

# 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).

## CT Imaging Agent CDISC Aligned NCI Standard Template Module Definitions

### Mapping to the CDASH:

N/A

### Mapping to the SDTM:

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

- AG – Procedure Agents (v3.3)
- DU – Device In-Use (SDTMIG for Medical Devices v1.1)

## CT Imaging Agent CDISC Aligned NCI Standard Template Module Template Instructions

### Field Descriptions and Instructions

| Field Name<br>(Partition Status)<br>CDE ID #<br>Short Name   | Definition<br>CDISC Mapping and<br>Instruction   | Format                      |
|--|--|-----------------------------|
| Oral Route of Administration<br>Contrast Agent Administered<br>Indicator<br>(o)<br>7072149<br>AGORCONT | The indication of whether or not a contrast agent was administered orally during the imaging procedure.<br><br>CDASH: No Match; SDTM: AGOCCUR (6841824)                            | CHARACTER. Use choice list. |
| Oral Route of Administration<br>Contrast Agent Administered<br>Type<br>(o)<br>7072150<br>AGSCAT        | The type of oral contrast agent administered either positive or negative as part of an imaging procedure.<br><br>CDASH: No Match; SDTM: AGSCAT (No CDE) where AGTRT = "Agent Name" | CHARACTER. Use choice list. |
| Oral Route of Administration<br>Contrast Agent Administered<br>Name<br>(o)<br>7072151<br>AGORCONM      | The name of the oral contrast agent administered during the imaging procedure.<br><br>CDASH: No Match; SDTM: AGTRT (6790641)   | CHARACTER                   |

| <b>Field Name<br/>(Partition Status)<br/>CDE ID #<br/>Short Name</b>  | <b>Definition<br/>CDISC Mapping and<br/>Instruction</b>   | <b>Format</b>               |
|---|---|-----------------------------|
| Oral Route of Administration<br>Contrast Agent Concentration<br>Value<br>(o)<br>7072152<br>AGCONCNT           | The concentration of the oral<br>contrast agent administered for<br>an imaging procedure<br>represented as a numerical<br>value.<br><br>CDASH: No Match; SDTM:<br>AGPSTRG (No CDE)  | NUMBER                      |
| Contrast Agent Concentration<br>Unit of Measure<br>(o)<br>7361508<br>AGCONCNU                                 | The unit of measure for the<br>concentration related to the<br>agents used as part of a<br>procedure.<br><br>CDASH: No Match; SDTM:<br>AGPSTRGU(No CDE)   | CHARACTER. Use choice list. |
| Oral Route of Administration<br>Contrast Agent Administered<br>Dose<br>(o)<br>7072153<br>AGCONTDS             | The amount of oral contrast<br>agent administered for an<br>imaging procedure.<br><br>CDASH: No Match; SDTM:<br>AGDOSE (6790646)  | NUMBER                      |
| Dose Units<br>(o)<br>6824805<br>AGDOSU  | The unit of measure for the<br>dosage form related to agents<br>used as part of a procedure.<br><br>CDASH: No Match; SDTM:<br>AGDOSU (6824805)  | CHARACTER. Use choice list. |
| Oral Route of Administration<br>Contrast Agent Administered<br>Time<br>(o)<br>7072154<br>AGSTRTM              | The time the contrast agent<br>was orally administered<br>represented in an unambiguous<br>time format (e.g., hh:mm:ss).<br><br>CDASH: No Match; SDTM:<br>AGSTDTC (6790381)   | CHARACTER                   |
| Intravenous Route of<br>Administration Contrast Agent<br>Infiltration Indicator<br>(c)<br>7072155<br>AGINFLTR | The indication of whether or not<br>a contrast agent is present in<br>amounts greater than normal in<br>tissue or cells.<br><br>CDASH: No Match; SDTM: No<br>Match, Can be supplemental<br>qualifier in SDTM;<br>Conditionality Rule: IV contrast<br>used in the imaging procedure<br>defined in the study. | CHARACTER. Use choice list. |

