

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).

Response 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)

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)
- RS – Disease Response and Clin Classification (v3.3)
- TU – Tumor/Lesion Identification (v3.3)

Response 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
Response or Clin Class Performed (m) 7165877 RSPERF	An indication whether or not a planned disease response or clinical classification assessment was performed. CDASH: No Match; SDTM: RSPERF (7165877)	CHARACTER. Use choice list.
Disease Response Most Recent Negation Evaluation Text (o) 7038805 RSDZRPTX	The description of the reason disease status was not evaluated. CDASH: No Match; SDTM: RSREASND (6642040)	CHARACTER
Disease Response Evaluation Interval Start Date (o) 7055123 RSSTDTC	The initial date of the period disease response was evaluated, represented in an unambiguous date format (e.g., DD-MON-YYYY). CDASH: No Match; SDTM: RSDTC (6791945)	DATE

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Disease Response Evaluation Interval End Date (o) 7055124 RSEDDTC	The final date of the period disease response was evaluated, represented in an unambiguous date format (e.g., DD-MON-YYYY). CDASH: No Match; SDTM: RSENDTC (No CDE)	DATE
Disease Response Evaluation Interval Type (o) 7055125 RSTMPNT	The specific point in the time continuum when disease status or response to treatment was assessed, including those established relative to an event. CDASH: No Match; SDTM: No Match	CHARACTER. Use choice list.
Disease Response Evaluation Method Type (o) 7055126 TURSMTHD	The name of the method used to establish disease status or response to treatment. CDASH: No Match; SDTM: TUMETHOD (6621680)	CHARACTER. Use choice list.
Acute Myeloid Leukemia Or Myelodysplastic Syndrome Morphologic Response Status (o) 7055127 AMLMDSMS	The disease status or response to treatment of acute myeloid leukemia or myelodysplastic syndrome based on a morphologic evaluation. CDASH: No Match; SDTM: RSORRES (6642369) where RSTESTCD = "AMLMDSMS" and RSTEST = "AML or MDS Morphologic Response Status"	CHARACTER. Use choice list.
Acute Leukemia Or Chronic Myelogenous Leukemia, BCR- ABL1 Positive Morphologic Response Status (o) 7055128 ALCMLMS	The disease status or response to treatment of acute leukemia or chronic myelogenous leukemia based on a morphologic evaluation. CDASH: No Match; SDTM: RSORRES (6642369) where RSTESTCD = "ALCMLMS" and RSTEST = "AL or CML Morphologic Response Status"	CHARACTER. Use choice list.

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Acute Myeloid Leukemia Or Myelodysplastic Syndrome Cytogenetic Response Status (o) 7055129 AMLMDSCS	The disease status or response to treatment of acute myeloid leukemia or myelodysplastic syndrome based on a cytogenetic evaluation. CDASH: No Match; SDTM: RSORRES (6642369) where RSTESTCD = "AMLMDSCS" and RSTEST = "AML or MDS Cytogenetic Response Status"	CHARACTER. Use choice list.
Acute Leukemia Or Chronic Myelogenous Leukemia, BCR- ABL1 Positive Cytogenetic Response Status (o) 7055130 ALCMLCS	The disease status or response to treatment of acute leukemia or blast phase chronic myelogenous leukemia based on a cytogenetic evaluation. CDASH: No Match; SDTM: RSORRES (6642369) where RSTESTCD = "ALCMLCS" and RSTEST = "AL or CML Cytogenetic Response Status"	CHARACTER. Use choice list.
Accelerated Phase Chronic Myelogenous Leukemia, BCR- ABL1 Positive Cytogenetic Response Status (o) 7055131 CMLAPCS	The disease status or response to treatment of accelerated phase chronic myelogenous leukemia based on a cytogenetic evaluation. CDASH: No Match; SDTM: RSORRES (6642369) where RSTESTCD = "CMLAPCS" and RSTEST = "AP CML Cytogenetic Response Status"	CHARACTER. Use choice list.
Leukemia Molecular Response Status (o) 7055132 LKMRS	The disease status or response to treatment of leukemia based on a molecular evaluation. CDASH: No Match; SDTM: RSORRES (6642369) where RSTESTCD = "LKMRS" and RSTEST = "Leukemia Molecular Response Status"	CHARACTER. Use choice list.

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Prostate Carcinoma PSA Progression Indicator (o) 7055133 RSPSAIND	The indication of whether or not disease progression was determined using a prostate specific antigen measurement. CDASH: No Match; SDTM: No Match	CHARACTER. Use choice list.
Prostate Carcinoma Prostate Specific Antigen Measurement Disease Response Status (o) 7055134 PSAS	The disease status or response to treatment of prostate carcinoma based on prostate specific antigen measurement. CDASH: No Match; SDTM: RSORRES (6642369) where RSTESTCD = "PSAS" and RSTEST = "PSA status"	CHARACTER. Use choice list.
Acute Myeloid Leukemia Or Myelodysplastic Syndrome Hematologic Response Status (o) 7055135 AMLMDSHS	The disease status or response to treatment of acute myeloid leukemia or myelodysplastic syndrome based on a hematologic evaluation. CDASH: No Match; SDTM: RSORRES (6642369) where RSTESTCD = "AMLMDSHS" and RSTEST = "AML or MDS Hematologic Response Status"	CHARACTER. Use choice list.
Accelerated Phase Chronic Myelogenous Leukemia, BCR- ABL1 Positive Hematologic Response Type (o) 7055136 CMLAPHS	The disease status or response to treatment of accelerated phase chronic myelogenous leukemia based on a hematologic evaluation. CDASH: No Match; SDTM: RSORRES (6642369) where RSTESTCD = "CMLAPHS" and RSTEST = "AP CML Hematologic Response Status"	CHARACTER. Use choice list.
Current Evaluation Interval Disease Response Status (o) 7055138 CUDISRS	The current disease status or response to treatment of a patient. CDASH: No Match; SDTM: RSORRES (6642369) where RSTESTCD = "OVRLRESP" and RSTEST = "Overall Response"	CHARACTER. Use choice list.

