

Change Notes

2400 Revision 4 - Pre-Transplant Essential Data

Public ID: 3938671 Version: 1.0

Notes:

- These change notes are based on a comparison with Form Builder report 3002012v2.0 (2400 Revision 2 - Pre-Transplant Essential Data (TED))
- These change notes do not list changes to module public IDs. The module public IDs for all modules have changed. Please refer to the AGNIS Metadata Tool output or the Excel spreadsheet downloaded from the caDSR's Form Builder application for more detailed information
- The “Major” changes section of the notes includes those changes which are most likely to impact database mapping applications. They include changes such as the addition or removal of CDEs
- The “Minor” changes section of the notes includes those changes which are least likely to impact database mapping applications. They include changes such as modifications to question or instruction texts.

Module: Center Identification:

Major:

- **Added the following CDEs:**
 - 3771974v1.0 (Clinics and Hospitals European Group for Blood And Marrow Transplantation Facility Identifier Number)
- **CDE version changes for the following questions:**
 - CIBMTR Center Number:
 - Old: 2527895v1.0 (Hematopoietic Stem Cell Transplantation Recipient Institution::Center for International Blood and Marrow Transplant Research Facility Number)
 - New: 2527895v2.0 (Hematopoietic Cell Transplantation Recipient Institution::Center for International Blood and Marrow Transplant Research Facility Number):
 - Hospital:

- Old: 2688299v1.0 (Hematopoietic Stem Cell Transplantation Institution Hospital Name)
 - New: 2688299v2.0 (Hematopoietic Cell Transplantation Institution Hospital Name)
 - Unit:
 - Old: 2688301v1.0 (Hematopoietic Stem Cell Transplantation Institution Department Name)
 - New: 2688301v2.0 (Hematopoietic Cell Transplantation Institution Department Name)
- **Removed the following CDEs:**
 - 2688251v1.0 (Organizational Unit::EBMT(CIC) Code Number)
 - 2691464v1.0 (Hematopoietic Stem Cell Transplantation Institution Department Name Specify)
 - 2179589v2.0 (Person Given/First Name)
 - 2179591v2.0 (Person Family/Last Name)
 - 2866737v1.0 (Clinical Data Form Today Date)
- **Removed the following permissible values for the following versioned CDE**
2688301v2.0 (Hematopoietic Cell Transplantation Institution Department Name):
 - 2724581v1.0 (Hematology)
 - 2724582v1.0 (Oncology)
 - 2724579v1.0 (Other unit)
- **The following Modules have been removed along with all the CDEs within the module:**
 - Recipient Identification: Part 1 of 2
 - Study ID Number
 - Recipient Identification: Part 2 of 2
 - Recipient Race
 - Disease Classification
 - Hematopoietic Stem Cell Transplant (HSCT) : Part 1 of 4
 - Cell Source
 - Autologous HSCT
 - Hematopoietic Stem Cell Transplant (HSCT) : Part 2 of 4
 - Donor Information
 - Hematopoietic Stem Cell Transplant (HSCT) : Part 3 of 4
 - Ex Vivo Graft Manipulation Type

- Hematopoietic Stem Cell Transplant (HSCT) : Part 4 of 4
- Preparative Regimen - Part 1 / 7
- Preparative Regimen - Part 2 / 7
- Preparative Regimen - Part 3 / 7 (Anthracyclines)
- Preparative Regimen - Part 4 / 7 (Monoclonal Antibodies)
- Preparative Regimen - Part 5 / 7 (Radiolabeled MAb)
- Preparative Regimen - Part 6 / 7 (Intent of Preparative Regimen)
- Preparative Regimen - Part 7 / 7 (Reason for NST / RIC)
- Comorbid Conditions
- Type of Comorbid Condition
- GVHD Prophylaxis
- Post-HSCT Disease Therapy Planned as of Day 0
- Type of Additional Post-HSCT Therapy
- Other Toxicity Modifying Regimen
- Pre-Transplant Essential Data Disease Classification Sheet
- Acute Myelogenous Leukemia (AML) or Acute Nonlymphocytic Leukemia (ANLL): Part 1 of 2
- Type of Therapy Related AML
- Acute Myelogenous Leukemia (AML) or Acute Nonlymphocytic Leukemia (ANLL): Part 2 of 2
- Acute Lymphoblastic Leukemia (ALL)
- Other Acute Leukemia
- Chronic Myelogenous Leukemia (CML): Part 1 of 2
- CML Prior HSCT Treatment
- Chronic Myelogenous Leukemia (CML): Part 2 of 2
- Myelodysplastic or Myeloproliferative Disease Classification at Diagnosis
- Myelodysplastic or Myeloproliferative Disease Status at Transplantation
- Myelodysplastic or Myeloproliferative Diseases: Part 1 of 2
- Type of Therapy Related MDS / MPS
- Myelodysplastic or Myeloproliferative Diseases: Part 2 of 2
- Other Leukemias
- Hodgkin Lymphoma
- Non-Hodgkin's Lymphoma
- Plasma Cell Disorders
- Breast Cancer
- Other Disease
- Other Malignancies
- Anemia/Hemoglobinopathy
- Platelet Disorders
- Histiocytic Disorders

- Inherited Disorders of Metabolism/Osteopetrosis
- Immune Deficiencies
- Autoimmune Disorders
- Systemic Sclerosis Involvement
- Systemic Sclerosis Laboratory Procedures
- Systemic Lupus Erythematosus (SLE) Involvement
- Systemic Lupus Erythematosus (SLE) Laboratory Procedures
- Sjogren Syndrome Involvement
- Polymyositis / Dermatomyositis Involvement
- Polymyositis / Dermatomyositis Laboratory Procedure
- Antiphospholipid Syndrome Involvement
- Antiphospholipid Syndrome Laboratory Procedures
- Wegener Granulomatosis Involvement
- Wegener Granulomatosis Laboratory Procedures
- Polyarteritis Nodosa Involvement
- Polyarteritis Nodosa Laboratory Procedures
- Rheumatoid Arthritis Involvement
- Psoriatic Arthritis / Psoriasis Involvement
- Multiple Sclerosis (MS) Involvement

The following are new modules in revision 4:

Module: Recipient Identification

Major:

- Added the following CDEs:
 - 2527897v2.0 (Hematopoietic Cell Transplantation Recipient Identification Number)

Module: Recipient Data - Part 1 of 4

Major:

- Added the following CDEs:
 - 3190237v1.0 (Person Birth Date)
 - 3171628v2.0 (Person Sex Type)
 - 2956817v1.0 (Person Ethnicity Group Category)

Module: Recipient Data - Part 2 of 4

Major:

- Added the following CDEs:
 - 2956195v1.0 (Person Race Category)

Module: Recipient Data - Part 3 of 4

Major:

- Added the following CDEs:
 - 316v5.0 (Person Address Postal Code)
 - 3158496v1.0 (Study Participation Occurrence Indicator)

Module: Recipient Data - Part 4 of 4

Major:

- Added the following CDEs:
 - 3938773v1.0 (Clinical Study Sponsor Identifier Group Name)
 - 3938791v1.0 (Clinical Study Sponsor Identifier Specify Text)
 - 3951371v1.0 (Hematopoietic Cell Transplantation Clinical Study Identifier)
 - 2181644v1.0 (Research Case Identifier)

Minor:

- Instruction text added for CDE 3951371v1.0 (Hematopoietic Cell Transplantation Clinical Study Identifier)
 - Old: *blank*
 - New: Please check the most updated study ID permissible value reference list for the value mapping in the reference document area.

