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).

Vital Signs 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:

- CO – Comments (v2.0)
- VS – Vital Signs (v2.0)

Mapping to the SDTM:

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

- CO – Comments (v3.3)
- QS – Questionnaires (v3.3)
- VS – Vital Signs (v3.3)

Vital Signs 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
Vital Signs Date (o) 6422928 VSDAT	The date of the vital signs measurement represented in an unambiguous date format (e.g., DD-MON-YYYY). CDASH: VSDAT (6422928); SDTM: VSDTC (No CDE)	DATE
Vital Signs Time (o) 6409571 VSTIM	The time of measurement represented in an unambiguous time format (e.g., hh:mm:ss). CDASH: VSTIM (6409571); SDTM: VSDTC (No CDE)	CHARACTER
Vital Signs Position Type (o) 7063894 VSBPOS	The position of the patient during the collection of vital signs. CDASH: SYSBP_VSPOS (6409645); SDTM: VSPOS (No CDE)	CHARACTER. Use choice list.

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
KPS Scale - Karnofsky Performance Status Score (o) 7063902 KPSS01	The numerical score that represents the functional capabilities of a patient using the Karnofsky Performance Status assessment. CDASH: No CDE; SDTM: QSSTRESN (6643174) where QSTESTCD (6659631) = "KPSS01" and QSTEST (6659629) = "KPSS-Karnofsky Performance Status" and QSCAT (6648971) = "KPS Scale"	CHARACTER. Use choice list.
Zubrod Performance Status Score (o) 7063910 ZUBROD01	The numerical score that represents the functional capabilities of a patient using the Zubrod Performance Status assessment. CDASH: No CDE; SDTM: QSSTRESN (6643174) where QSTESTCD (6659631) = "ZUBROD01" and QSTEST (6659629) = "Zubrod Performance Status" and QSCAT (6648971) = "ZUBROD"	CHARACTER. Use choice list.
LPSS - Lansky Play-Performance Status Score (o) 7063911 LANSKY01	The numerical score that represents the functional capabilities of a patient using the Lansky Play-Performance Status assessment. CDASH: No CDE; SDTM: QSSTRESN (6643174) where QSTESTCD (6659631) = "LANSKY01" and QSTEST (6659629) = "Lansky Performance Status" and QSCAT 6648971) = "LANSKY"	CHARACTER. Use choice list.

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
ECOG - Performance Status Score (o) 7063912 ECOG01	The numerical score that represents the functional capabilities of a patient using the Eastern Cooperative Oncology Group Performance Status assessment. CDASH: No CDE; SDTM: QSSTRESN (6643174) where QSTESTCD (6659631) = "ECOG101" and QSTEST 6659629) = "ECOG1-Performance Status" and QSCAT (6648971) = "ECOG"	CHARACTER. Use choice list.
Weight Vital Signs Original Result Value (o) 7063915 WEIGHT	The vertical force exerted by the mass of an individual represented as a numerical value. CDASH: VSORRES (6355977); SDTM: VSORRES (No CDE) where VSTEST = "Weight" and VSTESTCD (6658790) = "WEIGHT"	NUMBER
Vital Signs Result Unit (o) 6355979 VSORRESU	The unit of the result as originally received or collected. CDASH: VSORRESU (6355979); SDTM: VSORRESU (No CDE)	CHARACTER. Use choice list.
Vital Signs Ideal Body Weight Value (o) 7063924 IDEALWT	The optimal weight of the patient based on height, gender, age and body type represented as a numerical value. CDASH: VSORRES (6355977); SDTM: VSORRES (No CDE) where VSTEST (No CDE) = "Ideal Body Weight" and VSTESTCD (6658790) = "IDEALWT"	NUMBER