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Overall Lesion Response irRC Measurable Category (o) 6922533 RSOVRRSP	A set of response criteria designed to capture additional response patterns observed with immune therapy beyond those described by Response Evaluation Criteria in Solid Tumors (RECIST) or WHO criteria. CDASH: No Match; SDTM: RSORRES (6642369) where RSTESTCD = "CUDISRS" and RSTEST = "Tumor Immune Response Type"	CHARACTER. Use choice list.
Plasma Cell Myeloma Current Evaluation Interval Disease Response Status (o) 7055139 MMCS	The current disease status or response to treatment of multiple myeloma. CDASH: No Match; SDTM: RSORRES (6642369) where RSTESTCD = "MMCS" and RSTEST = "Multiple Myeloma Current Response Status"	CHARACTER. Use choice list.
Acute Myeloid Leukemia Or Acute Lymphoblastic Leukemia Current Evaluation Interval Disease Response Status (o) 7055140 AMLALLCS	The current disease status or response to treatment of acute myeloid leukemia or acute lymphoblastic leukemia. CDASH: No Match; SDTM: RSORRES (6642369) where RSTESTCD = "AMLALLCS" and RSTEST = "AML/ALL Current Response Status"	CHARACTER. Use choice list.
Accelerated Phase Chronic Myelogenous Leukemia, BCR- ABL1 Positive Current Evaluation Interval Disease Response Status (o) 7055141 APLCS	The current disease status or response to treatment of acute promyelocytic leukemia. CDASH: No Match; SDTM: RSORRES (6642369) where RSTESTCD = "APLCS" and RSTEST = "APL Current Response Status"	CHARACTER. Use choice list.

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Chronic Myelogenous Leukemia, BCR-ABL1 Positive Current Evaluation Interval Disease Response Status (o) 7055142 CMLCS	The current disease status or response to treatment of chronic myelogenous leukemia. CDASH: No Match; SDTM: RSORRES (6642369) where RSTESTCD = "CMLCS" and RSTEST = "CML Current Response Status"	CHARACTER. Use choice list.
Chronic Lymphocytic Leukemia Current Evaluation Interval Disease Response Status (o) 7055143 CLLCS	The current disease status or response to treatment of chronic lymphocytic leukemia. CDASH: No Match; SDTM: RSORRES (6642369) where RSTESTCD = "CLLCS" and RSTEST = "CLL Current Response Status"	CHARACTER. Use choice list.
Myelodysplastic Syndrome Current Evaluation Interval Disease Response Status (o) 7055144 MDSCS	The current disease status or response to treatment of myelodysplastic syndrome. CDASH: No Match; SDTM: RSORRES (6642369) where RSTESTCD = "MDSCS" and RSTEST = "MDS Current Response Status"	CHARACTER. Use choice list.
Lymphoma Current Evaluation Interval Disease Response Status (o) 7055145 LYMPCS	The current disease status or response to treatment of lymphoma. CDASH: No Match; SDTM: RSORRES (6642369) where RSTESTCD = "LYMPCS" and RSTEST = "Lymphoma Current Response Status"	CHARACTER. Use choice list.
Intratumoral Or Peritumoral Lymphocytic Disease Response Status (o) 7055146 IPLS	The disease status or response to treatment of intratumoral or peritumoral lymphocytes. CDASH: No Match; SDTM: RSORRES (6642369) where RSTESTCD = "IPLS" and RSTEST = "IPL Response Status"	CHARACTER. Use choice list.

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Leukemia Therapeutic Procedure Failure Indicator (o) 7055147 RSLKTHFL	The indication whether or not leukemia intervention failed. CDASH: No Match; SDTM: No Match	CHARACTER. Use choice list.
Leukemia Therapeutic Procedure Failure Type (o) 7055148 RSTHFLRN	The description of why the leukemia patient is considered to be a treatment failure. CDASH: No Match; SDTM: No Match	CHARACTER. Use choice list.
Disease Response Confirmation Date (o) 7055149 RSCNFMDT	The date disease status or response to treatment was confirmed, represented in an unambiguous date format (e.g., DD-MON-YYYY). CDASH: No Match; SDTM: No Match	DATE
Recurrent Disease Or Progressive Disease ICD-O Tumor Topography Code (o) 7055150 RSRPICD	The ICD-O-3 code representing the anatomic site of confirmed relapse or disease progression. CDASH: No Match; SDTM: No Match	CHARACTER. Use choice list.
Comment (o) 6355806 COVAL	A free text comment. CDASH: COVAL (6355806); SDTM: COVAL (No CDE)	CHARACTER