| Field Name<br>(Partition Status)<br>CDE ID #<br>Short Name  | Definition<br>CDISC Mapping and<br>Instruction  | Format                      |
|---|---|-----------------------------|
| Imaging Technique Prior<br>Contrast Agent Administered<br>Indicator<br>(o)<br>7072156<br>AGPRCONA             | The indication of whether or not<br>an agent that improves<br>visualization of structures was<br>administered prior to the<br>administration of a contrast<br>agent during an imaging<br>procedure.<br><br>CDASH: No Match; SDTM:<br>AGOCCUR (6841824) where<br>AGTRT = "Agent Name" and<br>AGSCAT = "Pre-contrast" | CHARACTER. Use choice list. |
| Intravenous Route of<br>Administration Contrast Agent<br>Administered Indicator<br>(o)<br>7072157<br>AGIVCONT | The indication of whether or not<br>a contrast agent was<br>administered intravenously<br>during the imaging procedure.<br><br>CDASH: No Match; SDTM:<br>AGOCCUR (6841824) where<br>AGTRT = "Agent Name" and<br>AGSCAT="IV contrast"  | CHARACTER. Use choice list. |
| Intravenous Route of<br>Administration Contrast Agent<br>Administered Name<br>(o)<br>7072158<br>AGIVNAME      | The name of the intravenous<br>contrast agent administered<br>during the imaging procedure.<br><br>CDASH: No Match; SDTM:<br>AGTRT (6790641) where<br>AGTRT = "Agent Name" and<br>AGSCAT="IV contrast"  | CHARACTER                   |
| Intravenous Route of<br>Administration Contrast Agent<br>Concentration Value<br>(o)<br>7072159<br>AGIVCON     | The concentration of the<br>intravenous contrast agent<br>administered for an imaging<br>procedure represented as a<br>numerical value.<br><br>CDASH: No Match; SDTM:<br>AGPSTRG (No CDE)   | NUMBER                      |
| Intravenous Route of<br>Administration Contrast Agent<br>Concentration Value<br>(o)<br>7361508<br>AGCONCNU    | Contrast Agent Concentration<br>Unit of Measure<br><br>CDASH: No Match; SDTM:<br>AGPSTRGU (No CDE)  | CHARACTER. Use choice list. |

| <b>Field Name<br/>(Partition Status)<br/>CDE ID #<br/>Short Name</b>   | <b>Definition<br/>CDISC Mapping and<br/>Instruction</b>  | <b>Format</b>               |
|--|--|-----------------------------|
| Intravenous Route of Administration Contrast Agent Administered Time<br>(o)<br>7072160<br>AGIVSTTM   | The time the contrast agent was intravenously administered represented in an unambiguous time format (e.g., hh:mm:ss).<br><br>CDASH: No Match; SDTM: AGSTDTC (6790381) where AGTRT = "Agent Name" and AGSCAT="IV contrast" | CHARACTER                   |
| Procedure Agent Injection Site Code<br>(o)<br>7072161<br>AGLOC   | The code assigned to the anatomic site where a contrast agent was administered intravenously.<br><br>CDASH: No Match; SDTM: AGLOC (7072161)  | CHARACTER. Use choice list. |
| Intravenous Route of Administration Contrast Agent Injection System Device Type<br>(o)<br>7072162<br>INJCTRTP                                  | The type of device used to inject an intravenous contrast agent.<br><br>CDASH: No Match; SDTM: DUORRES (No CDE) where DUTEST = "Type of contrast injector" and DUTESTCD = "INJCTRTP"                                       | CHARACTER. Use choice list. |
| Intravenous Route of Administration Contrast Agent Flow Rate Value<br>(o)<br>7072163<br>AGFLRT   | The flow rate of the contrast agent intravenously administered represented as a numerical value.<br><br>CDASH: No Match; SDTM: AGFLRT (7072163)  | NUMBER                      |
| Intravenous Route of Administration Contrast Agent Flow Rate Unit of Measure<br>(o)<br>7363021<br>AGFLRTU                                      | The unit of measure for the flow rate related to the agent used as part of a procedure.<br><br>CDASH: No Match; SDTM: AGFLRTU (7363021)  | CHARACTER. Use choice list. |
| Intravenous Route of Administration Contrast Agent Test Dosing Unit Bolus Infusion Procedure Performed Indicator<br>(o)<br>7072164<br>AGIVBLUS | The indication of whether or not a test bolus infusion dose was administered intravenously.<br><br>CDASH: No Match; SDTM: AGOCCUR (6841824) where AGTRT = "Agent Name" and AGSCAT="Test bolus"                             | CHARACTER. Use choice list. |