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Vital Signs Result Unit (o) 6355979 VSORRESU	The unit of the result as originally received or collected. CDASH: VSORRESU (6355979); SDTM: VSORRESU (No CDE)	CHARACTER. Use choice list.
Height Vital Signs Original Result Value (o) 7063933 HEIGHT	The vertical length of an individual represented as a numerical value. CDASH: VSORRES (6355977); SDTM: VSORRES (No CDE) where VSTEST (No CDE) = "Height" and VSTESTCD (6658790) = "HEIGHT"	NUMBER
Vital Signs Result Unit (o) 6355979 VSORRESU	The unit of the result as originally received or collected. CDASH: VSORRESU (6355979); SDTM: VSORRESU (No CDE)	CHARACTER. Use choice list.
Body Surface Area Vital Signs Original Result Value (o) 7063942 BSA	The calculated quantity of the 2-dimensional body surface relating height to weight represented as a numerical value. CDASH: VSORRES (6355977); SDTM: VSORRES (No CDE) where VSTEST (No CDE) = "Body Surface Area" and VSTESTCD (6658790) = "BSA"	NUMBER
Vital Signs Result Unit (o) 6355979 VSORRESU	The unit of the result as originally received or collected. CDASH: VSORRESU (6355979); SDTM: VSORRESU (No CDE)	CHARACTER. Use choice list.

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Vital Signs Body Mass Index Value (o) 7063953 BMI	The calculated quantity of an individual's weight to height ratio represented as a numerical value. CDASH: VSORRES (6355977); SDTM: VSORRES (No CDE) where VSTEST (No CDE) = "Body Mass Index" and VSTESTCD (6658790) = "BMI"	NUMBER
Vital Signs Result Unit (o) 6355979 VSORRESU	The unit of the result as originally received or collected. CDASH: VSORRESU (6355979); SDTM: VSORRESU (No CDE)	CHARACTER. Use choice list.
Temperature Vital Signs Original Result Value (o) 7063954 TEMP	The patient's body temperature represented as a numerical value. CDASH: VSORRES (6355977); SDTM: VSORRES (No CDE) where VSTEST (No CDE) = "Body Temperature" and VSTESTCD (6658790) = "TEMP"	NUMBER
Vital Signs Result Unit (o) 6355979 VSORRESU	The unit of the result as originally received or collected. CDASH: VSORRESU (6355979); SDTM: VSORRESU (No CDE)	CHARACTER. Use choice list.
Vital Signs Body Temperature Measurement Method Type (o) 7063955 TEMPLOC	The method used to determine a patient's body temperature. CDASH: VSLOC (6408751); SDTM: VSLOC (No CDE)	CHARACTER. Use choice list.
Pulse Rate Vital Signs Original Result Rate (o) 7063963 PULSE	The measurement of the heart contractions represented as a numerical value. CDASH: VSORRES (6355977); SDTM: VSORRES (No CDE) where VSTEST (No CDE) = "Pulse Rate" and VSTESTCD (6658790) = "PULSE"	CHARACTER

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Vital Signs Result Unit (o) 6355979 VSORRESU	The unit of the result as originally received or collected. CDASH: VSORRESU (6355979); SDTM: VSORRESU (No CDE)	CHARACTER. Use choice list.
Oxygen Saturation Measurement Vital Signs Original Result Value (o) 7063971 OXYSAT	The percentage of oxygen in the blood measure through cutaneous assessment represented as a numerical value. CDASH: VSORRES (6355977); SDTM: VSORRES (No CDE) where VSTEST (No CDE) = "Oxygen Saturation" and VSTESTCD (6658790) = "OXYSAT"	NUMBER
Vital Signs Result Unit (o) 6355979 VSORRESU	The unit of the result as originally received or collected. CDASH: VSORRESU (6355979); SDTM: VSORRESU (No CDE)	CHARACTER. Use choice list.
Respiratory Rate Vital Signs Original Result Rate (o) 7063986 RESPIRAT	The rate of breathing measured within a unit of time represented as a numerical value. CDASH: VSORRES (6355977); SDTM: VSORRES (No CDE) where VSTEST (No CDE) = "Respiratory Rate" and VSTESTCD (6658790) = "RESP"	CHARACTER
Vital Signs Result Unit (o) 6355979 VSORRESU	The unit of the result as originally received or collected. CDASH: VSORRESU (6355979); SDTM: VSORRESU (No CDE)	CHARACTER. Use choice list.