Module: Hematopoietic Cellular Transplant (HCT) - Part 1 of 3

Major:

- Added the following CDEs:
 - 2866938v2.0 (Hematopoietic Cell Transplantation Occurrence Date)
 - 2815272v2.0 (Hematopoietic Cell Transplantation First Occurrence Indicator)
 - 2815328v2.0 (Next Hematopoietic Cell Transplantation Plan Treatment Regimen Indicator)

- 2815342v2.0 (Next Hematopoietic Cell Transplantation Plan Treatment Regimen Tissue Donor Type)
- 2815349v2.0 (Hematopoietic Cell Transplantation Prior Occurrence Therapeutic Procedure Number)
- 2957396v2.0 (Prior Hematopoietic Cell Graft Source Name)
- 2957398v2.0 (Prior Hematopoietic Cell Graft Source Indicator)

Module: Hematopoietic Cellular Transplant (HCT) - Part 3 of 3

Major:

- Added the following CDEs:
 - 2866424v2.0 (Hematopoietic Cell Transplantation Most Recent Prior Date)
 - 2815568v2.0 (Most Recent Prior Hematopoietic Cell Transplantation Performed Other Institution Indicator)
 - 2532036v2.0 (Hematopoietic Cell Transplantation Previous Institution Name)
 - 2532039v2.0 (Hematopoietic Cell Transplantation Previous Institution City Name)
 - 2686045v2.0 (Hematopoietic Cell Transplantation Previous Institution State Name)
 - 2684981v2.0 (Hematopoietic Cell Transplantation Previous Institution Country Text Name)
 - 2957417v2.0 (Hematopoietic Cell Transplantation Most Recent Prior Source Type)
 - 2957419v2.0 (Current Hematopoietic Cell Transplantation Indication Type)
 - 3935811v1.0 (Graft Failure And/Or Graft Rejection Occurrence Date)
 - 2947021v1.0 (Disease or Disorder Recurrent Disease Status Date)
 - 2957536v1.0 (Secondary Malignant Neoplasm Occurrence Date)
 - 2957528v2.0 (Current Hematopoietic Cell Transplantation Indication Specify Text)

Module: Donor Information - Part 1 of 2

Major:

- Added the following CDEs:
 - 3578142v1.0 (Hematopoietic Cell Transplantation Multiple Tissue Donor Indicator)
 - 2912008v2.0 (Hematopoietic Cell Transplantation Multiple Tissue Donor Count)

Module: Donor Information - Part 2 of 2

Major:

- Added the following CDEs:
 - 2675075v2.0 (Hematopoietic Cell Graft Source Tissue Donor Type)
 - 2808120v2.0 (Hematopoietic Cell Graft Umbilical Cord Blood Type Institution::National Marrow Donor Program Identifier)
 - 2897748v2.0 (Hematopoietic Cell Transplantation Tissue Donor Institution::National Marrow Donor Program Identifier)
 - 3809537v1.0 (Hematopoietic Cell Graft Unrelated Tissue Donor Negation National Marrow Donor Program Identifier)
 - 3874258v1.0 (Hematopoietic Cell Graft Umbilical Cord Blood Type Negation National Marrow Donor Program Identifier)
 - 3869975v1.0 (Umbilical Cord Blood Unit Identifier Same ISBT-128 Donor Identification Number Indicator)
 - 3191872v2.0 (Hematopoietic Cell Transplantation Tissue Donor ISBT-128 Donor Identification Number)
 - 2682159v4.0 (Unrelated Tissue Donor Registry Name)
 - 3837671v1.0 (Unrelated Tissue Donor Registry Specify Text)
 - 3924953v1.0 (Hematopoietic Cell Tissue Donor Relationship Type)
 - 3809532v1.0 (Person Birth Date Known Unknown Indicator)
 - 3190237v1.0 (Person Birth Date)
 - 3809551v1.0 (Person Age Known Unknown Indicator)
 - 3809533v1.0 (Person Age Value)
 - 3809811v1.0 (Person Age Time Unit of Measure Text Name)
 - 3171628v2.0 (Person Sex Type)
 - 3837059v1.0 (Hematopoietic Cell Graft Bone Marrow Type Indicator)
 - 3837060v1.0 (Hematopoietic Cell Graft Peripheral Blood Stem Cell Type Indicator)
 - 3837061v1.0 (Hematopoietic Cell Graft Single Umbilical Cord Blood Type Indicator)
 - 3837062v1.0 (Hematopoietic Cell Graft Other Source Type Indicator)
 - 2527917v2.0 (Hematopoietic Cell Graft Other Type Specify)
 - 3837073v1.0 (Graft Administered Total Count)
 - 3851541v1.0 (Stem Cell Mobilization Therapy Multiple Occurrence Performed Indicator)
 - 3851542v1.0 (Stem Cell Mobilization Therapy Multiple Occurrence Performed Total Count)
 - 2873953v1.0 (Recombinant Granulocyte Colony-Stimulating Factor Administered Indicator)

- 3915434v1.0 (Recombinant Granulocyte-Macrophage Colony-Stimulating Factor Administered Indicator)
- 2873841v1.0 (Pegfilgrastim Administered Indicator)
- 3837091v1.0 (Plerixafor Administered Indicator)
- 3854191v1.0 (Other CXCR4 Inhibitor Administered Indicator)
- 3851546v1.0 (Stem Cell Mobilization Therapy Combined Chemotherapy Indicator)
- 3837713v1.0 (Donor Provide Prior Hematopoietic Cell Transplantation Indicator)
- 3880639v1.0 (Cytomegalovirus Antibody Laboratory Procedure Performed Laboratory Finding Result)
- 3919234v1.0 (Plerixafor Prior Preparative Regimen Administered Indicator)

Minor:

- Changed the question text for the following CDEs:
 - 3190237v1.0 (Person Birth Date)
 - Old: Birth Date
 - New: Date of birth:
- Changed the instruction text for the following CDEs:
 - 3190237v1.0 (Person Birth Date)
 - Old: Donor /infant
 - New: Donor / infant

Module: Consent - Part 1 of 4

Major:

- Added the following CDEs:
 - 3852280v1.0 (Institutional Review Board Approval Consent Form Research Activity Data Submission Signature Indicator)
 - 3837111v1.0 (Consent Form Signature Date)
- Removed the permissible value 2838911v1.0 (Not applicable) for the following CDE:
 - 3852280v1.0 (Institutional Review Board Approval Consent Form Research Activity Data Submission Signature Indicator)

Module: Consent - Part 2 of 4

Major:

- Added the following CDEs:
 - 3852291v1.0 (Consent Direct Communication Contact Future Research Activity Indicator)
 - 3837111v1.0 (Consent Form Signature Date)

- Added the permissible value 2839358v1.0 (Not approached) for the following CDE:
 - 3852291v1.0 (Consent Direct Communication Contact Future Research Activity Indicator)
- Removed the permissible value 2838911v1.0 (Not applicable) for the following CDE:
 - 3852291v1.0 (Consent Direct Communication Contact Future Research Activity Indicator)

Minor:

- Changed the permissible value 2560453v1.0 (Yes) instruction text for the following CDEs:
 - 3852291v1.0 (Consent Direct Communication Contact Future Research Activity Indicator)
 - Old: Patient provided permission
 - New: Patient consented

Module: Consent - Part 3 of 4

Major:

- Added the following CDEs:
 - 3852292v1.0 (Institutional Review Board Approval Recipient Consent Form Research Activity Blood Sample Submission Signature Indicator)
 - 3837111v1.0 (Consent Form Signature Date)

Module: Consent - Part 4 of 4

Major:

- Added the following CDEs:
 - 3938871v1.0 (Institutional Review Board Approval Donor Consent Form Research Activity Blood Sample Submission Signature Indicator)
 - 3837111v1.0 (Consent Form Signature Date)

Module: Product Processing / Manipulation - Part 1 of 2

Major:

- Added the following CDEs:
 - 3921966v1.0 (Hematopoietic Cell Graft Prior Infusion Procedure Alteration Indicator)
 - 3921984v1.0 (Hematopoietic Cell Graft Prior Infusion Procedure Alteration Part Type)

Module: Product Processing / Manipulation - Part 2 of 2

Major:

- Added the following CDEs:
 - 3852216v1.0 (Hematopoietic Cell Graft Prior Infusion Procedure Alteration Method Type)
 - 3922018v1.0 (Hematopoietic Cell Graft Alteration Method Indicator)
 - 3922023v1.0 (Hematopoietic Cell Graft Alteration Method Specify Text)
- Added the permissible value 4114306v1.0 (Genetic manipulation) for the following CDE:
 - 3852216v1.0 (Hematopoietic Cell Graft Prior Infusion Procedure Alteration Method Type)
- Removed the permissible value 3852198v1.0 (Genetic manipulation (gene transfer / transduction)) for the following CDE:
 - 3852216v1.0 (Hematopoietic Cell Graft Prior Infusion Procedure Alteration Method Type)

Minor:

- Instruction Text added for Permissible Value 4114306v1.0 (Genetic manipulation)
 - (gene transfer / transduction)

Module: Clinical Status of Recipient Prior to the Preparative Regimen (Conditioning)

Major:

- Added the following CDEs:
 - 2494701v2.0 (Performance Status Type)
 - 2003853v4.2 (Karnofsky Performance Status Score)
 - 3141228v1.0 (Performance Status Assessment Lansky Score)
 - 3880639v1.0 (Cytomegalovirus Antibody Laboratory Procedure Performed Laboratory Finding Result)
- Permissible Value change for CDE 2494701v2.0 (Performance Status Type)
 - Was: Karnofsky (recipient age \geq 16 years)

 - Now: Karnofsky (recipient age \geq 16 years)

Minor:

- Question Text change for CDE 2494701v2.0 (Performance Status Type)
 - Old: What scale was used to determine the recipients functional status?
 - New: What scale was used to determine the recipient's functional status?
- Question Text change for CDE 3141228v1.0 (Performance Status Assessment Lansky Score)
 - Old: Lansky Scale (recipient age $<$ 16 years):
 - New: Lansky Scale (recipient age $<$ 16 years)
- Question Text change for CDE 2003853v4.2 (Karnofsky Performance Status Score)
 - Old: Karnofsky Scale (recipient age \geq 16 years):
 - New: Karnofsky Scale (recipient age \geq 16 years)
-

Module: Comorbid Conditions - Part 1 of 5

Major:

- Added the following CDEs:
 - 3577533v1.0 (Patient History Mechanical Ventilation Indicator)
 - 3577522v1.0 (Patient History Verification Invasive Fungal Infection Indicator)
 - 3946394v1.0 (Significant Concurrent Disease or Disorder Present Indicator)

Module: Comorbid Conditions - Part 2 of 5

Major:

- Added the following CDEs:
 - 2737130v1.0 (Clinical Significant Comorbidity Type)
 - 3946394v1.0 (Significant Concurrent Disease or Disorder Present Indicator)
 - 2737638v1.0 (Clinical Significant Comorbidity Other Type Disease Diagnosis Other Specify)

Module: Comorbid Conditions - Part 3 of 5

Major:

- Added the following CDEs:
 - 3838571v1.0 (Solid Tumor Classification Type)
 - 2957824v1.0 (Person Prior Solid Neoplasm Personal Medical History Ind-3)
 - 2798743v1.0 (Diagnosis Present Year Date)

Module: Comorbid Conditions - Part 4 of 5

Major:

- Added the following CDEs:
 - 2798673v1.0 (Personal Medical History Malignant Neoplasm Negation Primary Disease or Disorder Occurrence Indicator)

Module: Comorbid Conditions - Part 5 of 5

Major:

- Added the following CDEs:
 - 2798697v1.0 (Personal Medical History Malignant Neoplasm Occurrence Type)
 - 2798741v1.0 (Personal Medical History Malignant Neoplasm Occurrence Indicator)
 - 2798743v1.0 (Diagnosis Present Year Date)
 - 3930237v1.0 (Malignant Neoplasm Epstein-Barr Virus Positive Finding Indicator)
 - 2798745v1.0 (Personal Medical History Malignant Neoplasm Occurrence Specify Text)

Module: Pre-HCT Preparative Regimen (Conditioning) - Part 1 of 9

Major:

- Added the following CDEs:
 - 2874163v1.0 (Person Height Integer::0 Decimal Place Value)
 - 3915571v1.0 (Person Height Unit of Measure Name)
 - 2875642v1.0 (Person Weight Integer::0 Decimal Place Value)
 - 3915611v1.0 (Person Weight Unit of Measure Name)
 - 3919343v1.0 (Preparative Regimen Planned Occurrence Administered Indicator)
 - 3852733v1.0 (Preparative Regimen Planned Occurrence Administered Classification Type)
 - 3919306v1.0 (Preparative Regimen Administered Begin Date)
 - 3852763v1.0 (Irradiation Plan Part Preparative Regimen Administered Indicator)
 - 3852771v1.0 (RT Planned Administered Radiation Field Type)
 - 3915633v1.0 (RT Planned Administered Total Dose Value)
 - 3852796v1.0 (RT Planned Administered Dose Unit of Measure Name)
 - 3018891v1.0 (Radiation Therapy Administered Begin Date)
 - 3578137v1.0 (Fractionation Radiation Therapy Administered Indicator)
 - 3852906v1.0 (Fractionation Radiation Therapy Administered Per Fraction Planned Occurrence Dose)
 - 3852914v1.0 (Fractionation Radiation Therapy Administered Per Fraction Plan Dose Unit of Measure Name)
 - 2954036v1.0 (Fractionation Radiation Therapy Administered Day Count)
 - 61465v3.0 (Radiation Therapy Total Fractions Count)

Minor:

- Changed the instruction text for the following CDEs:
 - 3852733v1.0 (Preparative Regimen Planned Occurrence Administered Classification Type)
 - Old: none
 - New: Allogeneic HCTs only

Module: Pre-HCT Preparative Regimen (Conditioning) - Part 2 of 9

Major:

- Added the following CDEs:
 - 2739625v2.0 (Preparative Regimen Medication Type)

- 2750714v1.0 (Preparative Regimen Medication Plan Administration Yes No Character Indicator)
- 3040323v1.0 (Preparative Regimen Medication Plan Administration Total Medication Dose Integer::0 Decimal Place Value)
- 2740606v1.0 (Preparative Regimen Medication Plan Administration Dose Unit of Measure Name)
- 3935911v2.0 (Preparative Regimen Busulfan Planned Occurrence Administered Dose Unit of Measure Name)
- 2960313v1.0 (Preparative Regimen Medication Administered Begin Date)
- 2787403v2.0 (Anti-Thymocyte Globulin Or Antilymphocyte Serum Source Animal Type)
- 2787415v1.0 (Anti-Thymocyte Globulin Or Antilymphocyte Serum Source Specify Text)
- 2960396v1.0 (Preparative Regimen Medication Administered Route of Administration Type)
- 2816467v1.0 (Pharmacokinetics Preparative Regimen Medication Dose Assessment Indicator)
- 3837204v1.0 (Pharmacokinetics Preparative Regimen Medication Dose Assessment Area Under Curve Milligram per Milliliter per Minute Value)
- 2740983v1.0 (Preparative Regimen Medication Other Type Therapies Specify)

**Permissible Value: Change to value name only (symbol change) for CDE
3935911v2.0 (Preparative Regimen Busulfan Planned Occurrence Administered Dose Unit of Measure Name)**

| <u>PV ID & Version</u> | <u>Old PV Value</u> | <u>New PV Value</u> |
|----------------------------|---------------------------------|-------------------------------------|
| 3935931v1.0 | Target total AUC (µmol x min/L) | Target total AUC (micromol x min/L) |

Minor:

- Added the permissible value 2739550v1.0 (Mitoxantrone) instruction text for the following CDEs:

- 2739625v2.0 (Preparative Regimen Medication Type)
 - Old: none
 - New: Novantrone

Module: Pre-HCT Preparative Regimen (Conditioning) - Part 3 of 9 (Anthracycline)

Major:

- Added the following CDEs:
 - 2750847v1.0 (Anthracycline Antineoplastic Antibiotic Preparative Regimen Type)
 - 2750714v1.0 (Preparative Regimen Medication Plan Administration Yes No Character Indicator)
 - 3040323v1.0 (Preparative Regimen Medication Plan Administration Total Medication Dose Integer::0 Decimal Place Value)
 - 2740606v1.0 (Preparative Regimen Medication Plan Administration Dose Unit of Measure Name)
 - 2960313v1.0 (Preparative Regimen Medication Administered Begin Date)
 - 2960398v1.0 (Preparative Regimen Medication Administered Specify Text)

Module: Pre-HCT Preparative Regimen (Conditioning) - Part 4 of 9 (Corticosteroids)

Major:

- Added the following CDEs:
 - 2958252v1.0 (Corticosteroid Preparative Regimen Administered Type)
 - 2750714v1.0 (Preparative Regimen Medication Plan Administration Yes No Character Indicator)
 - 3040323v1.0 (Preparative Regimen Medication Plan Administration Total Medication Dose Integer::0 Decimal Place Value)
 - 2740606v1.0 (Preparative Regimen Medication Plan Administration Dose Unit of Measure Name)
 - 2960313v1.0 (Preparative Regimen Medication Administered Begin Date)
 - 2960398v1.0 (Preparative Regimen Medication Administered Specify Text)

Module: Pre-HCT Preparative Regimen (Conditioning) - Part 5 of 9 (Intrathecal Therapy (Chemotherapy))

Major:

- Added the following CDEs:
 - 2960392v1.0 (Intrathecal Chemotherapy Preparative Regimen Administered Type)
 - 2750714v1.0 (Preparative Regimen Medication Plan Administration Yes No Character Indicator)
 - 3040323v1.0 (Preparative Regimen Medication Plan Administration Total Medication Dose Integer::0 Decimal Place Value)
 - 2740606v1.0 (Preparative Regimen Medication Plan Administration Dose Unit of Measure Name)
 - 2960313v1.0 (Preparative Regimen Medication Administered Begin Date)
 - 2960398v1.0 (Preparative Regimen Medication Administered Specify Text)

Module: Pre-HCT Preparative Regimen (Conditioning) - Part 6 of 9 (Radio Labeled mAb)

Major:

