Manual for the Completion of CDISC Aligned NCI Standard Case Report Form (CRF) Modules

Introduction

In 2006, members of the National Cancer Institute's Center for Biomedical Informatics and Information Technology (NCI CBIIT) in conjunction with the cancer Data Standards Registry and Repository (caDSR) user community initiated a Case Report Form (CRF) harmonization activity. CRFs submitted from the community were reviewed and inventoried. The Harmonization group then reviewed all questions on the CRF and partitioned them into four categories:

- Mandatory – A data collection variable that must be on the CRF (e.g., a regulatory requirement (if applicable)).
- Conditional – A data collection variable that must be collected on the CRF for specific cases that may be dictated by local or sponsor defined business rules.
- Optional – A data collection variable that is available for use if needed. There is no regulatory or business requirement for inclusion of this element on the CRF; if the design and scientific questions posed in the study dictate the need to collect this type of data; this is the element to include on the CRF.
- Non-harmonized – A data collection variable that is, by consensus, to primarily belong to a different CRF module or is not belonging to any defined module.

A template form with modules that contain questions or variables representing data to be collected and a companion electronic CRF instruction manual was developed. These CRF modules were vetted and adopted by the caDSR stakeholder community as metadata standards.

Since the original CRFs and manuals were adopted, the Food & Drug Administration (FDA) published guidelines for submission of clinical trial study data using the Clinical Data Interchange Standards Consortium (CDISC) Study Data Tabulation Model (SDTM) for Investigational New Drug (IND) trials starting after December 2017. In response, NCI CBIIT has aligned the NCI Standard CRF modules with the CDISC data collection standard, Clinical Data Acquisition Standards Harmonization (CDASH) where data is expected to be submitted to FDA in SDTM format.

The instruction manual is a set of directions to guide data collection in each module template. Specific implementation instructions are not present; various groups may wish to implement the contents of a module in a variety of software applications.

The instructions include the field name, description or definition of each field, and any special formatting notes that apply to entries – such as the inclusion of full dates, use of values from a choice list only, etc. Finally, each question (or data item) is noted as Mandatory (m), Conditional (c), or Optional (o).

Footer CDISC Aligned NCI Standard Template Module Definitions

Mapping to the CDASH:

Not for FDA submission

Mapping to the SDTM:

Not for FDA submission

Footer CDISC Aligned NCI Standard Template Module Template Instructions

Field Descriptions and Instructions

Field Name **(Partition Status)** **CDE ID #** **Short Name**	**Definition** **CDISC Mapping and Instruction**	**Format**
Case Report Form Identifier (m) 3008882 2684601v1.0:3009014v1.0	The unique alphanumeric string used to identify, name, or characterize the nature, properties, or contents of the case report form. Not for FDA submission	ALPHANUMERIC
Case Report Form Version Number (m) 3008888 3008884v1.0:3008886v1.0	The number that represents the sequence of copies different from others of the same type of a case report form. Not for FDA submission	NUMBER
Case Report Form Version Date (m) 3008890 3008884v1.0:2017121v1.0	The released or published date of the specific version of a case report form. Not for FDA submission	DATE
Case Report Form Total Page Number (m) 3008880 CRF_TTL_PAGE_NUM	The complete number of pages of the case report form document. Not for FDA submission	CHARACTER

Field Name **(Partition Status)** **CDE ID #** **Short Name**	**Definition** **CDISC Mapping and Instruction**	**Format**
Case Report Form Page Number (m) 3008875 3008873v1.0:2646319v1.0	The specific page number being referenced in the case report form document. Not for FDA submission	CHARACTER

Annotated CRF: Footer CDISC Aligned NCI Standard Template

This annotated CRF is ONLY used to show CDISC mapping without consideration of the CRF layout. CDASH mapping is in **Blue**, and SDTM mapping is in **Red**.

Form Name: Footer CDISC Aligned NCI Standard Template

Mandatary Questions

CRF Question	Value Domain
CRF Identifier (3008882) **CDE Short Name:** 2684601v1.0:3009014v1.0 CDASH: Not for FDA submission SDTM: Not for FDA submission	ALPHANUMERIC Maximum Length = 50
CRF Version # (3008888) **CDE Short Name:** 3008884v1.0:3008886v1.0 CDASH: Not for FDA submission SDTM: Not for FDA submission	NUMBER – Maximum Length = 3
CRF Version Date (3008890) **CDE Short Name:** 3008884v1.0:2017121v1.0 CDASH: Not for FDA submission SDTM: Not for FDA submission	DATE – Maximum Length = 8
Total Number of Pages in CRF (3008880) **CDE Short Name:** CRF_TTL_PAGE_NUM CDASH: Not for FDA submission SDTM: Not for FDA submission	CHARACTER– Maximum Length = 4
CRF Page # (3008875) **CDE Short Name:** 3008873v1.0:2646319v1.0 CDASH: Not for FDA submission SDTM: Not for FDA submission	CHARACTER– Maximum Length = 4