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Systolic Blood Pressure Vital Signs Original Result Value (o) 7063994 SYSBP	The pressure of the blood against the artery walls during systole represented as a numerical value. CDASH: VSORRES (6355977); SDTM: VSORRES (No CDE) where VSTEST (No CDE) = "Systolic Blood Pressure" and VSTESTCD (6658790) = "SYSBP"	NUMBER
Vital Signs Result Unit (o) 6355979 VSORRESU	The unit of the result as originally received or collected. CDASH: VSORRESU (6355979); SDTM: VSORRESU (No CDE)	CHARACTER. Use choice list.
Diastolic Blood Pressure Vital Signs Original Result Value (o) 7064009 DIASBP	The pressure of the blood against the artery walls during diastole represented as a numerical value. CDASH: VSORRES (6355977); SDTM: VSORRES (No CDE) where VSTEST (No CDE) = "Diastolic Blood Pressure" and VSTESTCD (6658790) = "DIABP"	NUMBER
Vital Signs Result Unit (o) 6355979 VSORRESU	The unit of the result as originally received or collected. CDASH: VSORRESU (6355979); SDTM: VSORRESU (No CDE)	CHARACTER. Use choice list.
Vital Signs Comment Value Text (o) 7148887 VSCOVAL	A free text comment used to describe details of the Vital Signs assessment. CDASH: COVAL (6355806); SDTM: COVAL (No CDE)	CHARACTER

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Comment Value Date (o) 7064010 VSCODTC	The date general notes or comments were entered, represented in an unambiguous date format (e.g., DD-MON-YYYY). CDASH: CODTC (No CDE); SDTM: CODTC (No CDE)	DATE

Annotated CRF: Vital Signs 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: Vital Signs CDISC Aligned NCI Standard Template

Optional Questions

CRF Question	Value Domain
Date of Measurement (6422928) **CDE Short Name:** VSDAT CDASH: VSDAT (6422928) SDTM: VSDTC (No CDE)	DATE – Maximum Length = 11
Time of Measurement (6409571) **CDE Short Name:** VSTIM CDASH: VSTIM (6409571) SDTM: VSDTC (No CDE)	CHARACTER – Maximum Length = 8
Participant Position (7063894) **CDE Short Name:** VSBPOS CDASH: SYSBP_VSPOS (6409645) SDTM: VSPOS (No CDE)	CHARACTER – Maximum Length = 15 ☐ Prone – Prone Position ☐ Semiprone – Semiprone ☐ Sitting – Sitting ☐ Standing – Standing ☐ Supine – Supine Position ☐ Unknown – Unknown ☐ Upright – Upright

CRF Question	Value Domain
Performance Status (Karnofsky) (7063902) **CDE Short Name:** KPSS01 CDASH: No CDE SDTM: QSSTRESN (6643174) where QSTESTCD (6659631) = "KPSS01" and QSTEST (6659629) = "KPSS-Karnofsky Performance Status" and QSCAT (6648971) = "KPS Scale"	CHARACTER – Maximum Length = 3 ☐ 0 – Dead ☐ 10 – Moribund, fatal processes progressing rapidly ☐ 100 – Normal, no complaints, no evidence of disease ☐ 20 – Very sick, hospitalization indicated. Death not imminent ☐ 30 – Severely disabled, hospitalization indicated. Death not imminent ☐ 40 – Disabled, requires special care and assistance ☐ 50 – Requires considerable assistance and frequent medical care ☐ 60 – Requires occasional assistance, but is able to care for most of his/her needs ☐ 70 – Cares for self, unable to carry on normal activity or to do active work ☐ 80 – Normal activity with effort; some signs or symptoms of disease ☐ 90 – Able to carry on normal activity; minor signs or symptoms of disease
Performance Status (Zubrod) (7063910) **CDE Short Name:** ZUBROD01 CDASH: No CDE SDTM: QSSTRESN (6643174) where QSTESTCD (6659631) = "ZUBROD01" and QSTEST (6659629) = "Zubrod Performance Status" and QSCAT (6648971) = "ZUBROD"	CHARACTER – Maximum Length = 1 ☐ 0 – Normal Activity ☐ 1 – Symptoms, but nearly fully ambulatory ☐ 2 – Some bed time, but needs to be in bed <50% of normal daytime ☐ 3 – Needs to be in bed > 50% of normal daytime ☐ 4 – Unable to get out of bed

