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).

Physical Examination CDISC Aligned NCI Standard Template Module Definitions

Mapping to the CDASH:

This NCI Standard Template Form maps to the following domains in the CDASHIG v2.0 metadata table:

- PE – Physical Examination (v2.0)

Mapping to the SDTM:

This NCI Standard Template Form maps to the following domains in the SDTMIG v3.3 metadata table:

- PE – Physical Examination (v3.3)

Physical Examination 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**
Date of Physical Examination (m) 6409603 PEDAT	The date when the physical examination was performed represented in an unambiguous date format (e.g., DD-MON-YYYY). CDASH: PEDAT (6409603); SDTM: PEDTC (No CDE)	Date
Physical Examination Test Body System Type (o) 7063544 PETESTTP	The component consisting of one or all members of an organ system or medical topic under examination. CDASH: PETEST (6421512); SDTM: PETEST (No CDE)	CHARACTER. Use choice list.
Physical Examination Test Text (o) 7063545 PETESTX	The component consisting of one or all members of an organ system or medical topic under examination not previously listed. CDASH: No CDE; SDTM: PETEST (No CDE)	CHARACTER

Field Name **(Partition Status)** **CDE ID #** **Short Name**	**Definition** **CDISC Mapping and Instruction**	**Format**
Physical Exam Abnormal Findings (o) 6421514 PEDESC	Text description of any abnormal findings. CDASH: PEDESC (6421514); SDTM: PEORRES (6659434)	CHARACTER
Physical Exam Result Finding Type (o) 7063546 PERESULT	The overall result of a physical examination category. CDASH: PERES (6421508); SDTM: PEORRES (6659434)	CHARACTER. Use choice list.
Physical Examination Performed (o) 7063547 PEPERF	An indication whether or not a planned physical examination was performed. CDASH: PEPERF (6408657); SDTM: No Match	CHARACTER. Use choice list.

Annotated CRF: Physical Examination 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: Physical Examination CDISC Aligned NCI Standard Template

Mandatary Questions

CRF Question	Value Domain
Evaluation Date (6409603) **CDE Short Name:** PEDAT CDASH: PEDAT (6409603) SDTM: PEDTC (No CDE)	DATE – Maximum Length = 11

Optional Questions

CRF Question	Value Domain
Body System (7063544) **CDE Short Name:** PETESTTP CDASH: PETEST (6421512) SDTM: PETEST (No CDE)	CHARACTER – Maximum Length = 64 List of 40 PVs
Specify Other Body System/Site (7063545) **CDE Short Name:** PETESTX CDASH: No CDE SDTM: PETEST (No CDE)	CHARACTER – Maximum Length = 200
Finding Description (6421514) **CDE Short Name:** PEDESC CDASH: PEDESC (6421514) SDTM: PEORRES (6659434)	CHARACTER – Maximum Length = 200
Finding Result (7063546) **CDE Short Name:** PERESULT CDASH: PERES (6421508) SDTM: PEORRES (6659434)	CHARACTER – Maximum Length = 12 ☐ Not Examined– None Examined ☐ Abnormal – Abnormal ☐ Normal – Normal
Overall Physical Exam Performed (7063547) **CDE Short Name:** PEPERF CDASH: PEPERF (6408657) SDTM: No Match	CHARACTER – Maximum Length = 2 ☐ N – No ☐ NA – Not Applicable ☐ U – Unknown ☐ Y – Yes