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).

End of Form CDISC Aligned NCI Standard Template Module Definitions

Mapping to the CDASH:

Not for FDA submission

Mapping to the SDTM:

Not for FDA submission

End of Form 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**
Responsible Person Name (o) 2006163 RSPBLPERSON_NAME	The legal name of the person who documented information on the case report form or other document. Not for FDA submission	CHARACTER
Form Completion Date (o) 2003745 FORM_COMPL_DT	The date on which a data capture form (CRF or case report form) was completed. Not for FDA submission	DATE
Investigator Signature Text (o) 58320 INVESTIGATOR_SIG_TXT	the signed name of the investigator who is responsible for completing a form or report for a clinical trial. Not for FDA submission	CHARACTER
Treating Physician Name (o) 62749 TREATING_DR_NAME	the name of the physician treating a person for specific medical conditions/problems. Not for FDA submission	CHARACTER
Reviewer Name (o) 3008899 2626294v1.0:2746719v1.0	The complete legal name of the person who evaluated the case report form. Not for FDA submission	CHARACTER

Field Name **(Partition Status)** **CDE ID #** **Short Name**	**Definition** **CDISC Mapping and Instruction**	**Format**
Case Report Form Review Date (o) 3008897 3008895v1.0:2017121v1.0	The date on which the case report form was evaluated. Not for FDA submission	DATE
Form Amended Complete Date (o) 64166 FORM_AMD_COMP_DT	the date the data on the form was last changed or revised. Not for FDA submission	DATE
Case Report Form Change Person Name (o) 3286567 CRF_CHG_PER_NM	Name of a person who amended data on a case report form (CRF). Not for FDA submission	CHARACTER

Annotated CRF: End of Form 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: End of Form CDISC Aligned NCI Standard Template

Optional Questions

CRF Question	Value Domain
Responsible Person Name (2006163) **CDE Short Name:** RSPBLPERSON_NAME Not for FDA submission Not for FDA submission	CHARACTER – Maximum Length = 100
Date Form Completed (2003745) **CDE Short Name:** FORM_COMPL_DT Not for FDA submission Not for FDA submission	DATE – Maximum Length = 8
Investigator Signature (58320) **CDE Short Name:** INVESTIGATOR_SIG_TXT Not for FDA submission Not for FDA submission	CHARACTER – Maximum Length = 100
Treating physician (62749) **CDE Short Name:** TREATING_DR_NAME Not for FDA submission Not for FDA submission	CHARACTER – Maximum Length = 100
Reviewer Name (3008899) **CDE Short Name:** 2626294v1.0:2746719v1.0 Not for FDA submission Not for FDA submission	CHARACTER – Maximum Length = 100

CRF Question	Value Domain
Review Date (3008897) **CDE Short Name:** 3008895v1.0:2017121v1.0 Not for FDA submission Not for FDA submission	DATE – Maximum Length = 8
Date Form Amended (64166) **CDE Short Name:** FORM_AMD_COMP_DT Not for FDA submission Not for FDA submission	DATE – Maximum Length = 8
Person Amending Form (3286567) **CDE Short Name:** CRF_CHG_PER_NM Not for FDA submission Not for FDA submission	CHARACTER – Maximum Length = 100