Annotated CRF: Response 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: Response CDISC Aligned NCI Standard Template

Mandatory Questions

CRF Question	Value Domain
Was response or disease status evaluated during this reporting period? (7165877) CDE Short Name: RSPERF <div style="border: 1px solid blue; padding: 2px; width: fit-content;">CDASH: No Match</div> <div style="border: 1px solid red; padding: 2px; width: fit-content;">SDTM: RSPERF (7165877)</div>	CHARACTER – Maximum Length = 2 <input type="checkbox"/> N – No <input type="checkbox"/> NA – Not Applicable <input type="checkbox"/> U – Unknown <input type="checkbox"/> Y – Yes

Optional Questions

CRF Question	Value Domain
<p>Reason evaluation not done (7038805) CDE Short Name: RSDZRPTX</p> <p>CDASH: No Match</p> <p>SDTM: RSREASND (6642040)</p>	<p>CHARACTER – Maximum Length = 200</p>
<p>Response evaluation period start date (7055123) CDE Short Name: RSSTDTC</p> <p>CDASH: No Match</p> <p>SDTM: RSDTC (6791945)</p>	<p>DATE – Maximum Length = 11</p>
<p>Response evaluation period end date (7055124) CDE Short Name: RSEDDTC</p> <p>CDASH: No Match</p> <p>SDTM: RSENDTC (No CDE)</p>	<p>DATE – Maximum Length = 11</p>
<p>Timepoint (7055125) CDE Short Name: RSTMPNT</p> <p>CDASH: No Match</p> <p>SDTM: No Match</p>	<p>CHARACTER – Maximum Length = 100</p> <p>List of 700 PVs</p>
<p>Method(s) used to determine response (7055126) CDE Short Name: TURSMTHD</p> <p>CDASH: No Match</p> <p>SDTM: TUMETHOD (6621680)</p>	<p>CHARACTER – Maximum Length = 25</p> <ul style="list-style-type: none"> <input type="checkbox"/> Biomarkers – Biomarker <input type="checkbox"/> Clinical Assessment – Clinical Assessment Tool <input type="checkbox"/> Cytogenetics – Cytogenetic Analysis <input type="checkbox"/> Imaging – Imaging Technique <input type="checkbox"/> Immunological – Immunologic Technique <input type="checkbox"/> Laboratory Test(s) – Laboratory Procedure <input type="checkbox"/> Molecular – Molecular Analysis <input type="checkbox"/> Morphologic – Morphologic Finding <input type="checkbox"/> Pathologic – Pathologic Finding

CRF Question	Value Domain
<p data-bbox="240 205 768 237">Morphologic status (AML/MDS) (7055127)</p> <p data-bbox="240 243 626 275">CDE Short Name: AMLMDSMS</p> <div data-bbox="289 321 769 373" style="border: 1px solid blue; padding: 2px; margin: 10px 0;"> <p data-bbox="302 331 524 363">CDASH: No Match</p> </div> <div data-bbox="289 407 769 550" style="border: 1px solid red; padding: 2px; margin: 10px 0;"> <p data-bbox="302 420 751 539">SDTM: RSORRES (6642369) where RSTESTCD = "AMLMDSMS" and RSTEST = "AML or MDS Morphologic Response Status"</p> </div>	<p data-bbox="821 205 1284 237">CHARACTER – Maximum Length = 75</p> <ul style="list-style-type: none"> <li data-bbox="821 296 1325 352"><input type="checkbox"/> Complete Remission (CR) – Complete Remission <li data-bbox="821 369 1304 489"><input type="checkbox"/> Complete Response with incomplete platelet recovery (CRp) – Complete Response with Incomplete Platelet Recovery <li data-bbox="821 506 1369 562"><input type="checkbox"/> Leukemic Transformation – Leukemic Cell Transformation <li data-bbox="821 579 1369 699"><input type="checkbox"/> Morphologic Complete Response with Incomplete Blood Count Recovery (CRi) – Morphologic Complete Remission with Incomplete Blood Count Recovery <li data-bbox="821 716 1295 772"><input type="checkbox"/> Morphologic Relapse – Morphologic Finding Recurrent Disease <li data-bbox="821 789 1252 821"><input type="checkbox"/> Not Assessed – No Assessment <li data-bbox="821 831 1214 863"><input type="checkbox"/> Not Evaluable – Unevaluable <li data-bbox="821 873 1036 905"><input type="checkbox"/> Other – Other <li data-bbox="821 915 1377 947"><input type="checkbox"/> Partial Remission (PR) – Partial Remission <li data-bbox="821 957 1349 1014"><input type="checkbox"/> Progressive Disease (PD) – Progressive Disease <li data-bbox="821 1031 1352 1062"><input type="checkbox"/> Refractory Disease – Refractory Disease <li data-bbox="821 1073 1097 1104"><input type="checkbox"/> Relapse – Relapse

