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).

Consent Withdrawal 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)

Consent Withdrawal 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**
Informed Consent Withdrawn Date (m) 6943377 DSCNWDDT	The date study participant withdrew consent represented in an unambiguous date format (e.g., DD-MON-YYYY). CDASH: DSTERM (6355980), DSSTDAT (6384212) where DSSCAT (6384142) = "Consent Withdrawn"; SDTM: DSSTDTC where DSTERM="CONSENT WITHDRAWN", DSDECOD = 'WITHDRAWAL BY SUBJECT", and DSCAT="DISPOSITION EVENT"	DATE
Patient Informed Consent Cancel Withdrawal Paperwork Type (o) 3775411 3775400v1.0:3775401v1.0	Term to describe the type of correspondence detailing a patient's withdrawal or cancellation of informed consent. Not for FDA submission	CHARACTER. Use choice list.

Field Name **(Partition Status)** **CDE ID #** **Short Name**	**Definition** **CDISC Mapping and Instruction**	**Format**
Patient Informed Consent Cancel Withdrawal Other Paperwork Text (o) 3781754 3781753v1.0:2181231v1.0	Text to describe the type of correspondence detailing a patient's withdrawal or cancellation of informed consent that is different from the options provided. Not for FDA submission	ALPHANUMERIC
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) where DSSCAT (6384142)= "Consent Withdrawn"; SDTM: If Yes, DSTERM= "INVESTIGATOR WITHDRAWAL BY SUBJECT KNOWLEDGE CONFIRMATION", DSDECOD = 'WITHDRAWAL BY SUBJECT', and DSCAT = 'DISPOSITION EVENT'	CHARACTER. Use choice list.
Informed Consent Withdrawn Cancel Date (o) 6943380 DSCFWDRS	The date participant canceled their consent withdrawal represented in an unambiguous date format (e.g., DD-MON-YYYY). CDASH: DSTERM (6355980), DSSTDAT (6384212) where DSSCAT (6384142) = "Consent Withdrawn"; SDTM: DSSTDTC where DSTERM = "CONSENT WITHDRAWN RESCINDED" and DSDECOD = 'OTHER' and DSCAT = 'DISPOSITION EVENT'	DATE

Field Name **(Partition Status)** **CDE ID #** **Short Name**	**Definition** **CDISC Mapping and Instruction**	**Format**
Informed Consent Withdrawn Cancel Text (o) 6943381 DSWDCNTX	An explanation why the withdrawn consent was canceled. CDASH: DSTERM (6355980) where DSSCAT (6384142) = "Consent Withdrawn"; SDTM: DSTERM where DSDECOD = 'WITHDRAWAL BY SUBJECT' and DSCAT = 'DISPOSITION EVENT'	CHARACTER

Annotated CRF: Consent Withdrawal 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: Consent Withdrawal CDISC Aligned NCI Standard Template

Mandatary Questions

CRF Question	Value Domain
Date study participant withdrew consent (6943377) **CDE Short Name:** DSCNWDDT CDASH: DSTERM (6355980), DSSTDAT (6384212) where DSSCAT (6384142) = "Consent Withdrawn" SDTM: DSSTDTC where DSTERM="CONSENT WITHDRAWN", DSDECOD = 'WITHDRAWAL BY SUBJECT", and DSCAT="DISPOSITION EVENT"	DATE – Maximum Length = 11

Optional Questions

CRF Question	Value Domain
Type of Correspondence (3775411) **CDE Short Name:** 3775400v1.0:3775401v1.0 CDASH: Not for FDA submission SDTM: Not for FDA submission	CHARACTER – Maximum Length = 100 ☐ Clinic Note – Clinic Note ☐ Signed and dated letter from study participant – Patient Signed Dated Letter ☐ Signed and dated letter from study participant's legal guardian/POA – Guardian Or Power of Attorney Signed Dated Letter ☐ Telephone Call from patient or legal guardian – Patient or Legal Guardian Telephone Call
Type of correspondence comments (3781754) **CDE Short Name:** 3781753v1.0:2181231v1.0 CDASH: Not for FDA submission SDTM: Not for FDA submission	ALPHANUMERIC – Maximum Length = 200
Investigator attestation (6943370) **CDE Short Name:** DSIVCFNY CDASH: DSTERM (6355980) where DSSCAT (6384142)= "Consent Withdrawn" SDTM: If Yes, DSTERM= "INVESTIGATOR WITHDRAWAL BY SUBJECT KNOWLEDGE CONFIRMATION", DSDECOD = 'WITHDRAWAL BY SUBJECT', and DSCAT = 'DISPOSITION EVENT'	CHARACTER – Maximum Length = 2 ☐ N – No ☐ NA – Not Applicable ☐ U – Unknown ☐ Y – Yes

CRF Question	Value Domain
Date study participant rescinded consent withdrawal (6943380) **CDE Short Name:** DSCFWDRS CDASH: DSTERM (6355980), DSSTDAT (6384212) where DSSCAT (6384142) = "Consent Withdrawn"; SDTM: DSSTDTC where DSTERM = "CONSENT WITHDRAWN RESCINDED" and DSDECOD = 'OTHER' and DSCAT = 'DISPOSITION EVENT'	DATE – Maximum Length = 11
Reason for withdrawal (6943381) **CDE Short Name:** DSWDCNTX CDASH: DSTERM (6355980) where DSSCAT (6384142) = "Consent Withdrawn" SDTM: DSTERM where DSDECOD = 'WITHDRAWAL BY SUBJECT' and DSCAT = 'DISPOSITION EVENT'	CHARACTER – Maximum Length = 200