- Added the following CDEs:
 - 2960406v1.0 (Radiolabeled Monoclonal Antibody Preparative Regimen Administered Indicator)
 - 3108427v1.0 (Preparative Regimen Medication Administered Dose Value)
 - 2741600v1.0 (Radiolabeled Monoclonal Antibody Preparative Regimen Plan Administration Dose Unit of Measure Name)
 - 2960313v1.0 (Preparative Regimen Medication Administered Begin Date)
 - 2672961v1.0 (Preparative Regimen Tositumomab Administered Indicator)
 - 2672969v1.0 (Preparative Regimen Ibritumomab Tiuxetan Administered Indicator)
 - 2672660v1.0 (Preparative Regimen Other Monoclonal Antibody Administered Indicator)
 - 2960398v1.0 (Preparative Regimen Medication Administered Specify Text)

Module: Pre-HCT Preparative Regimen (Conditioning) - Part 7 of 9 (Monoclonal Antibody)

Major:

- Added the following CDEs:
 - 2741209v2.0 (Monoclonal Antibody Preparative Regimen Type)
 - 2750714v1.0 (Preparative Regimen Medication Plan Administration Yes No Character Indicator)

- 3040323v1.0 (Preparative Regimen Medication Plan Administration Total Medication Dose Integer::0 Decimal Place Value)
- 2740606v1.0 (Preparative Regimen Medication Plan Administration Dose Unit of Measure Name)
- 2960313v1.0 (Preparative Regimen Medication Administered Begin Date)
- 2960398v1.0 (Preparative Regimen Medication Administered Specify Text)
- Permissible Value Change to value names only for CDE 2741209v2.0 (Monoclonal Antibody Preparative Regimen Type)

| <u>PV ID & Version</u> | <u>Old PV Value</u> | <u>New PV Value</u> | <u>PV instruction text removed</u> |
|----------------------------|---------------------|-----------------------|------------------------------------|
| 2577772v1.0 | Campath | Alemtuzumab (Campath) | Alemtuzumab (Campath) |

Module: Pre-HCT Preparative Regimen (Conditioning) - Part 8 of 9 (Nitrosourea)

Major:

- Added the following CDEs:
 - 2960478v1.0 (Nitrosourea Compound Preparative Regimen Administered Type)
 - 2750714v1.0 (Preparative Regimen Medication Plan Administration Yes No Character Indicator)
 - 3040323v1.0 (Preparative Regimen Medication Plan Administration Total Medication Dose Integer::0 Decimal Place Value)
 - 2740606v1.0 (Preparative Regimen Medication Plan Administration Dose Unit of Measure Name)
 - 2960313v1.0 (Preparative Regimen Medication Administered Begin Date)
 - 2960398v1.0 (Preparative Regimen Medication Administered Specify Text)

Module: Pre-HCT Preparative Regimen (Conditioning) - Part 8 of 9 (Nitrosourea)

Major:

- Added the following CDEs:
 - 3916241v1.0 (Tyrosine Kinase Inhibitor Preparative Regimen Administered Type)

- 2750714v1.0 (Preparative Regimen Medication Plan Administration Yes No Character Indicator)
- 3040323v1.0 (Preparative Regimen Medication Plan Administration Total Medication Dose Integer::0 Decimal Place Value)
- 2740606v1.0 (Preparative Regimen Medication Plan Administration Dose Unit of Measure Name)
- 2960313v1.0 (Preparative Regimen Medication Administered Begin Date)

Module: GVHD Prophylaxis - Part 1 of 3

Major:

- Added the following CDEs:
 - 3919799v1.0 (Graft Versus Host Disease Preventive Intervention Planned Occurrence And/Or Administered Indicator)

Module: GVHD Prophylaxis - Part 2 of 3

Major:

- Added the following CDEs:
 - 2777660v1.0 (Graft Versus Host Disease Preventive Intervention Type)
 - 3919799v1.0 (Graft Versus Host Disease Preventive Intervention Planned Occurrence And/Or Administered Indicator)
 - 2787403v2.0 (Anti-Thymocyte Globulin Or Antilymphocyte Serum Source Animal Type)
 - 2787415v1.0 (Anti-Thymocyte Globulin Or Antilymphocyte Serum Source Specify Text)
 - 3837871v1.0 (Graft Versus Host Disease Preventive Intervention Administration Specify Text)

Module: GVHD Prophylaxis - Part 3 of 3

Major:

- Added the following CDEs:
 - 3235993v1.0 (in vivo Monoclonal Antibody Administered Type)
 - 2787459v1.0 (in vivo Monoclonal Antibody Administered Indicator)
 - 3837872v1.0 (in vivo Monoclonal Antibody Administered Specify Text)

Module: Other Toxicity Modifying Regimen

Major:

- Added the following CDEs:

- 3922931v1.0 (Palifermin Planned Occurrence Or Administered Therapeutic Procedure Indicator)

Module: Post-HCT Disease Therapy Planned as of Day 0 - Part 1 of 2

Major:

- Added the following CDEs:
 - 3601190v1.0 (Current HCT Planned Multiple HCT Protocol Indicator)
 - 2738491v1.0 (Post Hematopoietic Cell Transplantation Therapeutic Procedure Plan Administration Yes No Character Indicator)

Module: Post-HCT Disease Therapy Planned as of Day 0 - Part 2 of 2

Major:

- Added the following CDEs:
 - 2738487v2.0 (Post Hematopoietic Cell Transplantation Therapeutic Procedure Type)
 - 2738491v1.0 (Post Hematopoietic Cell Transplantation Therapeutic Procedure Plan Administration Yes No Character Indicator)
 - 2673840v2.0 (Post Hematopoietic Cell Transplantation Other Planned Therapeutic Procedure Specify)

Module: Primary Disease for HCT

Major:

- Added the following CDEs:
 - 2932795v1.0 (Diagnosis Present Date)
 - 2494565v3.0 (Hematopoietic Cell Transplantation Primary Disease Classification Type)

Module: Acute Myelogenous Leukemia (AML) - Part 1 of 5

Major:

- Added the following CDEs:
 - 2682630v3.0 (Acute Myeloid Leukemia Classification Type)
 - 3577517v1.0 (Acute Myeloid Leukemia Conversion From Myelodysplastic Syndrome And/Or Myeloproliferative Neoplasm Occurrence Indicator)
 - 3837937v1.0 (Therapy-Related Neoplasm Occurrence Indicator)
 - 2738877v1.0 (Susceptibility Disease or Disorder Occurrence Indicator)
 - 2738883v1.0 (Susceptibility Disease or Disorder Occurrence Name)
 - 2738971v1.0 (Susceptibility Disease or Disorder Occurrence Specify Text)

- 3017711v1.0 (Cytogenetic Analysis Performed Indicator)
- 3017713v1.0 (Cytogenetic Analysis Performed Outcome)
- Added the permissible value 4358932v1.0 (AML (megakaryoblastic) with t(1;22) (p13;q13); RBM15-MKL1) for the following CDE:
 - 2682630v3.0 (Acute Myeloid Leukemia Classification Type)
- Removed the permissible value 2558163v1.0 (AML (megakaryoblastic) with t(1;22) (p13;q13); RBM15-MKL1) for the following CDE:
 - 2682630v3.0 (Acute Myeloid Leukemia Classification Type)
- Permissible Value Change to value names only for 2682630v3.0 (Acute Myeloid Leukemia Classification Type)

| <u>PV ID & Version</u> | <u>Old PV Value</u> | <u>New PV Value</u> | <u>PV instruction text removed</u> |
|----------------------------|--|--|------------------------------------|
| 3926632v1.0 | AML with t(9;11) (p22;q23); MLLT 3-MLL | AML with t(9;11)(p22;q23); MLLT3-MLL | |
| 3257034v1.0 | AML with t(6;9) (p23;q24); DEK-NUP214 | AML with t(6;9) (p23;q34); DEK-NUP214 | |
| 2672720v1.0 | AML with t(8;21); (q22;q22); RUNX1/RUNX1T1 | AML with t(8;21)(q22;q22); RUNX1-RUNX1T1 | |
| 2672718v1.0 | AML with inv(16); (p13.1;q22) or t(16;16) (p13.1;q22); CBF/MYH11 | AML with inv(16)(p13.1q22) or t(16;16)(p13.1;q22); CBF-MYH11 | |
| 2672716v1.0 | APL with t(15;17); (q22;q12); RARA;PML | APL with t(15;17)(q22;q12); PML-RARA | |

Module: Acute Myelogenous Leukemia (AML) - Part 2 of 5

Major:

- Added the following CDEs:
 - 2760451v2.0 (Cytogenetic Abnormality Diagnosis Type)
 - 2459201v1.0 (Cytogenetic Abnormality Present Indicator)
 - 2760473v1.0 (Cytogenetic Abnormality Diagnosis Specify Text)