CRF Question	Value Domain
<p>Morphologic status (Acute leukemia/CML) (7055128) CDE Short Name: ALCMLMS</p> <div data-bbox="289 352 769 405" style="border: 1px solid blue; padding: 2px; margin-bottom: 10px;">CDASH: No Match</div> <div data-bbox="289 436 769 579" style="border: 1px solid red; padding: 2px; color: red;">SDTM: RSORRES (6642369) where RSTESTCD = "ALCMLMS" and RSTEST = "AL or CML Morphologic Response Status"</div>	<p>CHARACTER – Maximum Length = 75</p> <ul style="list-style-type: none"> <input type="checkbox"/> Complete Remission (CR) – Complete Remission <input type="checkbox"/> Morphologic Complete Remission with Incomplete Blood Count Recovery (CRi) – Morphologic Complete Remission with Incomplete Blood Count Recovery <input type="checkbox"/> Morphologic Leukemia Free State – Morphologic Finding Leukemia Absent State <input type="checkbox"/> Morphologic Relapse – Morphologic Finding Recurrent Disease <input type="checkbox"/> Not Assessed – No Assessment <input type="checkbox"/> Not Evaluable – Unevaluable <input type="checkbox"/> Other – Other <input type="checkbox"/> Partial Remission (PR) – Partial Remission <input type="checkbox"/> Progressive Disease (PD) – Progressive Disease <input type="checkbox"/> Refractory Disease – Refractory Disease <input type="checkbox"/> Relapse – Relapse <input type="checkbox"/> Stable Disease (SD) – Stable Disease
<p>Cytogenetic status (AML/MDS) (7055129) CDE Short Name: AMLMDSCS</p> <div data-bbox="289 1178 769 1230" style="border: 1px solid blue; padding: 2px; margin-bottom: 10px;">CDASH: No Match</div> <div data-bbox="289 1262 769 1404" style="border: 1px solid red; padding: 2px; color: red;">SDTM: RSORRES (6642369) where RSTESTCD = "AMLMDSCS" and RSTEST = "AML or MDS Cytogenetic Response Status"</div>	<p>CHARACTER – Maximum Length = 50</p> <ul style="list-style-type: none"> <input type="checkbox"/> Complete cytogenetic response (CCyR) – Cytogenetic Complete Response <input type="checkbox"/> Not Assessed – No Assessment <input type="checkbox"/> Not Evaluable – Unevaluable
<p>Cytogenetic status (Acute Leukemia/CML (BC)) (7055130) CDE Short Name: ALCMLCS</p> <div data-bbox="289 1566 769 1619" style="border: 1px solid blue; padding: 2px; margin-bottom: 10px;">CDASH: No Match</div> <div data-bbox="289 1650 769 1793" style="border: 1px solid red; padding: 2px; color: red;">SDTM: RSORRES (6642369) where RSTESTCD = "ALCMLCS" and RSTEST = "AL or CML Cytogenetic Response Status"</div>	<p>CHARACTER – Maximum Length = 50</p> <ul style="list-style-type: none"> <input type="checkbox"/> Cytogenetic Complete Remission (CRc) – Cytogenetic Analysis Complete Remission <input type="checkbox"/> Cytogenetic Relapse – Cytogenetic Analysis Recurrent Disease <input type="checkbox"/> Not Assessed – No Assessment <input type="checkbox"/> Not Evaluable – Unevaluable <input type="checkbox"/> Persistent Cytogenetic Abnormality – Persistent Cytogenetic Abnormality

CRF Question	Value Domain
<p>Cytogenetic status (CML (AP)) (7055131) CDE Short Name: CMLAPCS</p> <div data-bbox="289 321 769 373" style="border: 1px solid blue; padding: 2px; margin-bottom: 10px;"> <p>CDASH: No Match</p> </div> <div data-bbox="289 407 769 550" style="border: 1px solid red; padding: 2px;"> <p>SDTM: RSORRES (6642369) where RSTESTCD = "CMLAPCS" and RSTEST = "AP CML Cytogenetic Response Status"</p> </div>	<p>CHARACTER – Maximum Length = 50</p> <ul style="list-style-type: none"> <input type="checkbox"/> Complete Cytogenetic Response (CCyR) – Cytogenetic Analysis Complete Remission <input type="checkbox"/> Major Cytogenetic Response (MCyR) – Major Cytogenetic Analysis Remission <input type="checkbox"/> Minimal Cytogenetic Response – Minimum Cytogenetic Analysis Remission <input type="checkbox"/> Minor Cytogenetic Response (MiCyR) – Minor Cytogenetic Analysis Remission <input type="checkbox"/> No Cytogenetic Response – No Cytogenetic Analysis Remission <input type="checkbox"/> Not Assessed – No Assessment <input type="checkbox"/> Not Evaluable – Unevaluable <input type="checkbox"/> Partial Cytogenetic Response (PCyR) – Cytogenetic Analysis Partial Remission
<p>Molecular status (7055132) CDE Short Name: LKMRS</p> <div data-bbox="289 982 769 1035" style="border: 1px solid blue; padding: 2px; margin-bottom: 10px;"> <p>CDASH: No Match</p> </div> <div data-bbox="289 1068 769 1211" style="border: 1px solid red; padding: 2px;"> <p>SDTM: RSORRES (6642369) where RSTESTCD = "LKMRS" and RSTEST = "Leukemia Molecular Response Status"</p> </div>	<p>CHARACTER – Maximum Length = 40</p> <ul style="list-style-type: none"> <input type="checkbox"/> Molecular Complete Remission (CRm) – Molecular Analysis Complete Remission <input type="checkbox"/> Molecular Relapse – Molecular Analysis Recurrent Disease <input type="checkbox"/> Not Assessed – No Assessment <input type="checkbox"/> Not Evaluable – Unevaluable
<p>Did study subject have PSA progression? (7055133) CDE Short Name: RSPSAIND</p> <div data-bbox="289 1371 769 1423" style="border: 1px solid blue; padding: 2px; margin-bottom: 10px;"> <p>CDASH: No Match</p> </div> <div data-bbox="289 1457 769 1512" style="border: 1px solid red; padding: 2px;"> <p>SDTM: No Match</p> </div>	<p>CHARACTER – Maximum Length = 2</p> <ul style="list-style-type: none"> <input type="checkbox"/> N – No <input type="checkbox"/> NA – Not Applicable <input type="checkbox"/> U – Unknown <input type="checkbox"/> Y – Yes