| Field Name<br>(Partition Status)<br>CDE ID #<br>Short Name   | Definition<br>CDISC Mapping and<br>Instruction   | Format                      |
|--|--|-----------------------------|
| Intravenous Route of Administration Contrast Agent Bolus Infusion Procedure Performed Category<br>(o)<br>7072165<br>AGCNBLUS     | The category of the contrast agent bolus infusion administered intravenously.<br><br>CDASH: No Match; SDTM: AGSCAT (No CDE) where AGTRT = "Agent Name" and AGCAT="Contrast bolus"    | CHARACTER. Use choice list. |
| Intravenous Route of Administration Contrast Agent Bolus Infusion Procedure Timing Method Category<br>(o)<br>7072166<br>AGTMMETH | The category of the method used to administer an intravenous contrast agent over time.<br><br>CDASH: No Match; SDTM: No Match, Can be a supplemental qualifier in SDTM               | CHARACTER. Use choice list. |
| Intravenous Route of Administration Contrast Agent Administered Dose<br>(o)<br>7072167<br>AGIVDOSE                               | The amount of contrast agent administered intravenously for an imaging procedure.<br><br>CDASH: No Match; SDTM: AGDOSE (6790646) where AGTRT = "Agent Name" and AGSCAT="IV contrast" | NUMBER                      |
| Dose Units<br>(o)<br>6824805<br>AGDOSU   | The unit of measure for the dosage form related to agents used as part of a procedure.<br><br>CDASH: No Match; SDTM: AGDOSU (6824805)  | CHARACTER. Use choice list. |

# Annotated CRF: CT Imaging Agent 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: CT Imaging Agent CDISC Aligned NCI Standard Template

Optional Questions

| CRF Question   | Value Domain   |
|--|--|
| <p><b>Oral contrast ingested (7072149)</b><br/> <b>CDE Short Name: AGORCONT</b></p> <div style="border: 1px solid blue; padding: 2px; margin-bottom: 5px; width: fit-content;">CDASH: No Match</div> <div style="border: 1px solid red; padding: 2px; margin-bottom: 5px; width: fit-content;">SDTM: AGOCCUR (6841824)</div>   | <p>CHARACTER – Maximum Length = 2</p> <p><input type="checkbox"/> N – No</p> <p><input type="checkbox"/> NA – Not Applicable</p> <p><input type="checkbox"/> U – Unknown</p> <p><input type="checkbox"/> Y – Yes</p> |
| <p><b>If oral contrast was used, specify type (7072150)</b><br/> <b>CDE Short Name: AGSCAT</b></p> <div style="border: 1px solid blue; padding: 2px; margin-bottom: 5px; width: fit-content;">CDASH: No Match</div> <div style="border: 1px solid red; padding: 2px; margin-bottom: 5px; width: fit-content;">SDTM: AGSCAT (No CDE) where AGTRT = "Agent Name"</div>       | <p>CHARACTER – Maximum Length = 8</p> <p><input type="checkbox"/> Negative – Negative Contrast Agent</p> <p><input type="checkbox"/> Positive – Positive Contrast Agent</p>  |
| <p><b>Oral contrast name (7072151)</b><br/> <b>CDE Short Name: AGORCONM</b></p> <div style="border: 1px solid blue; padding: 2px; margin-bottom: 5px; width: fit-content;">CDASH: No Match</div> <div style="border: 1px solid red; padding: 2px; margin-bottom: 5px; width: fit-content;">SDTM: AGTRT (6790641)</div>   | <p>CHARACTER – Maximum Length = 200</p>  |
| <p><b>Concentration of oral contrast ingested (Concentration of the bottle) (7072152)</b><br/> <b>CDE Short Name: AGCONCNT</b></p> <div style="border: 1px solid blue; padding: 2px; margin-bottom: 5px; width: fit-content;">CDASH: No Match</div> <div style="border: 1px solid red; padding: 2px; margin-bottom: 5px; width: fit-content;">SDTM: AGPSTRG (No CDE)</div> | <p>NUMBER – Maximum Length = 5</p>   |

| CRF Question   | Value Domain   |
|--|--|
| <p><b>Unit (7361508)</b><br/> <b>CDE Short Name: AGCONCNU</b></p> <p>CDASH: No Match</p> <p>SDTM: AGPSTRGU(No CDE)</p>                                 | <p>CHARACTER – Maximum Length = 100</p> <p>List of 754 PVs</p> |
| <p><b>Amount of oral contrast administered (7072153)</b><br/> <b>CDE Short Name: AGCONTDS</b></p> <p>CDASH: No Match</p> <p>SDTM: AGDOSE (6790646)</p> | <p>NUMBER – Maximum Length = 10</p>                            |
| <p><b>Dose Units (6824805)</b><br/> <b>CDE Short Name: AGDOSU</b></p> <p>CDASH: No Match</p> <p>SDTM: AGDOSU (6824805)</p>                             | <p>CHARACTER – Maximum Length = 100</p> <p>List of 754 PVs</p> |
| <p><b>Time oral contrast administered (7072154)</b><br/> <b>CDE Short Name: AGSTRTM</b></p> <p>CDASH: No Match</p> <p>SDTM: AGSTDTC (6790381)</p>      | <p>CHARACTER – Maximum Length = 8</p>                          |