CRF Question	Value Domain
Performance Status (Lansky) (7063911) **CDE Short Name:** LANSKY01 CDASH: No CDE SDTM: QSSTRESN (6643174) where QSTESTCD (6659631) = "LANSKY01" and QSTEST (6659629) = "Lansky Performance Status" and QSCAT 6648971) = "LANSKY"	CHARACTER – Maximum Length = 3 ☐ 0 – Unresponsive ☐ 10 – No play; does not get out of bed. ☐ 100 – Fully active, normal ☐ 20 – Often sleeping; play entirely limited to very passive activities. ☐ 30 – In bed; needs assistance even for quiet play. ☐ 40 – Mostly in bed; participates in quiet activities. ☐ 50 – Gets dressed, but lies around much of the day; no active play, able to participate in all quiet play and activities. ☐ 60 – Up and around, but minimal active play; keeps busy with quieter activities. ☐ 70 – Both greater restriction of and less time spent in play activity ☐ 80 – Active, but tires more quickly ☐ 90 – Minor restrictions in physically strenuous activity
Performance Status (ECOG) (7063912) **CDE Short Name:** ECOG01 CDASH: No CDE SDTM: QSSTRESN (6643174) where QSTESTCD (6659631) = "ECOG101" and QSTEST 6659629) = "ECOG1-Performance Status" and QSCAT (6648971) = "ECOG"	CHARACTER – Maximum Length = 1 ☐ 0 – Fully active, able to carry on all pre-disease performance without restriction. ☐ 1 – Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light housework, office work. ☐ 2 – Ambulatory and capable of all selfcare but unable to carry out any work activities. Up and about more than 50% of waking hours. ☐ 3 – Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours. ☐ 4 – Completely disabled. Cannot carry on any selfcare. Totally confined to bed or chair. ☐ 5 – Dead

CRF Question	Value Domain
Weight (7063915) **CDE Short Name:** WEIGHT CDASH: VSORRES (6355977) SDTM: VSORRES (No CDE) where VSTEST = "Weight" and VSTESTCD (6658790) = "WEIGHT"	NUMBER – Maximum Length = 5
Unit (6355979) **CDE Short Name:** VSORRESU CDASH: VSORRESU (6355979) SDTM: VSORRESU (No CDE)	CHARACTER – Maximum Length = 100 ☐ kg – Kilogram ☐ LB – Pound
Ideal Weight (7063924) **CDE Short Name:** IDEALWT CDASH: VSORRES (6355977) SDTM: VSORRES (No CDE) where VSTEST (No CDE) = "Ideal Body Weight" and VSTESTCD (6658790) = "IDEALWT"	NUMBER – Maximum Length = 5
Unit (6355979) **CDE Short Name:** VSORRESU CDASH: VSORRESU (6355979) SDTM: VSORRESU (No CDE)	CHARACTER – Maximum Length = 100 ☐ kg – Kilogram ☐ LB – Pound
Height (7063933) **CDE Short Name:** HEIGHT CDASH: VSORRES (6355977) SDTM: VSORRES (No CDE) where VSTEST (No CDE) = "Height" and VSTESTCD (6658790) = "HEIGHT"	NUMBER– Maximum Length = 5

CRF Question	Value Domain
Unit (6355979) **CDE Short Name:** VSORRESU CDASH: VSORRESU (6355979) SDTM: VSORRESU (No CDE)	CHARACTER – Maximum Length = 100 ☐ cm – Centimeter ☐ in – Inch ☐ m – Meter
Body Surface Area (BSA) (7063942) **CDE Short Name:** BSA CDASH: VSORRES (6355977) SDTM: VSORRES (No CDE) where VSTEST (No CDE) = "Body Surface Area" and VSTESTCD (6658790) = "BSA"	NUMBER – Maximum Length = 5
Unit (6355979) **CDE Short Name:** VSORRESU CDASH: VSORRESU (6355979) SDTM: VSORRESU (No CDE)	CHARACTER – Maximum Length = 100 ☐ m2 – Square Meter
Body Mass Index (BMI) (7063953) **CDE Short Name:** BMI CDASH: VSORRES (6355977) SDTM: VSORRES (No CDE) where VSTEST (No CDE) = "Body Mass Index" and VSTESTCD (6658790) = "BMI"	NUMBER – Maximum Length = 5
Unit (6355979) **CDE Short Name:** VSORRESU CDASH: VSORRESU (6355979) SDTM: VSORRESU (No CDE)	CHARACTER – Maximum Length = 100 ☐ kg/m2 – Kilogram Per Square Meter