**Permissible Values: Changes to value names only (includes spacing changes) for
CDE 2760451v2.0 (Cytogenetic Abnormality Diagnosis Type)**

| <u>PV ID & Version</u> | <u>Old PV Value</u> | <u>New PV Value</u> | <u>PV instruction text removed</u> |
|----------------------------|--|--|--|
| 3021246v1.0 | Monosomy 5 | -5 | -5 |
| 2762295v1.0 | Monosomy 7 | -7 | -7 |
| 3021245v1.0 | Monosomy 17 | -17 | -17 |
| 3021244v1.0 | Monosomy 18 | -18 | -18 |
| 3021241v1.0 | Monosomy X | -X | -X |
| 3021240v1.0 | Monosomy Y | -Y | -Y |
| 3021200v1.0 | Trisomy 4 | +4 | +4 |
| 3021201v1.0 | Trisomy 8 | +8 | +8 |
| 3021292v1.0 | Trisomy 11 | +11 | +11 |
| 3021290v1.0 | Trisomy 13 | +13 | +13 |
| 3021289v1.0 | Trisomy 14 | +14 | +14 |
| 3021286v1.0 | Trisomy 21 | +21 | +21 |
| 3021285v1.0 | Trisomy 22 | +22 | +22 |
| 3021320v1.0 | t (3;3) | t(3;3) | |
| 3021328v1.0 | t (6;9) | t(6;9) | |
| 3021333v1.0 | t (8;21) | t(8;21) | |
| 3133341v1.0 | t (9;11) | t(9;11) | |
| 3021236v1.0 | t(9;22) | t(9;22) | |
| 3021325v1.0 | t (15;17) | t(15;17) and variants | and variants |
| 3021323v1.0 | t (16;16) | t(16;16) | |
| 3685347v1.0 | del(3q) / 3q- | del(3q) / 3q- | |
| 3021309v1.0 | del (5q) / 5q- | del(5q) / 5q- | |
| 3021307v1.0 | del (7q) / 7q- | del(7q) / 7q- | |
| 3021306v1.0 | del (9q) / 9q- | del(9q) / 9q- | |
| 3021305v1.0 | del (11q) / 11q- | del(11q) / 11q- | |
| 3021302v1.0 | del (16q) / 16q- | del(16q) / 16q- | |
| 3021300v1.0 | del (17q) / 17q- | del(17q) / 17q- | |
| 3021298v1.0 | del (20q) / 20q- | del(20q) / 20q- | |
| 3685349v1.0 | del(21q) / 21q- | del(21q) / 21q- | |
| 3021294v1.0 | inv (3) | inv(3) | |
| 3021284v1.0 | inv (16) | inv(16) | |
| 3943192v1.0 | (11q23) any abnormality | (11q23) any abnormality | |
| 3021273v1.0 | abnormal (12p) | 12p any abnormality | 12p any abnormality |
| 3017722v1.0 | Complex (greater than or equal to 3 distinct abnormalities) | Complex - >= 3 distinct abnormalities | |

| | | | |
|-------------|-------------------|-------------------|--|
| 3021310v1.0 | Other abnormality | Other abnormality | |
|-------------|-------------------|-------------------|--|

Module: Acute Myelogenous Leukemia (AML) - Part 3 of 5

Major:

- Added the following CDEs:
 - 2761520v1.0 (Molecular Analysis Laboratory Procedure Performed Indicator)

Module: Acute Myelogenous Leukemia (AML) - Part 4 of 5

Major:

- Added the following CDEs:
 - 3854443v1.0 (Biomarker Laboratory Procedure Performed Name)
 - 2761927v1.0 (Molecular Analysis Laboratory Procedure Performed Laboratory Finding Result)
 - 5464v2.31 (Biomarker Name Other)

Module: Acute Myelogenous Leukemia (AML) - Part 5 of 5

Major:

- Added the following CDEs:
 - 3588591v2.0 (Disease or Disorder Hematologic Status Leukemia Type)
 - 3838471v2.0 (Induction Therapeutic Procedure Accomplishment Complete Remission Required Cycle Count)
 - 3624380v1.0 (Molecular Analysis Remission Occurrence Indicator)
 - 3837926v1.0 (Remission Detection Flow Cytometry Occurrence Indicator)
 - 3624385v1.0 (Cytogenetic Analysis Remission Occurrence Indicator)
 - 2947021v1.0 (Disease or Disorder Recurrent Disease Status Date)
 - 2936618v1.0 (Disease or Disorder Status Date)
- Permissible Value Change for CDE 3588591v2.0: (Disease or Disorder Hematologic Status Leukemia Type)
 - Permissible Value change for ID: 3072089v1.0

Was: \geq 3rd complete remission

Now: \geq 3rd complete remission

- Permissible Value change for ID: 3053622v1.0
Was: \geq 3rd relapse

Now: \geq 3rd relapse
- Permissible Value change for ID: 2770751v1.0
Was: 1st complete remission (no previous bone marrow or extramedullary relapse)
Now: 1st complete remission
- Permissible Value Change for 3838471v2.0 (Induction Therapeutic Procedure Accomplishment Complete Remission Required Cycle Count)
 - Permissible Value change for: 3926024v1.0
Was: \geq 3
Now: \geq 3

Module: Acute Lymphoblastic Leukemia (ALL) - Part 1 of 5

Major:

- Added the following CDEs:
 - 2675085v3.0 (Acute Lymphoblastic Leukemia Classification Type)
 - 2934704v1.0 (Tyrosine Kinase Inhibitor Administered Indicator)
 - 3017711v1.0 (Cytogenetic Analysis Performed Indicator)
 - 3017713v1.0 (Cytogenetic Analysis Performed Outcome)
- Permissible Value Change to value names only for 3588591v1.0 (Disease or Disorder Hematologic Leukemia Status Type)

| <u>PV ID & Version</u> | <u>Old PV Value</u> | <u>New PV Value</u> | <u>PV instruction text removed</u> |
|----------------------------|-----------------------------|------------------------------|------------------------------------|
| 3935833v1.0 | t(9;22)(q34;q11); BCR/ABL1 | t(9;22)(q34;q11.2); BCR-ABL1 | |
| 3965205v1.0 | t(1;19)(q23;p13.3) E2A-PBX1 | t(1;19)(q23;p13.3); E2A-PBX1 | |
| 3925971v1.0 | t(12;21)(p13q22); TEL-AML1 | t(12;21)(p13;q22); TEL-AML1 | |

Module: Acute Lymphoblastic Leukemia (ALL) - Part 2 of 5

Major:

- Added the following CDEs:
 - 2760451v2.0 (Cytogenetic Abnormality Diagnosis Type)
 - 2459201v1.0 (Cytogenetic Abnormality Present Indicator)
 - 2760473v1.0 (Cytogenetic Abnormality Diagnosis Specify Text)

Permissible Values: Changes to value names only (includes spacing changes) for CDE 2760451v2.0 (Cytogenetic Abnormality Diagnosis Type)

| <u>PV ID & Version</u> | <u>Old PV Value</u> | <u>New PV Value</u> | <u>PV instruction text removed</u> |
|----------------------------|---|--------------------------------------|------------------------------------|
| 2762295v1.0 | Monosomy 7 | -7 | -7 |
| 3021200v1.0 | Trisomy 4 | +4 | +4 |
| 3021201v1.0 | Trisomy 8 | +8 | +8 |
| 3021199v1.0 | Trisomy 17 | +17 | +17 |
| 3021286v1.0 | Trisomy 21 | +21 | +21 |
| 3021232v1.0 | t(1;19) | t(1;19) | |
| 3321386v1.0 | t(2;8) | t(2;8) | |
| 3021233v1.0 | t(4;11) | t(4;11) | |
| 3685574v1.0 | t(5;14) | t(5;14) | |
| 3021235v1.0 | t(8;14) | t(8;14) | |
| 3321385v1.0 | t(8;22) | t(8;22) | |
| 3021236v1.0 | t(9;22) | t(9;22) | |
| 3021202v1.0 | t(10;14) | t(10;14) | |
| 3021312v1.0 | t(11;14) | t(11;14) | |
| 3021203v1.0 | t(12;21) | t(12;21) | |
| 3021308v1.0 | del(6q) / 6q- | del(6q) / 6q- | |
| 2936671v1.0 | del(9p) / 9p- | del(9p) / 9p- | |
| 2762283v1.0 | del(12p) / 12p- | del(12p) / 12p- | |
| 3021279v1.0 | add(14q) | add(14q) | |
| 3943192v1.0 | (11q23) any abnormality | (11q23) any abnormality | |
| 3685575v1.0 | abnormal (9p) | 9p any abnormality | 9p any abnormality |
| 3021273v1.0 | abnormal (12p) | 12p any abnormality | 12p any abnormality |
| 3029115v1.0 | Hyperdiploid (Greater than 50) | Hyperdiploid (> 50) | Hyperdiploid (>50) |
| 3029114v1.0 | Hypodiploid (Less than 46) | Hypodiploid (< 46) | Hypodiploid (<46) |
| 3017722v1.0 | Complex (greater than or equal to 3 distinct abnormalities) | Complex - >=3 distinct abnormalities | |
| 3021310v1.0 | Other abnormality | Other abnormality | |

