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 Quality of Life Study 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 Quality of Life Study 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**
Quality of Life Consent Withdrawn Indicator (m) 6943371 DSCFWHDR	An indication whether or not the participant withdrew consent for participation in the Quality of Life portion of the study. CDASH: DSTERM (6355980) where DSSCAT (6384142) = "Quality of Life Consent Withdrawn"; SDTM: If Yes, DSTERM="PATIENT COMPANION STUDY QUALITY OF LIFE CONSENT WITHDRAWN", DSDECOD = 'WITHDRAWAL BY SUBJECT', DSCAT = 'DISPOSITION EVENT', and DSSCAT = "QUALITY OF LIFE CONSENT WITHDRAWN"	CHARACTER. Use choice list.

Field Name **(Partition Status)** **CDE ID #** **Short Name**	**Definition** **CDISC Mapping and Instruction**	**Format**
Quality of Life Consent Withdrawn Date (m) 6943372 DSCFWDDT	The date the participant withdrew consent for participation in the Quality of Life portion of the study represented in an unambiguous date format (e.g., DD-MON-YYYY) CDASH: DSTERM (6355980) DSSTDAT (6384212) where DSSCAT (6384142) = "Quality of Life Consent Withdrawn"; SDTM: DSSTDTC where DSTERM='DATE STUDY PARTICIPANT WITHDREW QOL CONSENT' and DSDECOD = 'WITHDRAWAL BY SUBJECT', DSCAT = 'OTHER EVENT", and DSSCAT = "QUALITY OF LIFE CONSENT WITHDRAWN"	DATE
Quality of Life Consent Withdrawn Reason (o) 6943373 DSCFWDRN	An explanation of why the patient withdrew consent for participation in the Quality of Life portion of the study. CDASH: DSDECOD (6355981) where DSSCAT (6384142) = "Quality of Life Consent Withdrawn"; SDTM: DSTERM where DSDECOD = 'WITHDRAWAL BY SUBJECT', DSCAT = 'DISPOSITION EVENT", and DSSCAT = "QUALITY OF LIFE CONSENT WITHDRAWN"	CHARACTER. Use choice list.

Field Name **(Partition Status)** **CDE ID #** **Short Name**	**Definition** **CDISC Mapping and Instruction**	**Format**
Quality of Life Consent Withdrawn Reason Text (o) 6943374 DSCFWRNX	An explanation why the patient withdrew consent for participation in the Quality of Life portion of the study not previously listed. CDASH: DSTERM (6355980) where DSSCAT (6384142) = "Quality of Life Consent Withdrawn"; SDTM: DSTERM where DSDECOD = 'WITHDRAWAL BY SUBJECT', DSCAT = 'DISPOSITION EVENT', and DSSCAT = "QUALITY OF LIFE CONSENT WITHDRAWN"	CHARACTER
Quality of Life Consent Withdrawn Witness Confirmation Date (o) 6943375 DSCFWDCF	The date of witness confirmation of participant's withdrawal of consent for participation in the Quality of Life portion of the study represented in an unambiguous date format (e.g., DD-MON-YYYY). CDASH: DSTERM (6355980) DSSTDAT (6384212) where DSSCAT (6384142) = "Quality of Life Consent Withdrawn"; SDTM: DSSTDTC where DSTERM='WITNESS CONFIRMATION PATIENT WITHDRAW QOL CONSENT' and DSCAT = 'DISPOSITION EVENT', and DSSCAT = "QUALITY OF LIFE CONSENT WITHDRAWN"	DATE

Field Name **(Partition Status)** **CDE ID #** **Short Name**	**Definition** **CDISC Mapping and Instruction**	**Format**
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) = "Quality of Life Consent Withdrawn"; SDTM: If Yes, DSTERM="INVESTIGATOR WITHDRAWAL BY SUBJECT QUALITY OF LIFE CONSENT KNOWLEDGE CONFIRMATION", DSDECOD = 'WITHDRAWAL BY SUBJECT', DSCAT = 'DISPOSITION EVENT', and DSSCAT = "QUALITY OF LIFE CONSENT WITHDRAWN"	CHARACTER. Use choice list.
Investigator Withdrawal by Subject Quality of Life Consent Knowledge Confirmation Date (o) 3783691 3783690v1.0:2018550v1.0	Calendar date Investigator acknowledges understanding of a study patient's decision to withdraw consent from the Quality of Life portion of a study. Not for FDA submission	DATE