CRF Question	Value Domain
<p>PSA status (7055134) CDE Short Name: PSAS</p> <div data-bbox="289 321 769 373" style="border: 1px solid blue; padding: 2px; margin: 10px 0;"> <p>CDASH: No Match</p> </div> <div data-bbox="289 407 769 520" style="border: 1px solid red; padding: 2px; margin: 10px 0;"> <p>SDTM: RSORRES (6642369) where RSTESTCD = "PSAS" and RSTEST = "PSA status"</p> </div>	<p>CHARACTER – Maximum Length = 30</p> <ul style="list-style-type: none"> <input type="checkbox"/> Not Assessed – No Assessment <input type="checkbox"/> Not Evaluable – Unevaluable <input type="checkbox"/> PSA-N (CR) – Prostate Specific Antigen Measurement Negative Finding Complete Remission <input type="checkbox"/> PSA-NR (Borderline Stable) – Prostate Specific Antigen Measurement Borderline Stable Disease <input type="checkbox"/> PSA-PR (PR) – Prostate Specific Antigen Measurement Partial Remission <input type="checkbox"/> PSA-Progression – Prostate Specific Antigen Measurement Tumor Progression <input type="checkbox"/> PSA-Stable – Prostate Specific Antigen Measurement Stable Disease <input type="checkbox"/> Unconfirmed PSA CR – Prostate Specific Antigen Measurement Unconfirmed Complete Remission <input type="checkbox"/> Unconfirmed PSA PR – Prostate Specific Antigen Measurement Unconfirmed Partial Remission
<p>Hematologic improvement response (AML/MDS) - Select all that apply (7055135) CDE Short Name: AMLMDSHS</p> <div data-bbox="289 1178 769 1230" style="border: 1px solid blue; padding: 2px; margin: 10px 0;"> <p>CDASH: No Match</p> </div> <div data-bbox="289 1264 769 1404" style="border: 1px solid red; padding: 2px; margin: 10px 0;"> <p>SDTM: RSORRES (6642369) where RSTESTCD = "AMLMDSHS" and RSTEST = "AML or MDS Hematologic Response Status"</p> </div>	<p>CHARACTER – Maximum Length = 75</p> <ul style="list-style-type: none"> <input type="checkbox"/> Erythroid Response – Erythroid Response <input type="checkbox"/> Neutrophil Response – Neutrophil Response <input type="checkbox"/> Not Assessed – No Assessment <input type="checkbox"/> Not Evaluable – Unevaluable <input type="checkbox"/> Platelet Response – Platelet Response <input type="checkbox"/> Progression or Relapse after Hematologic Improvement – Disease Progression Or Recurrent Disease Post Hematologic Improvement