Module: Acute Lymphoblastic Leukemia (ALL) - Part 3 of 5

Major:

- Added the following CDEs:
 - 2761520v1.0 (Molecular Analysis Laboratory Procedure Performed Indicator)

Module: Acute Lymphoblastic Leukemia (ALL) - Part 4 of 5

Major:

- Added the following CDEs:
 - 3854443v1.0 (Biomarker Laboratory Procedure Performed Name)
 - 2761927v1.0 (Molecular Analysis Laboratory Procedure Performed Laboratory Finding Result)
 - 5464v2.31 (Biomarker Name Other)

Module: Acute Lymphoblastic Leukemia (ALL) - Part 5 of 5

Major:

- Added the following CDEs:
 - 3588591v2.0 (Disease or Disorder Hematologic Status Leukemia Type)
 - 3838471v2.0 (Induction Therapeutic Procedure Accomplishment Complete Remission Required Cycle Count)
 - 3624380v1.0 (Molecular Analysis Remission Occurrence Indicator)
 - 3837926v1.0 (Remission Detection Flow Cytometry Occurrence Indicator)
 - 3624385v1.0 (Cytogenetic Analysis Remission Occurrence Indicator)
 - 2947021v1.0 (Disease or Disorder Recurrent Disease Status Date)
 - 2936618v1.0 (Disease or Disorder Status Date)
- Permissible Value change for CDE 3588591v2.0: Disease or Disorder Hematologic Status Leukemia Type
 - Permissible Value change for ID: 3072089v1.0
 - Was: \geq 3rd complete remission
 - Now: \geq 3rd complete remission
 - Permissible Value change for ID: 3053622v1.0
 - Was: \geq 3rd relapse
 - Now: \geq 3rd relapse
 - Permissible Value change for ID: 2770751v1.0
 - Was: 1st complete remission (no previous bone marrow or extramedullary relapse)

- Now: 1st complete remission
- Permissible Value change for CDE 3838471v1.0 (: Induction Therapeutic Procedure Accomplishment Complete Remission Required Cycle Count)
 - Permissible Value change for: 3926024v1.0
 - Was: ≥ 3
 - Now: ≥ 3

Module: Other Acute Leukemia

Major:

- Added the following CDEs:
 - 2675089v2.0 (Other Acute Leukemia Classification Type)
 - 2675091v2.0 (Other Acute Leukemia Classification Diagnosis Specify)
 - 3588591v1.0 (Disease or Disorder Hematologic Status Leukemia Type)
 - 2936618v1.0 (Disease or Disorder Status Date)
- Permissible Value change for CDE 3588591v2.0: Disease or Disorder Hematologic Status Leukemia Type
 - Permissible Value change for: 3072089v1.0
 - Was: \geq 3rd complete remission
 - Now: \geq 3rd complete remission
 - Permissible Value change for: 3053622v1.0
 - Was: \geq 3rd relapse
 - Now: \geq 3rd relapse
- Permissible Value Change to value names only for 3588591v1.0 (Disease or Disorder Hematologic Leukemia Status Type)

| <u>PV ID & Version</u> | <u>Old PV Value</u> | <u>New PV Value</u> | <u>PV instruction text added</u> |
|----------------------------|--|------------------------|---|
| 2770751v1.0 | 1st complete remission (no previous bone marrow or extramedullary relapse) | 1st complete remission | No previous bone marrow or extramedullary relapse |

Module: Chronic Myelogenous Leukemia (CML)

Major:

- Added the following CDEs:
 - 2688790v2.0 (Chronic Myelogenous Leukemia Classification Type)
 - 2763213v1.0 (Therapeutic Procedure Administered Indicator)
 - 3186480v1.0 (Combination Chemotherapy Administered Ind-3)
 - 2861531v1.0 (Hydroxyurea Administered Indicator)
 - 2934704v1.0 (Tyrosine Kinase Inhibitor Administered Indicator)
 - 2867240v1.0 (Interferon Alpha Administered Indicator)
 - 2793029v1.0 (Other Therapeutic Procedure Administered Indicator)
 - 3061476v1.0 (Other Therapeutic Procedure Administered Specify Text)
 - 2939802v2.0 (Disease or Disorder CML Status Type)
 - 2760856v1.0 (Cytogenetic Analysis Complete Remission Confirmed Indicator)
 - 2760858v1.0 (Molecular Analysis Complete Remission Confirmed Indicator)
 - 3923101v2.0 (Chronic Myelogenous Leukemia Prior Therapeutic Procedure Complete Remission Phase Category)
 - 3838317v1.0 (Chronic Myelogenous Leukemia Phase Status Diseases and Disorders Count)
 - 2936618v1.0 (Disease or Disorder Status Date)

- Permissible Value Change to value names only for 2939802v2.0 (Disease or Disorder CML Status Type)

| <u>PV ID & Version</u> | <u>Old PV Value</u> | <u>New PV Value</u> | <u>PV instruction text added</u> |
|----------------------------|---------------------|---------------------|----------------------------------|
| 2675142v1.0 | Blast crisis | Blast phase | |

- Permissible Value Change to value names only for 3849480v1.0 (Other Leukemia Status Atypical Chronic Myeloid Leukemia Type)

| <u>PV ID & Version</u> | <u>Old PV Value</u> | <u>New PV Value</u> | <u>PV instruction text</u> |
|----------------------------|--|--|----------------------------|
| 2770751v1.0 | 1st complete remission (no previous bone marrow or extramedullary relapse) | 1st complete remission (no previous bone marrow or extramedullary relapse) | |

- Added the permissible value 3304774v1.0 (Accelerated Phase) for the following CDE:
 - 3923101v2.0 (Chronic Myelogenous Leukemia Prior Therapeutic Procedure Complete Remission Phase Category)
- Removed the permissible value 2675144v1.0 (Accelerated Phase) for the following CDE:
 - 3923101v2.0 (Chronic Myelogenous Leukemia Prior Therapeutic Procedure Complete Remission Phase Category)

Minor:

- Question Text change for CDE 2763213v1.0 (Therapeutic Procedure Administered Indicator)
 - Old: Was therapy given prior to this HCT?
 - New: Was therapy given?
- Instruction Text change for CDE 2763213v1.0 (Therapeutic Procedure Administered Indicator)
 - Old: *blank*
 - New: Prior to this HCT

Module: Myelodysplastic (MDS) / Myeloproliferative (MPN) Disease - Part 1 of 5

Major:

- Added the following CDEs:
 - 2738448v2.0 (Myelodysplastic Syndrome And/Or Chronic Myeloproliferative Disease or Disorder Classification Type)
 - 3837937v1.0 (Therapy-Related Neoplasm Occurrence Indicator)
 - 2738877v1.0 (Susceptibility Disease or Disorder Occurrence Indicator)
 - 2738883v1.0 (Susceptibility Disease or Disorder Occurrence Name)
 - 2738971v1.0 (Susceptibility Disease or Disorder Occurrence Specify Text)
 - 2860462v1.0 (Laboratory Procedure Leukocyte Result Status Indicator)
 - 2775872v1.0 (Laboratory Procedure Leukocyte Result Outcome Integer::1 Decimal Place Value)
 - 2775874v1.0 (Laboratory Procedure Leukocyte Result Unit of Measure Name)
 - 2860470v1.0 (Laboratory Procedure Hemoglobin Result Status Indicator)

- 2798928v1.0 (Laboratory Procedure Hemoglobin Result Outcome Integer::2 Decimal Place Value)
- 2775909v1.0 (Laboratory Procedure Hemoglobin Result Lab Unit of Measure Name)
- 3883362v1.0 (Erythrocyte Prior Laboratory Procedure Blood Transfusion Indicator)
- 2860841v1.0 (Laboratory Procedure Platelet Result Status Indicator)
- 2799091v1.0 (Laboratory Procedure Platelet Result Integer::0 Decimal Place Value)
- 2799093v1.0 (Laboratory Procedure Platelet Result Lab Unit of Measure Name)
- 3883369v1.0 (Platelet Prior Laboratory Procedure Blood Transfusion Indicator)
- 2940075v1.0 (Laboratory Procedure Neutrophil Result Status Indicator)
- 2795147v1.0 (Laboratory Procedure Neutrophil Result Percentage Integer::0 Decimal Place Value)
- 2934447v1.0 (Laboratory Procedure Bone Marrow Blast Cell Outcome Finding Status Indicator)
- 2861157v1.0 (Laboratory Procedure Bone Marrow Blast Cell Outcome Percentage Integer::0 Decimal Place Value)
- 3017711v1.0 (Cytogenetic Analysis Performed Indicator)
- 3017713v1.0 (Cytogenetic Analysis Performed Outcome)
- 3926291v1.0 (Marked Cytogenetic Abnormality Present Number)