Annotated CRF: Consent Withdrawal Quality of Life Study 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 Quality of Life Study CDISC Aligned NCI Standard Template

Mandatary Questions

CRF Question	Value Domain
Has participant withdrawn consent from Quality of Life portion of the study? (6943371) **CDE Short Name:** DSCFWHDR CDASH: DSTERM (6355980) where DSSCAT (6384142) = "Quality of Life Consent Withdrawn" SDTM: If Yes, DSTERM="PATIENT COMPANION STUDY QUALITY OF LIFE CONSENT WITHDRAWN", DSDECOD = 'WITHDRAWAL BY SUBJECT', DSCAT = 'DISPOSITION EVENT', and DSSCAT = "QUALITY OF LIFE CONSENT WITHDRAWN"	CHARACTER – Maximum Length = 2 ☐ N – No ☐ NA – Not Applicable ☐ U – Unknown ☐ Y – Yes
Date study participant withdrew consent (6943372) **CDE Short Name:** DSCFWDDT CDASH: DSTERM (6355980) DSSTDAT (6384212) where DSSCAT (6384142) = "Quality of Life Consent Withdrawn SDTM: DSSTDTC where DSTERM='DATE STUDY PARTICIPANT WITHDREW QOL CONSENT' and DSDECOD = 'WITHDRAWAL BY SUBJECT', DSCAT = 'OTHER EVENT", and DSSCAT = "QUALITY OF LIFE CONSENT WITHDRAWN"	DATE – Maximum Length = 11

Optional Questions

CRF Question	Value Domain
Reason for withdrawal from Quality of Life portion of study (6943373) **CDE Short Name:** DSCFWDRN CDASH: DSDECOD (6355981) where DSSCAT (6384142) = "Quality of Life Consent Withdrawn" SDTM: DSTERM where DSDECOD = 'WITHDRAWAL BY SUBJECT', DSCAT = 'DISPOSITION EVENT', and DSSCAT = "QUALITY OF LIFE CONSENT WITHDRAWN"	CHARACTER – Maximum Length = 50 ☐ I am not comfortable with the questions being asked – Discomfort with questions asked ☐ No reason given – No Reason Given ☐ Other – Other, specify ☐ The questionnaires are too time consuming – Questionnaires too time consuming
Reason for withdrawal from Quality of Life portion of study, other (6943374) **CDE Short Name:** DSCFWRNX CDASH: DSTERM (6355980) where DSSCAT (6384142) = "Quality of Life Consent Withdrawn SDTM: DSTERM where DSDECOD = 'WITHDRAWAL BY SUBJECT', DSCAT = 'DISPOSITION EVENT', and DSSCAT = "QUALITY OF LIFE CONSENT WITHDRAWN"	CHARACTER – Maximum Length = 200
Date witness confirmed study participant withdrew consent (6943375) **CDE Short Name:** DSCFWDCF CDASH: DSTERM (6355980) DSSTDAT (6384212) where DSSCAT (6384142) = "Quality of Life Consent Withdrawn" SDTM: DSSTDTC where DSTERM='WITNESS CONFIRMATION PATIENT WITHDRAW QOL CONSENT' and DSCAT = 'DISPOSITION EVENT', and DSSCAT = "QUALITY OF LIFE CONSENT WITHDRAWN"	DATE – Maximum Length = 11

CRF Question	Value Domain
Investigator attestation (6943370) **CDE Short Name:** DSIVCFNY CDASH: DSTERM (6355980) where DSSCAT (6384142) = "Quality of Life Consent Withdrawn" SDTM: If Yes, DSTERM= "INVESTIGATOR WITHDRAWAL BY SUBJECT QUALITY OF LIFE CONSENT KNOWLEDGE CONFIRMATION", DSDECOD = 'WITHDRAWAL BY SUBJECT', DSCAT = 'DISPOSITION EVENT', and DSSCAT = "QUALITY OF LIFE CONSENT WITHDRAWN"	CHARACTER – Maximum Length = 2 ☐ N – No ☐ NA – Not Applicable ☐ U – Unknown ☐ Y – Yes
Investigator date signature (3783691) **CDE Short Name:** 3783690v1.0:2018550v1.0 CDASH: Not for FDA submission SDTM: Not for FDA submission	DATE – Maximum Length = 8