## Conditional Questions

| CRF Question  | Value Domain  |
|---|---|
| <p data-bbox="240 262 781 296"><b>Any infiltration at injection site? (7072155)</b></p> <p data-bbox="240 300 607 333"><b>CDE Short Name: AGINFLTR</b></p> <div data-bbox="289 380 769 430" style="border: 1px solid blue; padding: 2px; margin: 10px 0;">CDASH: No Match; SDTM</div> <div data-bbox="289 464 769 543" style="border: 1px solid red; padding: 2px; margin: 10px 0;">No Match, Can be supplemental<br/>qualifier in SDTM</div> | <p data-bbox="818 262 1271 296">CHARACTER – Maximum Length = 2</p> <ul style="list-style-type: none"><li data-bbox="818 348 954 382"><input type="checkbox"/> N – No</li><li data-bbox="818 394 1110 428"><input type="checkbox"/> NA – Not Applicable</li><li data-bbox="818 441 1032 474"><input type="checkbox"/> U – Unknown</li><li data-bbox="818 487 967 520"><input type="checkbox"/> Y – Yes</li></ul> |

Optional

| CRF Question  | Value Domain   |
|---|--|
| <p><b>Pre-contrast administered (7072156)</b><br/> <b>CDE Short Name:</b> AGPRCONA</p> <p>CDASH: No Match</p> <p>SDTM: AGOCCUR (6841824) where AGTRT = "Agent Name" and AGSCAT = "Pre-contrast"</p> | <p>CHARACTER – Maximum Length = 2</p> <p><input type="checkbox"/> N – No</p> <p><input type="checkbox"/> NA – Not Applicable</p> <p><input type="checkbox"/> U – Unknown</p> <p><input type="checkbox"/> Y – Yes</p> |
| <p><b>IV contrast administered (7072157)</b><br/> <b>CDE Short Name:</b> AGIVCONT</p> <p>CDASH: No Match</p> <p>AGOCCUR (6841824) where AGTRT = "Agent Name" and AGSCAT="IV contrast"</p>           | <p>CHARACTER – Maximum Length = 2</p> <p><input type="checkbox"/> N – No</p> <p><input type="checkbox"/> NA – Not Applicable</p> <p><input type="checkbox"/> U – Unknown</p> <p><input type="checkbox"/> Y – Yes</p> |
| <p><b>IV contrast name (7072158)</b><br/> <b>CDE Short Name:</b> AGIVNAME</p> <p>CDASH: No Match</p> <p>SDTM: AGTRT (6790641) where AGTRT = "Agent Name" and AGSCAT="IV contrast"</p>               | <p>CHARACTER – Maximum Length = 200</p>  |
| <p><b>IV contrast concentration (7072159)</b><br/> <b>CDE Short Name:</b> AGIVCON</p> <p>CDASH: No Match</p> <p>SDTM: AGPSTRG (No CDE)</p>  | <p>NUMBER – Maximum Length = 5</p>   |
| <p><b>Unit (7361508)</b><br/> <b>CDE Short Name:</b> AGCONCNU</p> <p>CDASH: No Match</p> <p>SDTM: AGPSTRGU (No CDE)</p>   | <p>CHARACTER – Maximum Length = 100</p> <p>List of 754 PVs</p>   |