Major:

- Changed 4 permissible values for CDE 2738448v2.0 (Myelodysplastic Syndrome And/Or Chronic Myeloproliferative Disease or Disorder Classification Type)
 - *Brackets { } replaced with ()*
 - Old: 3928692v1.0 (Atypical chronic myeloid leukemia, Ph unknown/bcr- {CML, NOS})
 - New: 3928692v1.0 (Atypical chronic myeloid leukemia, Ph unknown/bcr- (CML, NOS))
 - Old: 3928691v1.0 (Atypical chronic myeloid leukemia, Ph unknown/bcr unknown {CML, NOS})
 - New: 3928691v1.0 (Atypical chronic myeloid leukemia, Ph unknown/bcr unknown (CML, NOS))
 - Old: 3928693v1.0 (Atypical chronic myeloid leukemia, Ph-/bcr unknown {CML, NOS})
 - New: 3928693v1.0 (Atypical chronic myeloid leukemia, Ph-/bcr unknown (CML, NOS))

- Old: 3928672v1.0 (Atypical chronic myeloid leukemia, Ph-/bcr/abl- {CML, NOS})
- New: 3928672v1.0 (Atypical chronic myeloid leukemia, Ph-/bcr/abl- (CML, NOS))
- Removed the Permissible Value 2962080v1.0 (Neurofibromatosis type 1) for the following CDE: ***In this module only***
 - 2738883v1.0 (Susceptibility Disease or Disorder Occurrence Name)

Minor:

- Question Text changed for CDE 2738448v1.0 (Myelodysplastic Syndrome And/Or Chronic Myeloproliferative Disease or Disorder Classification Type)
 - Old: What was the MDS / MPS subtype?
 - New: What was the MDS / MPN subtype?

Module: Myelodysplastic (MDS) / Myeloproliferative (MPN) Disease - Part 2 of 5

Major:

- Added the following CDEs:
 - 2760451v2.0 (Cytogenetic Abnormality Diagnosis Type)
 - 2459201v1.0 (Cytogenetic Abnormality Present Indicator)
 - 2760473v1.0 (Cytogenetic Abnormality Diagnosis Specify Text)

Permissible Values: Changes to value names only (includes spacing changes) for CDE 2760451v2.0 (Cytogenetic Abnormality Diagnosis Type)

| <u>PV ID & Version</u> | <u>Old PV Value</u> | <u>New PV Value</u> | <u>PV instruction text removed</u> |
|----------------------------|---------------------|---------------------|------------------------------------|
| 3021246v1.0 | Monosomy 5 | -5 | -5 |
| 2762295v1.0 | Monosomy 7 | -7 | -7 |
| 3021243v1.0 | Monosomy 13 | -13 | -13 |
| 3021242v1.0 | Monosomy 20 | -20 | -20 |
| 3021240v1.0 | Monosomy Y | -Y | -Y |
| 3021201v1.0 | Trisomy 8 | +8 | +8 |
| 3021287v1.0 | Trisomy 19 | +19 | +19 |
| 3855614v1.0 | t (1;3) | t(1;3) | |
| 3855613v1.0 | t (2;11) | t(2;11) | |
| 3021320v1.0 | t (3;3) | t(3;3) | |
| 3855612v1.0 | t (3;21) | t(3;21) | |
| 3021328v1.0 | t (6;9) | t(6;9) | |
| 3855611v1.0 | t (11;16) | t(11;16) | |

| | | | |
|-------------|-------------------|-------------------|--|
| 3685347v1.0 | del(3q) / 3q- | del(3q) / 3q- | |
| 3021309v1.0 | del (5q) / 5q- | del(5q) / 5q- | |
| 3021307v1.0 | del (7q) / 7q- | del(7q) / 7q- | |
| 3021306v1.0 | del (9q) / 9q- | del(9q) / 9q- | |
| 3021305v1.0 | del (11q) / 11q- | del(11q) / 11q- | |
| 2762283v1.0 | del(12p)/12p- | del(12p) / 12p- | |
| 3021304v1.0 | del (13q) / 13q- | del(13q) / 13q- | |
| 3021298v1.0 | del (20q) / 20q- | del(20q) / 20q- | |
| 3021294v1.0 | inv (3) | inv(3) | |
| 3685345v1.0 | i17q | i17q | |
| 3021310v1.0 | Other abnormality | Other abnormality | |

Module: Myelodysplastic (MDS) / Myeloproliferative (MPN) Disease - Part 3 of 5

Major:

- Added the following CDEs:
 - 3946491v1.0 (Disease Progression And/Or Conversion Difference Myelodysplastic Syndrome And/Or Myeloproliferative Neoplasm Subtype Indicator)
 - 3946522v1.0 (Disease Progression And/Or Conversion Difference Myelodysplastic Syndrome And/Or Myeloproliferative Neoplasm Subtype Date)
 - 2738448v2.0 (Myelodysplastic Syndrome And/Or Chronic Myeloproliferative Disease or Disorder Classification Type)
 - 2860462v1.0 (Laboratory Procedure Leukocyte Result Status Indicator)
 - 2775872v1.0 (Laboratory Procedure Leukocyte Result Outcome Integer::1 Decimal Place Value)
 - 2775874v1.0 (Laboratory Procedure Leukocyte Result Unit of Measure Name)
 - 2860470v1.0 (Laboratory Procedure Hemoglobin Result Status Indicator)
 - 2798928v1.0 (Laboratory Procedure Hemoglobin Result Outcome Integer::2 Decimal Place Value)
 - 2775909v1.0 (Laboratory Procedure Hemoglobin Result Lab Unit of Measure Name)
 - 3883362v1.0 (Erythrocyte Prior Laboratory Procedure Blood Transfusion Indicator)
 - 2860841v1.0 (Laboratory Procedure Platelet Result Status Indicator)
 - 2799091v1.0 (Laboratory Procedure Platelet Result Integer::0 Decimal Place Value)
 - 2799093v1.0 (Laboratory Procedure Platelet Result Lab Unit of Measure Name)

- 3883369v1.0 (Platelet Prior Laboratory Procedure Blood Transfusion Indicator)
- 2940075v1.0 (Laboratory Procedure Neutrophil Result Status Indicator)
- 2795147v1.0 (Laboratory Procedure Neutrophil Result Percentage Integer::0 Decimal Place Value)
- 2934447v1.0 (Laboratory Procedure Bone Marrow Blast Cell Outcome Finding Status Indicator)
- 2861157v1.0 (Laboratory Procedure Bone Marrow Blast Cell Outcome Percentage Integer::0 Decimal Place Value)
- 3017711v1.0 (Cytogenetic Analysis Performed Indicator)
- 3017713v1.0 (Cytogenetic Analysis Performed Outcome)
- 3926291v1.0 (Marked Cytogenetic Abnormality Present Number)

Minor:

- Question Text changed for CDE 2738448v1.0 (Myelodysplastic Syndrome And/Or Chronic Myeloproliferative Disease or Disorder Classification Type)
 - Old: What was the MDS / MPS subtype?
 - New: Specify the MDS / MPN subtype

Module: Myelodysplastic (MDS) / Myeloproliferative (MPN) Disease - Part 4 of 5

Major:

- Added the following CDEs:
 - 2760451v2.0 (Cytogenetic Abnormality Diagnosis Type)
 - 2459201v1.0 (Cytogenetic Abnormality Present Indicator)
 - 2760473v1.0 (Cytogenetic Abnormality Diagnosis Specify Text)

Permissible Values: Changes to value names only (includes spacing changes) for CDE 2760451v2.0 (Cytogenetic Abnormality Diagnosis Type)

| <u>PV ID & Version</u> | <u>Old PV Value</u> | <u>New PV Value</u> | <u>PV instruction text removed</u> |
|-----------------------------------|----------------------------|----------------------------|---|
| 3021246v1.0 | Monosomy 5 | -5 | -5 |
| 2762295v1.0 | Monosomy 7 | -7 | -7 |
| 3021243v1.0 | Monosomy 13 | -13 | -13 |
| 3021242v1.0 | Monosomy 20 | -20 | -20 |
| | | | -Y |

| | | | |
|-------------|-------------------|-------------------|-----|
| 3021240v1.0 | Monosomy Y | -Y | +8 |
| 3021201v1.0 | Trisomy 8 | +8 | +19 |
| 3021287v1.0 | Trisomy 19 | +19 | |
| 3855614v1.0 | t (1;3) | t(1;3) | |
| 3855613v1.0 | t (2;11) | t(2;11) | |
| 3021320v1.0 | t (3;3) | t(3;3) | |
| 3855612v1.0 | t (3;21) | t(3;21) | |
| 3021328v1.0 | t (6;9) | t(6;9) | |
| 3855611v1.0 | t (11;16) | t(11;16) | |
| 3685347v1.0 | del(3q) / 3q- | del(3q) / 3q- | |
| 3021309v1.0 | del (5q) / 5q- | del(5q) / 5q- | |
| 3021307v1.0 | del (7q) / 7q- | del(7q) / 7q- | |
| 3021306v1.0 | del (9q) / 9q- | del(9q) / 9q- | |
| 3021305v1.0 | del (11q) / 11q- | del(11q) / 11q- | |
| 2762283v1.0 | del(12p)/12p- | del(12p) / 12p- | |
| 3021304v1.0 | del (13q) / 13q- | del(13q) / 13q- | |
| 3021298v1.0 | del (20q) / 20q- | del(20q) / 20q- | |
| 3021294v1.0 | inv (3) | inv(3) | |
| 3685345v1.0 | i17q | i17q | |
| 3021310v1.0 | Other abnormality | Other abnormality | |

