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).

Lost to Follow-Up 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:

- DS – Disposition (v2.0)

Mapping to the SDTM:

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

- DS – Disposition (v3.3)

Lost to Follow-Up 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**
Lost To Follow-up Report Indicator (o) 6943382 DSLFRPNY	The indication of whether or not the patient is being reported lost to follow-up. CDASH: DSTERM (6355980); SDTM: If Yes, DSTERM='LOST TO FOLLOW-UP REPORTED', DSDECOD = 'LOST TO FOLLOW-UP', and DSCAT="DISPOSITION EVENT"	CHARACTER. Use choice list.
Lost To Follow-up Report Date (o) 6943383 DSLFWLDT	The date the patient was reported lost to follow-up represented in an unambiguous date format (e.g., DD-MON-YYYY). CDASH: DSTERM (6355980) DSSTDAT (6384212); SDTM: DSSTDTC where DSTERM='LOST TO FOLLOW-UP', DSDECOD = 'LOST TO FOLLOW-UP', and DSCAT="DISPOSITION EVENT"	DATE

Field Name **(Partition Status)** **CDE ID #** **Short Name**	**Definition** **CDISC Mapping and Instruction**	**Format**
Lost To Follow-up Institutional Review Board Approval Indicator (o) 6943384 DSLFIRNY	The indication of whether or not the Institutional Review Board approves the the patient's lost to follow-up status. CDASH: DSTERM (6355980); SDTM: If Yes, DSTERM='LOST TO FOLLOW-UP IRB APPROVED', DSDECOD = 'LOST TO FOLLOW-UP', and DSCAT="DISPOSITION EVENT"	CHARACTER. Use choice list.
Lost To Follow-up Investigator Notification Indicator (o) 6943385 DSIVNFNY	An indication of whether the study investigator was notified the patient was lost to follow-up. CDASH: DSTERM (6355980); SDTM: If Yes, DSTERM='LOST TO FOLLOW-UP INVESTIGATOR NOTIFIED', DSDECOD = 'LOST TO FOLLOW-UP', and DSCAT="DISPOSITION EVENT"	CHARACTER. Use choice list.
Investigator Confirmation Signature Indicator (o) 6943370 DSIVCFNY	An indication of whether the study investigator confirmed the participants withdrawal of consent with a signature. CDASH: DSTERM (6355980); SDTM: If Yes, DSTERM='LOST TO FOLLOW-UP INVESTIGATOR CONFIRMED', DSDECOD = 'LOST TO FOLLOW-UP', and DSCAT="DISPOSITION EVENT"	CHARACTER. Use choice list.

Field Name **(Partition Status)** **CDE ID #** **Short Name**	**Definition** **CDISC Mapping and Instruction**	**Format**
Lost To Follow-up Status Cancel Indicator (o) 6943386 DSLFRSNY	An indication of whether a patient previously lost to follow-up was able to be contacted. CDASH: DSTERM (6355980); SDTM: If Yes, DSTERM='LOST TO FOLLOW-UP CANCELLED', DSDECOD = 'OTHER', and DSCAT="DISPOSITION EVENT"	CHARACTER. Use choice list.
Lost To Follow-up Status Cancel Date (o) 6943387 DSLFRSDT	The date the patient's report of lost to follow-up was withdrawn represented in an unambiguous date format (e.g., DD-MON-YYYY). CDASH: DSTERM (6355980) DSSTDAT (6384212); SDTM: DSSTDTC where DSTERM='LOST TO FOLLOW-UP CANCELLED', DSDECOD = 'OTHER', and DSCAT="DISPOSITION EVENT"	DATE

Annotated CRF: Lost to Follow-Up 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: Lost to Follow-Up CDISC Aligned NCI Standard Template

Optional Questions

CRF Question	Value Domain
Are you reporting the participant lost to follow-up? (6943382) **CDE Short Name:** DSLFRPNY CDASH: DSTERM (6355980) SDTM: If Yes, DSTERM='LOST TO FOLLOW-UP REPORTED', DSDECOD = 'LOST TO FOLLOW-UP', and DSCAT="DISPOSITION EVENT"	CHARACTER – Maximum Length = 2 ☐ N – No ☐ NA – Not Applicable ☐ U – Unknown ☐ Y – Yes
Date study participant declared lost to follow-up (6943383) **CDE Short Name:** DSLFWLDT CDASH: DSTERM (6355980) DSSTDAT (6384212) SDTM: DSSTDTC where DSTERM='LOST TO FOLLOW-UP', DSDECOD = 'LOST TO FOLLOW-UP', and DSCAT="DISPOSITION EVENT"	DATE – Maximum Length = 11
Study participant lost to follow-up approved (6943384) **CDE Short Name:** DSLFIRNY CDASH: DSTERM (6355980) SDTM: If Yes, DSTERM='LOST TO FOLLOW-UP IRB APPROVED', DSDECOD = 'LOST TO FOLLOW-UP', and DSCAT="DISPOSITION EVENT"	CHARACTER – Maximum Length = 2 ☐ N – No ☐ NA – Not Applicable ☐ U – Unknown ☐ Y – Yes

CRF Question	Value Domain
Investigator notified (6943385) **CDE Short Name:** DSIVNFNY CDASH: DSTERM (6355980) SDTM: If Yes, DSTERM='LOST TO FOLLOW-UP INVESTIGATOR NOTIFIED', DSDECOD = 'LOST TO FOLLOW-UP', and DSCAT="DISPOSITION EVENT"	CHARACTER – Maximum Length = 2 ☐ N – No ☐ NA – Not Applicable ☐ U – Unknown ☐ Y – Yes
Investigator confirmation (6943370) **CDE Short Name:** DSIVCFNY CDASH: DSTERM (6355980) SDTM: If Yes, DSTERM='LOST TO FOLLOW-UP INVESTIGATOR CONFIRMED', DSDECOD = 'LOST TO FOLLOW-UP', and DSCAT="DISPOSITION EVENT"	CHARACTER – Maximum Length = 2 ☐ N – No ☐ NA – Not Applicable ☐ U – Unknown ☐ Y – Yes
Was the study participant, previously deemed lost to follow-up, able to be contacted? (6943386) **CDE Short Name:** DSLFRSNY CDASH: DSTERM (6355980) SDTM: If Yes, DSTERM='LOST TO FOLLOW-UP CANCELLED', DSDECOD = 'OTHER', and DSCAT="DISPOSITION EVENT"	CHARACTER – Maximum Length = 2 ☐ N – No ☐ NA – Not Applicable ☐ U – Unknown ☐ Y – Yes
Date lost to follow-up is rescinded (6943387) **CDE Short Name:** DSLFRSDT CDASH: DSTERM (6355980) DSSTDAT (6384212) SDTM: DSSTDTC where DSTERM='LOST TO FOLLOW-UP CANCELLED', DSDECOD = 'OTHER', and DSCAT="DISPOSITION EVENT"	DATE – Maximum Length = 11