

# 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).

## Medical History 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:

- MH – Medical History (v2.0)

### Mapping to the SDTM:

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

- MH – Medical History (v3.3)

## Medical History 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 Medical History Collection (m) 6409588 MHDAT	The date on which the medical history was collected represented in an unambiguous date format (e.g., DD-MON-YYYY).  CDASH: MHDAT (6409588); SDTM: MHDTC (No CDE)	DATE
Ongoing Medical History Event (o) 6408640 MHONGO	Indication the medical condition or event is ongoing when no end date is provided.  CDASH: MHONGO (6408640); SDTM: If Yes, MHENRTPT (No CDE) = 'ONGOING'	CHARACTER. Use choice list.
Medical History Event Reported Term (o) 6421489 MHTERM	The reported or pre-specified name of the medical condition or event.  CDASH: MHTERM (6421489); SDTM: MHTERM (No CDE)	CHARACTER

<b>Field Name (Partition Status) CDE ID # Short Name</b>	<b>Definition CDISC Mapping and Instruction</b>	<b>Format</b>
Medical History Body System or Organ Class Findings Type (o) 7050295 MHFINDTY	The overall status of the body system or organ category assessment.  CDASH: No Match; SDTM: No Match	CHARACTER. Use choice list.
Medical History Body System or Organ Class Category (o) 7050296 MHBODORG	The body system or organ category objectively and/or subjectively assessed.  CDASH: MHSOC (6421497) SDTM: MHBODSYS (6658794)	CHARACTER. Use choice list.
Medical History Body System or Organ Class Text (o) 7050297 MHSOCX	The body system or organ category objectively and/or subjectively assessed not previously listed.  CDASH: No Match; SDTM: MHBODSYS (6658794)	CHARACTER
Personal Medical History Assessment Indicator (o) 7050298 MHASSIND	The indication of whether or not a patient's medical history has been assessed.  CDASH: No Match; SDTM: If no, MHSTAT (6622014) = "Not Done"	CHARACTER. Use choice list.

## Annotated CRF: Medical History 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: Medical History CDISC Aligned NCI Standard Template

Mandatory Questions

CRF Question	Value Domain
<p><b>What was the date the medical history was collected? (6409588)</b> CDE Short Name: MHDAT</p> <p>CDASH: MHDAT (6409588)</p> <p>SDTM: MHDTC (No CDE)</p>	<p>DATE – Maximum Length = 11</p>

## Optional Questions

CRF Question	Value Domain
<p><b>Is the medical condition or event ongoing? (6408640)</b>  <b>CDE Short Name: MHONGO</b></p> <p>CDASH: MHONGO (6408640)</p> <p>SDTM: If Yes, MHENRTPT (No CDE) = 'ONGOING'</p>	<p>CHARACTER – Maximum Length = 2</p> <p><input type="checkbox"/> N – No</p> <p><input type="checkbox"/> NA – Not Applicable</p> <p><input type="checkbox"/> U – Unknown</p> <p><input type="checkbox"/> Y – Yes</p>
<p><b>Description (6421489)</b>  <b>CDE Short Name: MHTERM</b></p> <p>CDASH: MHTERM (6421489)</p> <p>SDTM: MHTERM (No CDE)</p>	<p>CHARACTER – Maximum Length = 200</p>
<p><b>Finding (7050295)</b>  <b>CDE Short Name: MHFINDTY</b></p> <p>CDASH: No Match</p> <p>SDTM: No Match</p>	<p>CHARACTER – Maximum Length = 12</p> <p><input type="checkbox"/> Abnormal – Abnormal</p> <p><input type="checkbox"/> Normal – Normal</p> <p><input type="checkbox"/> Not Assessed – No Assessment</p>

CRF Question	Value Domain
<p><b>Body System (7050296)</b>  <b>CDE Short Name: MHBODORG</b></p> <p>CDASH: MHSOC (6421497)</p> <p>SDTM: MHBODSYS (6658794)</p>	<p>CHARACTER – Maximum Length = 30</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Abdomen – Abdomen</li> <li><input type="checkbox"/> Breasts – Breasts</li> <li><input type="checkbox"/> Cardiovascular – Cardiovascular System</li> <li><input type="checkbox"/> Dermatologic – Dermatologic</li> <li><input type="checkbox"/> Endocrine/Metabolic – Endocrine System</li> <li><input type="checkbox"/> Gastrointestinal – Gastrointestinal System</li> <li><input type="checkbox"/> Genitourinary – Genitourinary System</li> <li><input type="checkbox"/> HEENT – Head, Ears, Eyes, Nose and Throat</li> <li><input type="checkbox"/> Hematopoietic/Lymph Nodes(s) – Hematopoietic and Lymphatic System</li> <li><input type="checkbox"/> Immune – Immune System</li> <li><input type="checkbox"/> Musculoskeletal – Musculoskeletal System</li> <li><input type="checkbox"/> Neck – Neck</li> <li><input type="checkbox"/> Neurologic – Neurologic Examination</li> <li><input type="checkbox"/> Other – Other</li> <li><input type="checkbox"/> Pelvis – Pelvic Examination</li> <li><input type="checkbox"/> Psychologic – Psychological</li> <li><input type="checkbox"/> Respiratory – Respiratory System</li> </ul>
<p><b>Other (Body) System/Site Text (7050297)</b>  <b>CDE Short Name: MHSOCX</b></p> <p>CDASH: No Match</p> <p>SDTM: MHBODSYS (6658794)</p>	<p>CHARACTER – Maximum Length = 200</p>
<p><b>Medical History Assessment Indicator (7050298)</b>  <b>CDE Short Name: MHASSIND</b></p> <p>CDASH: No Match</p> <p>SDTM: If no, MHSTAT (6622014) = "Not Done"</p>	<p>CHARACTER – Maximum Length = 2</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> N – No</li> <li><input type="checkbox"/> NA – Not Applicable</li> <li><input type="checkbox"/> U – Unknown</li> <li><input type="checkbox"/> Y – Yes</li> </ul>