CRF Question	Value Domain
<p>Hematologic response (CML(AP)) (7055136) CDE Short Name: CMLAPHS</p> <div data-bbox="289 321 769 373" style="border: 1px solid blue; padding: 2px; margin: 10px 0;"> <p>CDASH: No Match</p> </div> <div data-bbox="289 407 769 550" style="border: 1px solid red; padding: 2px; margin: 10px 0;"> <p>SDTM: RSORRES (6642369) where RSTESTCD = "CMLAPHS" and RSTEST = "AP CML Hematologic Response Status"</p> </div>	<p>CHARACTER – Maximum Length = 50</p> <ul style="list-style-type: none"> <input type="checkbox"/> Complete Hematologic Response (CHR) – Hematologic Complete Remission <input type="checkbox"/> Major Hematologic Response (MaHR) – Major Hematologic Response <input type="checkbox"/> Minor Hematologic Response (MiHR) – Minor Hematologic Response <input type="checkbox"/> No Evidence of Leukemia (NEL) – Negation Evidence Leukemia <input type="checkbox"/> Not Assessed – No Assessment <input type="checkbox"/> Not Evaluable – Unevaluable
<p>Current response (7055138) CDE Short Name: CUDISRS</p> <div data-bbox="289 800 769 852" style="border: 1px solid blue; padding: 2px; margin: 10px 0;"> <p>CDASH: No Match</p> </div> <div data-bbox="289 886 769 995" style="border: 1px solid red; padding: 2px; margin: 10px 0;"> <p>SDTM: RSORRES (6642369) where RSTESTCD = "OVLRESP" and RSTEST = "Overall Response"</p> </div>	<p>CHARACTER – Maximum Length = 30</p> <ul style="list-style-type: none"> <input type="checkbox"/> Borderline Stable Disease – Borderline Stable Disease <input type="checkbox"/> Complete Remission (CR) – Complete Remission <input type="checkbox"/> No Evidence of Disease (NED) – No Evidence of Disease <input type="checkbox"/> No Treatment – No Treatment <input type="checkbox"/> Not Evaluable – Unevaluable <input type="checkbox"/> Partial Remission (PR) – Partial Remission <input type="checkbox"/> Primary Induction Failure – Primary Induction Failure <input type="checkbox"/> Progressive Disease (PD) – PD <input type="checkbox"/> Relapse – Recurrent Disease <input type="checkbox"/> Stable Disease (SD) – Stable Disease <input type="checkbox"/> Unconfirmed Complete Remission – Not Confirmed Complete Remission <input type="checkbox"/> Unconfirmed Partial Remission – Not Confirmed Partial Remission
<p>irRC response (6922533) CDE Short Name:</p> <div data-bbox="289 1604 769 1656" style="border: 1px solid blue; padding: 2px; margin: 10px 0;"> <p>CDASH: No Match</p> </div> <div data-bbox="289 1690 769 1833" style="border: 1px solid red; padding: 2px; margin: 10px 0;"> <p>SDTM: RSORRES (6642369) where RSTESTCD = "CUDISRS" and RSTEST = "Tumor Immune Response Type"</p> </div>	<p>CHARACTER – Maximum Length = 30</p> <ul style="list-style-type: none"> <input type="checkbox"/> irCR –irCR (Immune-Related Response Criteria) <input type="checkbox"/> irPD – irPD (Immune-Related Response Criteria) <input type="checkbox"/> irPR – irPR (Immune-Related Response Criteria) <input type="checkbox"/> irSD – ilrSD (Immune-Related Response Criteria)

CRF Question	Value Domain
<p data-bbox="240 205 800 268">Plasma Cell Myeloma Current Evaluation Interval Disease Response Status (7055139)</p> <p data-bbox="240 275 557 306">CDE Short Name: MMCS</p> <div data-bbox="289 352 769 405" style="border: 1px solid blue; padding: 2px; margin: 10px 0;"> <p data-bbox="300 363 524 394">CDASH: No Match</p> </div> <div data-bbox="289 436 769 579" style="border: 1px solid red; padding: 2px; margin: 10px 0;"> <p data-bbox="300 447 743 569">SDTM: RSORRES (6642369) where RSTESTCD = "MMCS" and RSTEST = "Multiple Myeloma Current Response Status"</p> </div>	<p data-bbox="821 205 1284 237">CHARACTER – Maximum Length = 40</p> <ul style="list-style-type: none"> <li data-bbox="821 296 1365 390"><input type="checkbox"/> Complete Response (CR) – Complete Response of Multiple Myeloma or Plasma Cell Leukemia <li data-bbox="821 401 1365 495"><input type="checkbox"/> Minimal Response (MR) – Minimal Response of Multiple Myeloma or Plasma Cell Leukemia <li data-bbox="821 506 1214 537"><input type="checkbox"/> Not Evaluable – Unevaluable <li data-bbox="821 548 1365 642"><input type="checkbox"/> Partial Response (PR) – Partial Response of Multiple Myeloma or Plasma Cell Leukemia <li data-bbox="821 653 1317 716"><input type="checkbox"/> Progression – Progression of Multiple Myeloma or Plasma Cell Leukemia <li data-bbox="821 726 1317 789"><input type="checkbox"/> Stable Disease (SD) – Stable Multiple Myeloma or Plasma Cell Leukemia <li data-bbox="821 800 1333 915"><input type="checkbox"/> Stringent Complete Response (sCR) – Stringent Complete Response (sCR) of Multiple Myeloma or Plasma Cell Leukemia <li data-bbox="821 926 1333 1020"><input type="checkbox"/> Very Good Partial Response (VGPR) – Very Good Partial Response of Multiple Myeloma or Plasma Cell Leukemia

