header and body for GET /mdr/adam/adam-2-1

```
HTTP/1.1 500  
status: 500  
  
{"detail":"'dataStructures'", "message": "Caught exception making response for requested variants: text/csv"}
```

[« Clarifications](#)