

Information About the TAUG-BrCa v1.0 Package

Included in the package:

- ReadMe for TAUG-BrCa v1.0 (1)
- TAUG-BrCa v1.0 (1)
- BrCa CDASH Metadata Tables (3)
 - Radiation Metadata Table
 - Tumor Identification and Results Metadata Table
 - Disease Response Metadata Table
- TAUG-BrCa Specification (1)

Draft standards of interest to the TAUG-BrCa v1.0:

- SDTM Examples for Oncology Use Cases
- Alternate Presentation of Non-Standard Variables

CDASH Metadata

The CDASH metadata in this package are provided in spreadsheet format for greater accessibility. Readers are requested to also review and provide comments on the CDASH metadata tables.

CDASH metadata for a biomedical concept include the following:

- Domain
- Question Text
- Prompt
- CDASH Variable Name
- CDASH Core
- SDTM Variable Name
- SDTM Core
- Description
- Case Report Form Completion Instructions
- Mapping Instructions
- Information for Sponsors
- Controlled Terminology CodeList Name
- Controlled Terminology Value
- TA Specific Usage Rules
- Value that appears on the CRF but is not entered by the user
- Pre-Defined Values

Each table of CDASH metadata corresponds to an example CRF, which has been annotated to show how the data collected on the CRF may be mapped to SDTM. CDASH metadata tables included in this package are:

Metadata Table	Example CRF
Radiation	1: Radiation Therapy
Tumor Identification and Results	2: Tumor Identification Target Lesions
	3: Tumor Identification Non-Target Lesions
	4: Tumor Identification New Lesions
Disease Response	5: Disease Response

Specification

This is a summary of the components included in the TAUG-BrCa, and their relation to the versions of CDISC data models in the FDA Data Standards Catalog. The specification also includes known issues and the anticipated future status of any variables not currently supported by the latest version of SDTM and ADaM.

Draft Standards of Interest

These are standards (or parts of standards) that are in development by other teams, and which have impacted the development of the TAUG-BrCa v1.0. To access these draft standards, go to <http://wiki.cdisc.org/x/5yuyAQ>.

- *SDTM Examples for Oncology Use Cases* is an updated version of the spreadsheet of examples that accompanied the TU/TR/RS domains in SDTMIG v3.2.
- *Alternate Presentation of Non-Standard Variables* is a proposed addition to SDTMIG Section 8.4, which would be inserted between the sections numbered 8.4.3 and 8.4.4 in SDTMIG v3.2, effectively becoming the new section 8.4.4.