CRF Question	Value Domain
<p>Acute Myeloid Leukemia Or Acute Lymphoblastic Leukemia Current Evaluation Interval Disease Response Status (7055140) CDE Short Name: AMLALLCS</p> <div data-bbox="289 384 769 436" style="border: 1px solid blue; padding: 2px; margin: 10px 0;"> <p>CDASH: No Match</p> </div> <div data-bbox="289 468 769 611" style="border: 1px solid red; padding: 2px; margin: 10px 0;"> <p>SDTM: RSORRES (6642369) where RSTESTCD = "AMLALLCS" and RSTEST = "AML/ALL Current Response Status"</p> </div>	<p>CHARACTER – Maximum Length =75</p> <ul style="list-style-type: none"> <input type="checkbox"/> Bone Marrow CR (CRm) – Bone Marrow Complete Remission <input type="checkbox"/> Complete Cytogenetic Remission (CCyR) – Cytogenetic Analysis Complete Remission <input type="checkbox"/> Complete Remission (CR) – Complete Remission <input type="checkbox"/> Complete Remission with Incomplete Blood Count Recovery (CRi) – Morphologic Complete Remission with Incomplete Blood Count Recovery <input type="checkbox"/> Complete Remission with Incomplete Platelet Recovery – Complete Remission With Incomplete Platelet Recovery <input type="checkbox"/> Complete Remission with MRD – Complete Remission With Minimal Residual Disease <input type="checkbox"/> Complete Remission without MRD – Complete Remission Without Minimal Residual Disease <input type="checkbox"/> Cytogenetic Response – Cytogenetic Analysis Response <input type="checkbox"/> Disease Progression – Disease Progression <input type="checkbox"/> Failure – Therapeutic Procedure Failure <input type="checkbox"/> Minimal Residual Disease (MRD) – Minimal Residual Disease <input type="checkbox"/> Minimum Residual Disease (MDR) – Minimal Residual Disease <input type="checkbox"/> Not Evaluable – Unevaluable <input type="checkbox"/> Partial Remission (PR) – Partial Remission <input type="checkbox"/> Progressive Disease (PD) – PD <input type="checkbox"/> Recurrent Disease – Recurrent Disease <input type="checkbox"/> Relapse after CR or PR – Recurrent Disease Post Complete Remission Or Partial Remission <input type="checkbox"/> Stable Disease (SD) – Stable Disease <input type="checkbox"/> Treatment Failure - Death from Indeterminate Cause – Treatment Failure Death from Indeterminate Cause <input type="checkbox"/> Treatment Failure - Death in Aplasia – Treatment Failure Death Due To Aplasia <input type="checkbox"/> Treatment Failure - Resistant Disease – Treatment Failure Resistant Disease

CRF Question	Value Domain
<p>Current response (APL - M3 AML) (7055141) CDE Short Name: APLCS</p> <div data-bbox="289 321 769 373" style="border: 1px solid blue; padding: 2px; margin: 10px 0;"> <p>CDASH: No Match</p> </div> <div data-bbox="289 407 769 520" style="border: 1px solid red; padding: 2px; margin: 10px 0;"> <p>SDTM: RSORRES (6642369) where RSTESTCD = "APLCS" and RSTEST = "APL Current Response Status"</p> </div>	<p>CHARACTER – Maximum Length = 30</p> <ul style="list-style-type: none"> <input type="checkbox"/> Cytogenetic Complete Remission (CRc) – Cytogenetic Analysis Complete Remission <input type="checkbox"/> Molecular Complete Remission (CRm) – Molecular Analysis Complete Remission <input type="checkbox"/> Molecular Relapse – Molecular Analysis Recurrent Disease <input type="checkbox"/> Morphologic Complete Remission – Morphologic Finding Complete Remission <input type="checkbox"/> Morphologic Complete Remission with Incomplete Blood Count Recovery (CRi) – Morphologic Complete Remission with Incomplete Blood Count Recovery <input type="checkbox"/> Not Evaluable - Unevaluable <input type="checkbox"/> Treatment Failure - Resistant Disease – Treatment Failure Resistant Disease
<p>Current response (CML) (7055142) CDE Short Name: CMLCS</p> <div data-bbox="289 972 769 1024" style="border: 1px solid blue; padding: 2px; margin: 10px 0;"> <p>CDASH: No Match</p> </div> <div data-bbox="289 1058 769 1171" style="border: 1px solid red; padding: 2px; margin: 10px 0;"> <p>SDTM: RSORRES (6642369) where RSTESTCD = "CMLCS" and RSTEST = "CML Current Response Status"</p> </div>	<p>CHARACTER – Maximum Length = 50</p> <ul style="list-style-type: none"> <input type="checkbox"/> Complete Cytogenetic Remission (CCyR) – Cytogenetic Analysis Complete Remission <input type="checkbox"/> Complete Hematologic Remission (CHR) – Hematologic Complete Remission <input type="checkbox"/> Cytogenetic Progression – Cytogenetic Analysis Disease Progression <input type="checkbox"/> Cytogenetic Relapse – Cytogenetic Analysis Recurrent Disease <input type="checkbox"/> Emergence of an Acquired ABL Kinase Domain Mutation – Acquired BCR-ABL TKI-Resistant Mutation <input type="checkbox"/> Karyotypic Evolution – Karyotype Evolution <input type="checkbox"/> Major Molecular Remission (MMR) – Major Molecular Analysis Response <input type="checkbox"/> Not Evaluable – Unevaluable

