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 Specimen 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 Specimen 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**
Biospecimen Collection Consent Withdrawn Indicator (m) 6943366 DSIRBANY	An indication whether or not the participant withdrew consent for further specimen collection. CDASH: DSTERM (6355980) where DSSCAT (6384142) = "Consent Withdrawan Specimen"; SDTM: If Yes, DSTERM="STUDY PARTICIPANT WITHDRAWS CONSENT TO FURTHER SPECIMEN COLLECTION IRB APPROVED", DSDECOD = 'WITHDRAWAL BY SUBJECT', and DSCAT = 'DISPOSITION EVENT'	CHARACTER. Use choice list.

Field Name **(Partition Status)** **CDE ID #** **Short Name**	**Definition** **CDISC Mapping and Instruction**	**Format**
Biospecimen Collection Informed Consent Amended Date (m) 6943367 DSCFAMDT	The date the informed consent form for specimen collection was amended represented in an unambiguous date format (e.g., DD-MON-YYYY). CDASH: DSTERM (6355980) DSSTDAT (6384212) where DSSCAT (6384142) = "Consent Withdrawal Specimen"; SDTM: DSSTDTC where DSTERM='PATIENT SPECIMEN AMENDED CONSENT' and DSDECOD = 'INFORMED CONSENT OBTAINED' and DSCAT = 'PROTOCOL MILESTONE'	DATE
Biospecimen Collection And Use Consent Withdrawn Indicator (m) 6943368 DSCFWDNY	An indication whether or not the participant withdrew consent for further specimen collection and use. CDASH: DSTERM (6355980) where DSSCAT (6384142) = "Consent Withdrawal Specimen"; SDTM: If Yes, DSTERM="STUDY PARTICIPANT CONSENT WITHDRAWAL FOR SPECIMEN(S)", DSDECOD = 'WITHDRAWAL BY SUBJECT', and DSCAT = 'DISPOSITION EVENT'	CHARACTER. Use choice list.

Field Name **(Partition Status)** **CDE ID #** **Short Name**	**Definition** **CDISC Mapping and Instruction**	**Format**
Biospecimen Collection and Use Informed Consent Amended Date (m) 6943369 DSCFNFDT	The date the informed consent form for specimen collection and use was amended represented in an unambiguous date format (e.g., DD-MON-YYYY). CDASH: CDSTERM (6355980) DSSTDAT (6384212) where DSSCAT (6384142) = "Consent Withdrawal Specimen"; SDTM: DSSTDTC where DSTERM='PATIENT NOTIFICATION TREATING SITE CONSENT AMENDED' and DSDECOD = 'INFORMED CONSENT OBTAINED' and DSCAT = 'OTHER EVENT'	DATE
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 Withdrawal Specimen"; SDTM: If Yes, DSTERM="INVESTIGATOR WITHDRAWAL BY SUBJECT BIOSPECIMEN COLLECTION CONSENT KNOWLEDGE CONFIRMATION", DSDECOD = 'WITHDRAWAL BY SUBJECT', and DSCAT = 'DISPOSITION EVENT'	CHARACTER. Use choice list.

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

Mandatary Questions

CRF Question	Value Domain
Study participant withdraws consent to further specimen collection (6943366) **CDE Short Name:** DSIRBANY CDASH: DSTERM (6355980) where DSSCAT (6384142) = "Consent Withdrawan Specimen" SDTM: If Yes, DSTERM="STUDY PARTICIPANT WITHDRAWS CONSENT TO FURTHER SPECIMEN COLLECTION IRB APPROVED", DSDECOD = 'WITHDRAWAL BY SUBJECT', and DSCAT = 'DISPOSITION EVENT'	CHARACTER – Maximum Length = 2 ☐ N – No ☐ NA – Not Applicable ☐ U – Unknown ☐ Y – Yes
If yes, date of amended consent (6943367) **CDE Short Name:** DSCFAMDT CDASH: DSTERM (6355980) DSSTDAT (6384212) where DSSCAT (6384142) = "Consent Withdrawal Specimen" SDTM: DSSTDTC where DSTERM='PATIENT SPECIMEN AMEDED CONSENT' and DSDECOD = 'INFORMED CONSENT OBTAINED' and DSCAT = 'PROTOCOL MILESTONE'	DATE – Maximum Length = 11

CRF Question	Value Domain
Study participant is changing original consent for specimen collected and use (6943368) **CDE Short Name:** DSCFWDNY CDASH: DSTERM (6355980) where DSSCAT (6384142) = "Consent Withdrawal Specimen" SDTM: If Yes, DSTERM="STUDY PARTICIPANT CONSENT WITHDRAWAL FOR SPECIMEN(S)", DSDECOD = 'WITHDRAWAL BY SUBJECT', and DSCAT = 'DISPOSITION EVENT'	CHARACTER – Maximum Length = 2 ☐ N – No ☐ NA – Not Applicable ☐ U – Unknown ☐ Y – Yes
If yes, date amended consent (6943369) **CDE Short Name:** DSCFNFDT CDASH: CDSTERM (6355980) DSSTDAT (6384212) where DSSCAT (6384142) = "Consent Withdrawal Specimen" SDTM: DSSTDTC where DSTERM='PATIENT NOTIFICATION TREATING SITE CONSENT AMENDED' and DSDECOD = 'INFORMED CONSENT OBTAINED' and DSCAT = 'OTHER EVENT'	DATE – Maximum Length = 11

Optional Questions

CRF Question	Value Domain
Investigator attestation (6943370) **CDE Short Name:** DSIVCFNY CDASH DSTERM (6355980) where DSSCAT (6384142) = "Consent Withdrawal Specimen"; SDTM: If Yes, DSTERM="INVESTIGATOR WITHDRAWAL BY SUBJECT BIOSPECIMEN COLLECTION CONSENT KNOWLEDGE CONFIRMATION", DSDECOD = 'WITHDRAWAL BY SUBJECT', and DSCAT = 'DISPOSITION EVENT'	CHARACTER – Maximum Length = 2 ☐ N – No ☐ NA – Not Applicable ☐ U – Unknown ☐ Y – Yes