| CRF Question  | Value Domain   |
|---|--|
| <p><b>Time IV contrast administered (7072160)</b><br/> <b>CDE Short Name: AGIVSTTM</b></p> <p>CDASH: No Match</p> <p>SDTM: AGSTDTC (6790381) where<br/> AGTRT = "Agent Name" and<br/> AGSCAT="IV contrast"</p>                  | <p>CHARACTER – Maximum Length = 8</p>  |
| <p><b>Location of injection site (7072161)</b><br/> <b>CDE Short Name: AGLOC</b></p> <p>CDASH: No Match</p> <p>SDTM: AGLOC (7072161)</p>  | <p>CHARACTER – Maximum Length = 20</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> 1 – Right antecubital</li> <li><input type="checkbox"/> 2 – Right wrist</li> <li><input type="checkbox"/> 3 – Left antecubital</li> <li><input type="checkbox"/> 4 – Left wrist</li> <li><input type="checkbox"/> 5 – Right foot</li> <li><input type="checkbox"/> 6 – Left foot</li> <li><input type="checkbox"/> 88 – Other specify</li> <li><input type="checkbox"/> 99 – Unknown</li> </ul> |
| <p><b>Type of contrast injector used (7072162)</b><br/> <b>CDE Short Name: INJCTRTP</b></p> <p>CDASH: No Match</p> <p>SDTM: DUORRES (No CDE) where<br/> DUTEST = "Type of contrast injector"<br/> and DUTESTCD = "INJCTRTP"</p> | <p>CHARACTER – Maximum Length = 46</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Dual chamber power injector – Dual Chamber Power Injector</li> <li><input type="checkbox"/> Dual chamber power injector with saline flush – Dual Chamber Power Injector With Saline Flush</li> <li><input type="checkbox"/> Single chamber power injector – Single Chamber Power Injector</li> </ul>  |
| <p><b>Flow rate (7072163)</b><br/> <b>CDE Short Name: AGFLRT</b></p> <p>CDASH: No Match</p> <p>SDTM: AGFLRT (7072163)</p>   | <p>NUMBER – Maximum Length = 5</p>   |

| CRF Question   | Value Domain  |
|--|---|
| <p><b>Unit (7363021)</b><br/> <b>CDE Short Name:</b> AGFLRTU</p> <p>CDASH: No Match</p> <p>SDTM: AGFLRTU (7363021)</p>   | <p>CHARACTER – Maximum Length = 50</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> mL/min – Milliliter per Minute</li> <li><input type="checkbox"/> mmol/day – Millimole per 24 Hours</li> <li><input type="checkbox"/> ug/day – Microgram per Day</li> <li><input type="checkbox"/> ug/min – Microgram per Minute</li> <li><input type="checkbox"/> umol/day – Micromole per 24 Hours</li> </ul> |
| <p><b>Was a test bolus performed? (7072164)</b><br/> <b>CDE Short Name:</b> AGIVBLUS</p> <p>CDASH: No Match</p> <p>SDTM: AGOCCUR (6841824) where AGTRT = "Agent Name" and AGSCAT="Test bolus"</p>                    | <p>CHARACTER – Maximum Length = 2</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> N – No</li> <li><input type="checkbox"/> NA – Not Applicable</li> <li><input type="checkbox"/> U – Unknown</li> <li><input type="checkbox"/> Y – Yes</li> </ul>   |
| <p><b>What type of contrast bolus was administered? (7072165)</b><br/> <b>CDE Short Name:</b> AGCNBLUS</p> <p>CDASH: No Match</p> <p>SDTM: AGSCAT (No CDE) where AGTRT = "Agent Name" and AGCAT="Contrast bolus"</p> | <p>CHARACTER – Maximum Length = 10</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Biphasic – Biphasic</li> <li><input type="checkbox"/> Monophasic – Monophasic</li> <li><input type="checkbox"/> None – None</li> <li><input type="checkbox"/> Triphasic – Triphasic</li> </ul>   |
| <p><b>Bolus timing method (7072166)</b><br/> <b>CDE Short Name:</b> AGTMMETH</p> <p>CDASH: No Match</p> <p>SDTM: No Match, Can be a supplemental qualifier in SDTM</p>   | <p>CHARACTER – Maximum Length = 20</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Auto-triggering used – Auto-triggered Administered</li> <li><input type="checkbox"/> Fixed time delay – Fix Time Delay</li> <li><input type="checkbox"/> Timing bolus used – Timing Bolus Infusion Administered</li> </ul>   |
| <p><b>Amount of IV contrast injected (7072167)</b><br/> <b>CDE Short Name:</b> AGIVDOSE</p> <p>CDASH: No Match</p> <p>SDTM: AGDOSE (6790646) where AGTRT = "Agent Name" and AGSCAT="IV contrast"</p>                 | <p>NUMBER – Maximum Length = 10</p>   |

| CRF Question  | Value Domain   |
|---|--|
| <p><b>Dose Units (6824805)</b><br/><b>CDE Short Name: AGDOSU</b></p> <p>CDASH: No Match</p> <p>SDTM: AGDOSU (6824805)</p> | <p>CHARACTER – Maximum Length = 100</p> <p>List of 754 PVs</p> |