CRF Question	Value Domain
<p>Current response (CLL) (7055143) CDE Short Name: CLLCS</p> <div data-bbox="289 321 769 373" style="border: 1px solid blue; padding: 2px; margin: 10px 0;"> <p>CDASH: No Match</p> </div> <div data-bbox="289 407 769 520" style="border: 1px solid red; padding: 2px; margin: 10px 0;"> <p>SDTM: RSORRES (6642369) where RSTESTCD = "CLLCS" and RSTEST = "CLL Current Response Status"</p> </div>	<p>CHARACTER – Maximum Length = 30</p> <ul style="list-style-type: none"> <input type="checkbox"/> Complete Clinical Remission (CCR) – Clinical Assessment Tool Complete Remission <input type="checkbox"/> Complete Remission (CR) – Complete Remission <input type="checkbox"/> Disease Transformation – Chronic Lymphocytic Leukemia Transformation <input type="checkbox"/> Nodular Partial Response (nPR) – Nodular Partial Response <input type="checkbox"/> Not Assessed – No Assessment <input type="checkbox"/> Not Evaluable – Unevaluable <input type="checkbox"/> Partial Remission (PR) – Partial Remission <input type="checkbox"/> Progressive Disease (PD) – PD <input type="checkbox"/> Stable Disease (SD) – Stable Disease
<p>Current response (MDS) (7055144) CDE Short Name: MDSCS</p> <div data-bbox="289 968 769 1020" style="border: 1px solid blue; padding: 2px; margin: 10px 0;"> <p>CDASH: No Match</p> </div> <div data-bbox="289 1054 769 1167" style="border: 1px solid red; padding: 2px; margin: 10px 0;"> <p>SDTM: RSORRES (6642369) where RSTESTCD = "MDSCS" and RSTEST = "MDS Current Response Status"</p> </div>	<p>CHARACTER – Maximum Length = 30</p> <ul style="list-style-type: none"> <input type="checkbox"/> Bone Marrow CR (CRm) – Bone Marrow Complete Remission <input type="checkbox"/> Complete Remission (CR) – Complete Remission <input type="checkbox"/> Disease Transformation – Myelodysplastic Syndrome Transformation <input type="checkbox"/> Failure – Therapeutic Procedure Failure <input type="checkbox"/> Hematologic Improvement (HI) – Hematologic Improvement <input type="checkbox"/> Not Assessed – No Assessment <input type="checkbox"/> Not Evaluable – Unevaluable <input type="checkbox"/> Partial Remission (PR) – Partial Remission <input type="checkbox"/> Progressive Disease (PD) – PD <input type="checkbox"/> Relapse after CR or PR – Recurrent Disease Post Complete Remission Or Partial Remission <input type="checkbox"/> Stable Disease (SD) – Stable Disease

CRF Question	Value Domain
<p>Current response (Lymphoma) (7055145) CDE Short Name: LYMPCS</p> <p>CDASH: No Match</p> <p>SDTM: RSORRES (6642369) where RSTESTCD = "LYMPCS" and RSTEST = "Lymphoma Current Response Status"</p>	<p>CHARACTER – Maximum Length = 30</p> <ul style="list-style-type: none"> <input type="checkbox"/> Complete Remission (CR) – Complete Remission <input type="checkbox"/> Not Assessed – No Assessment <input type="checkbox"/> Not Evaluable – Unevaluable <input type="checkbox"/> Partial Remission (PR) – Partial Remission <input type="checkbox"/> Progressive Disease (PD) – PD <input type="checkbox"/> Stable Disease (SD) – Stable Disease
<p>Intratumoral/Peritumoral lymphocyte response (7055146) CDE Short Name: IPLS</p> <p>CDASH: No Match</p> <p>SDTM: RSORRES (6642369) where RSTESTCD = "IPLS" and RSTEST = "IPL Response Status"</p>	<p>CHARACTER – Maximum Length = 50</p> <ul style="list-style-type: none"> <input type="checkbox"/> Marked (including Crohn-like response) – Marked Response <input type="checkbox"/> Mild to moderate – Mild Moderate Response <input type="checkbox"/> None – None at all
<p>Leukemia treatment failure (7055147) CDE Short Name: RSLKTHFL</p> <p>CDASH: No Match</p> <p>SDTM: No Match</p>	<p>CHARACTER – Maximum Length = 2</p> <ul style="list-style-type: none"> <input type="checkbox"/> N – No <input type="checkbox"/> NA – Not Applicable <input type="checkbox"/> U – Unknown <input type="checkbox"/> Y – Yes
<p>If considered treatment failure, provide reason (7055148) CDE Short Name: RSTHFLRN</p> <p>CDASH: No Match</p> <p>SDTM: No Match</p>	<p>CHARACTER – Maximum Length = 60</p> <ul style="list-style-type: none"> <input type="checkbox"/> Aplasia – Bone Marrow Aplasia <input type="checkbox"/> Death of Patient with Evidence of Persistent Leukemia – Death With Evidence Persistent Leukemia <input type="checkbox"/> Death of Patient without Evidence of Persistent Leukemia – Death Without Evidence Persistent Leukemia <input type="checkbox"/> Extramedullary Disease – Extramedullary Involvement Disease or Disorder <input type="checkbox"/> Indeterminate Cause – Indeterminate <input type="checkbox"/> Molecular or Cytogenetic Relapse – Molecular Analysis Or Cytogenetic Analysis Recurrent Disease <input type="checkbox"/> Morphologic Relapse – Morphologic Finding Recurrent Disease <input type="checkbox"/> Resistant Disease – Refractory Carcinoma

CRF Question	Value Domain
<p>Response date (7055149) CDE Short Name: RSCNFMDT</p> <p>CDASH: No Match</p> <p>SDTM: No Match</p>	<p>DATE – Maximum Length = 11</p>
<p>If response is relapse or progression, indicate site(s) (7055150) CDE Short Name: RSRPICD</p> <p>CDASH: No Match</p> <p>SDTM: No Match</p>	<p>CHARACTER – Maximum Length = 7</p> <p>List of 409 PVs</p>
<p>Comment (6355806) CDE Short Name: COVAL</p> <p>CDASH: COVAL (6355806)</p> <p>SDTM: COVAL (No CDE)</p>	<p>CHARACTER – Maximum Length = 200</p>