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).

PET Patient Prep 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:

- LB – Laboratory Test Results (v2.0)

Mapping to the SDTM:

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

- LB – Laboratory Test Results (v3.3)

PET Patient Prep 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**
Fasting Prior Positron Emission Tomography Duration Value (c) 7097977 PRFASTDR	The number of hours a patient fasted prior to the positron emission tomography represented as a numerical value. CDASH: No Match; SDTM: No Match; Conditionality Rule: This data element is captured based on the imaging agent used for the PET scan.	NUMBER
Lab Result (c) 6421484 LBORRES	Result of the measurement or finding as originally received or collected. CDASH: LBORRES (6421484); SDTM: LBORRES (No CDE) where LBTEST = "Glucose" and LBTPT = "PET Blood Glucose Prior to Injection"; Conditionality Rule: This element is captured based on the imaging agent used for the PET scan.	CHARACTER

Field Name **(Partition Status)** **CDE ID #** **Short Name**	**Definition** **CDISC Mapping and Instruction**	**Format**
Lab Result Unit (c) 6409054 LBORRESU	The unit of the result as originally received or collected. CDASH: LBORRESU (6409054), SDTM: LBORRESU (No CDE)	CHARACTER. Use choice list.
Time of Specimen Collection (c) 6402020 LBTIM	Time of specimen collection represented in an unambiguous time format (e.g., hh:mm:ss). CDASH: LBTIM (6402020) SDTM: LBDTC (No CDE); Conditionality Rule: This element is captured based on the imaging agent used for the PET scan.	CHARACTER
Foley Catheter Prior Positron Emission Tomography Placement Indicator (c) 7097978 PRFOLEY	An indication whether or not a Foley catheter was placed prior to the positron emission tomography. CDASH: No Match; SDTM: No Match; Conditionality Rule: This data element is captured based on the imaging agent used for the PET scan.	CHARACTER. Use choice list.
Urination Prior Positron Emission Tomography Occurrence Indicator (c) 7097979 PRURPRAG	An indication whether or not the patient voided prior to positron emission tomography. CDASH: No Match; SDTM: No Match, Can be a supplemental qualifier in SDTM; Conditionality Rule: This data element is captured based on the imaging agent used for the PET scan.	CHARACTER. Use choice list.
Positron Emission Tomography Fasting Requirement Fulfill Indicator (c) 7097980 PRFASTNY	An indication whether or not positron emission tomography fasting requirements were met. CDASH: No Match; SDTM: No Match; Conditionality Rule: This data element is captured based on the imaging agent used for the PET scan.	CHARACTER. Use choice list.

Field Name **(Partition Status)** **CDE ID #** **Short Name**	**Definition** **CDISC Mapping and Instruction**	**Format**
Urination Post Positron Tomography Occurrence Indicator (o) 7097981 PRURPSAG	An indication whether or not the patient voided after positron emission tomography. CDASH: No Match; SDTM: No Match, Can be submitted as a supplemental qualifier in SDTM	CHARACTER. Use choice list.

Annotated CRF: PET Patient Prep 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: PET Patient Prep CDISC Aligned NCI Standard Template

Conditional Questions

CRF Question	Value Domain
Duration of patient fasting pre-PET imaging (7097977) **CDE Short Name:** PRFASTDR CDASH: No Match SDTM: No Match	NUMBER – Maximum Length = 5
PET Blood Glucose (6421484) **CDE Short Name:** LBORRES CDASH: LBORRES (6421484) SDTM: LBORRES (No CDE) where LBTEST = "Glucose" and LBTPT = "PET Blood Glucose Prior to Injection"	CHARACTER – Maximum Length = 100
Unit (6409054) **CDE Short Name:** LBORRESU CDASH: LBORRESU (6409054) SDTM: LBORRESU (No CDE)	ALPHANUMERIC – Maximum Length = 100 ☐ mg/dL – Milligram per Deciliter
Time blood sample was obtained for glucose measurement (6402020) **CDE Short Name:** LBTIM CDASH: LBTIM (6402020) SDTM: LBDTC (No CDE)	CHARACTER – Maximum Length = 8

CRF Question	Value Domain
Was Foley catheter in place for scan? (7097978) **CDE Short Name:** PRFOLEY CDASH: No Match SDTM: No Match	CHARACTER – Maximum Length = 2 ☐ N – No ☐ NA – Not Applicable ☐ U – Unknown ☐ Y – Yes
Patient voided immediately pre-imaging? (7097979) **CDE Short Name:** PRURPRAG CDASH: No Match SDTM: No Match, Can be a supplemental qualifier in SDTM	CHARACTER – Maximum Length = 2 ☐ N – No ☐ NA – Not Applicable ☐ U – Unknown ☐ Y – Yes
Confirmation of fasting requirements (7097980) **CDE Short Name:** PRFASTNY CDASH: No Match SDTM: No Match	CHARACTER – Maximum Length = 2 ☐ N – No ☐ NA – Not Applicable ☐ U – Unknown ☐ Y – Yes

Optional Questions

CRF Question	Value Domain
Patient voided immediately post-imaging? (7097981) **CDE Short Name:** PRURPSAG CDASH: No Match SDTM: No Match, Can be submitted as a supplemental qualifier in SDTM	CHARACTER – Maximum Length = 2 ☐ N – No ☐ NA – Not Applicable ☐ U – Unknown ☐ Y – Yes