CRF Question	Value Domain
Body Temperature (7063954) **CDE Short Name:** TEMP CDASH: VSORRES (6355977) SDTM: VSORRES (No CDE) where VSTEST (No CDE) = "Body Temperature" and VSTESTCD (6658790) = "TEMP"	NUMBER – Maximum Length = 5
Unit (6355979) **CDE Short Name:** VSORRESU CDASH: VSORRESU (6355979) SDTM: VSORRESU (No CDE)	CHARACTER – Maximum Length = 100 ☐ C – Degree Celsius ☐ F – Fahrenheit
Temperature Route (7063955) **CDE Short Name:** TEMPLOC CDASH: VSLOC (6408751) SDTM: VSLOC (No CDE)	CHARACTER – Maximum Length = 25 ☐ Axillary – Axillary ☐ Dermal – Dermal ☐ Nasopharyngeal – Nasopharyngeal ☐ Oral – Oral ☐ Rectal – Rectal ☐ Tympanic (Ear) – Ear
Pulse (7063963) **CDE Short Name:** PULSE CDASH: VSORRES (6355977) SDTM: VSORRES (No CDE) where VSTEST (No CDE) = "Pulse Rate" and VSTESTCD (6658790) = "PULSE"	CHARACTER – Maximum Length = 40
Unit (6355979) **CDE Short Name:** VSORRESU CDASH: VSORRESU (6355979) SDTM: VSORRESU (No CDE)	CHARACTER – Maximum Length = 100 ☐ beats/min – Beats per Minute

CRF Question	Value Domain
Pulse Ox (7063971) **CDE Short Name:** OXYSAT CDASH: VSORRES (6355977) SDTM: VSORRES (No CDE) where VSTEST (No CDE) = "Oxygen Saturation" and VSTESTCD (6658790) = "OXYSAT"	NUMBER – Maximum Length = 5
Unit (6355979) **CDE Short Name:** VSORRESU CDASH: VSORRESU (6355979) SDTM: VSORRESU (No CDE)	CHARACTER – Maximum Length = 100 ☐ % – Percentage
Respiratory Rate (7063986) **CDE Short Name:** RESPIRAT CDASH: VSORRES (6355977) SDTM: VSORRES (No CDE) where VSTEST (No CDE) = "Respiratory Rate" and VSTESTCD (6658790) = "RESP"	CHARACTER – Maximum Length = 40
Unit (6355979) **CDE Short Name:** VSORRESU CDASH: VSORRESU (6355979) SDTM: VSORRESU (No CDE)	CHARACTER – Maximum Length = 100 ☐ breaths/min – Breaths per Minute
Systolic BP (7063994) **CDE Short Name:** SYSBP CDASH: VSORRES (6355977) SDTM: VSORRES (No CDE) where VSTEST (No CDE) = "Systolic Blood Pressure" and VSTESTCD (6658790) = "SYSBP"	NUMBER – Maximum Length = 5

CRF Question	Value Domain
Unit (6355979) **CDE Short Name:** VSORRESU CDASH: VSORRESU (6355979) SDTM: VSORRESU (No CDE)	CHARACTER – Maximum Length = 100 ☐ mmHg – Millimeter of Mercury
Diastolic BP (7064009) **CDE Short Name:** DIASBP CDASH: VSORRES (6355977) SDTM: VSORRES (No CDE) where VSTEST (No CDE) = "Diastolic Blood Pressure" and VSTESTCD (6658790) = "DIABP"	NUMBER – Maximum Length = 5
Unit (6355979) **CDE Short Name:** VSORRESU CDASH: VSORRESU (6355979) SDTM: VSORRESU (No CDE)	CHARACTER – Maximum Length = 100 ☐ mmHg – Millimeter of Mercury
Comments (7148887) **CDE Short Name:** VSCOVAL CDASH: COVAL (6355806) SDTM: COVAL (No CDE)	CHARACTER – Maximum Length = 200
Comments Date (7064010) **CDE Short Name:** [CDE short name] CDASH: CODTC (No CDE) SDTM: CODTC (No CDE)	DATE – Maximum Length = 11