Module: Myelodysplastic (MDS) / Myeloproliferative (MPN) Disease - Part 5 of 5

Major:

- Added the following CDEs:
 - 3124484v1.0 (Disease or Disorder Status Myelodysplastic Syndrome And/Or Myeloproliferative Neoplasm Type)
 - 2955919v1.0 (Hematopoietic Cell Laboratory Procedure Performed Hematologic Improvement Status)
 - 3947473v1.0 (Disease or Disorder Disease Progression Status Date)
 - 2947021v1.0 (Disease or Disorder Recurrent Disease Status Date)
 - 2936618v1.0 (Disease or Disorder Status Date)

Minor:

Module: Myelodysplastic (MDS) / Myeloproliferative (MPN) Disease - Part 5 of 5

(Preceding space has been removed in title)

- Old: Myelodysplastic (MDS) / Myeloproliferative (MPN) Disease - Part 5 of 5
- New: Myelodysplastic (MDS) / Myeloproliferative (MPN) Disease - Part 5 of 5

Module: Other Leukemia (OL)

Major:

- Added the following CDEs:
 - 2688882v2.0 (Other Leukemia Classification Type)
 - 2685380v2.0 (Other Leukemia Classification Diagnosis Specify)
 - 3838314v1.0 (17p Cytogenetic Abnormality Detection Indicator)
 - 3851893v1.0 (Diffuse Large B-Cell Lymphoma Histologic Conversion Occurrence Indicator)
 - 3849480v2.0 (Other Leukemia Status Atypical Chronic Myeloid Leukemia Type)
 - 3844251v1.0 (Other Leukemia Status Chronic Lymphocytic Leukemia Prolymphocytic Leukemia Hairy Cell Leukemia Type)
 - 2936618v1.0 (Disease or Disorder Status Date)

- Permissible Value change for CDE 3849480v2.0 Other Leukemia Status Atypical Chronic Myeloid Leukemia)
 - Permissible Value change for ID: 3072089v1.0

Was: \geq 3rd complete remission

Now: \geq 3rd complete remission

 - Permissible Value change for ID: 3053622v1.0

Was: \geq 3rd relapse

Now: \geq 3rd relapse

Module: Hodgkin Lymphoma

Major:

- Added the following CDEs:
 - 3930393v1.0 (Disease or Disorder Hodgkin Lymphoma Histology Classification Type)
 - 3923501v1.0 (Disease or Disorder Status LymphomaType)
 - 2936618v1.0 (Disease or Disorder Status Date)

Module: Non-Hodgkin Lymphoma

Major:

- Added the following CDEs:
 - 2685061v4.0 (Disease or Disorder Status Date)
 - 2950700v1.0 (Lymphoma Histology Specify Text)
 - 3946614v1.0 (Histology Conversion From Chronic Lymphocytic Leukemia Occurrence Indicator)
 - 3851894v1.0 (Non-Hodgkin Lymphoma Histology Conversion From Other Lymphoma Occurrence Indicator)
 - 3923501v1.0 (Disease or Disorder Status LymphomaType)
 - 2936618v1.0 (Disease or Disorder Status Date)

- Permissible Value change for 2685061v4.0 (Non-Hodgkin's Lymphoma Classification Type)
 - Permissible Value change for ID: 2838642v1.0
 - Was: Nodal marginal zone B-cell lymphoma (\pm monocytoid B-cells)
 - Now: Nodal marginal zone B-cell lymphoma (+/- monocytoid B-cells)

Module: Multiple Myeloma / Plasma Cell Disorder (PCD) - Part 1 of 3

Major:

- Added the following CDEs:
 - 2688923v2.0 (Plasma Cell Disorder Classification Type)
 - 2685348v1.0 (Plasma Cell Disease Other Classification Diagnosis Other Specify)
 - 2658051v2.0 (Immunoglobulin Light Chain Involved Type)
 - 2181363v1.0 (Myeloma Diagnosis Stage)
 - 2181361v1.0 (Myeloma Diagnosis Renal Stage)
 - 2861058v2.0 (Serum Beta-2-Microglobulin Protein Laboratory Procedure Performed Result Integer::3 Decimal Place Value)
 - 2861060v2.0 (Serum Beta-2-Microglobulin Protein Laboratory Procedure Performed Lab Unit of Measure Name)
 - 2861067v1.0 (Serum Albumin Laboratory Procedure Performed Outcome Integer::1 Decimal Place Value)
 - 2861069v1.0 (Serum Albumin Laboratory Procedure Performed Lab Unit of Measure Name)

- 2689280v3.0 (Plasma Cell Myeloma International Staging System for Myeloma Stage)
- 3017711v1.0 (Cytogenetic Analysis Performed Indicator)
- 3017713v1.0 (Cytogenetic Analysis Performed Outcome)
- Permissible Value change for 2689280v3.0 (Plasma Cell Myeloma International Staging System for Myeloma Stage)
 - Permissible value change for: 3928731v1.0
Was: 1 (β 2-mic < 3.5, S. albumin > 3.5)
Now: 1 (beta2-mic < 3.5, S. albumin > 3.5)
 - Permissible value change for: 2689277v1.0
Was: 2 (β 2-mic 3.5 - < 5.5, S. albumin-)
Now: 2 (beta2-mic 3.5 - < 5.5, S. albumin-)
 - Permissible value change for: 2689276v1.0
Was: 3 (β 2-mic \geq 5.5; S. albumin-)
Now: 3 (beta2-mic \geq 5.5; S. albumin-)

Added the permissible values for 2658051v2.0 (Immunoglobulin Light Chain Involved Type)

- 4166229v1.0 (kappa)
- 4174200v1.0 (lambda)

Removed the permissible value for 2658051v1.0 (Immunoglobulin Light Chain Involved Type)

- 2561939v1.0 (kappa)
- 2561941v1.0 (lambda)

Minor:

Question Text change for CDE 2861058v2.0 (**Plasma Cell Myeloma International Staging System for Myeloma Stage**)

Was: Serum β 2-microglobulin:

Now: Serum beta2-microglobulin:

Major:

- Added the following CDEs:
 - 2760451v2.0 (Cytogenetic Abnormality Diagnosis Type)
 - 2459201v1.0 (Cytogenetic Abnormality Present Indicator)
 - 2760473v1.0 (Cytogenetic Abnormality Diagnosis Specify Text)

Permissible Values: Changes to value names only (includes spacing changes) for CDE 2760451v2.0 (Cytogenetic Abnormality Diagnosis Type)

| <u>PV ID & Version</u> | <u>Old PV Value</u> | <u>New PV Value</u> | <u>PV instruction text removed</u> |
|-----------------------------------|--------------------------------|----------------------------|---|
| 3021264v1.0 | Trisomy 3 | +3 | +3 |
| 3021263v1.0 | Trisomy 5 | +5 | +5 |
| 3021262v1.0 | Trisomy 7 | +7 | +7 |
| 3021293v1.0 | Trisomy 9 | +9 | +9 |
| 3021292v1.0 | Trisomy 11 | +11 | +11 |
| 3021288v1.0 | Trisomy 15 | +15 | +15 |
| 3021287v1.0 | Trisomy 19 | +19 | +19 |
| 3021317v1.0 | t (4;14) | t(4;14) | |
| 3021326v1.0 | t (6;14) | t(6;14) | |
| 3021312v1.0 | t (11;14) | t(11;14) | |
| 3021327v1.0 | t (14;16) | t(14;16) | |
| 3855615v1.0 | t (14;20) | t(14;20) | |
| 3021304v1.0 | del (13q) / 13q- | del(13q) / 13q- | del 13/13q |
| 3021299v1.0 | del (17p) / 17p- | del(17p) / 17p- | del 17/17p |
| 3029115v1.0 | Hyperdiploid (Greater than 50) | Hyperdiploid (> 50) | Hyperdiploid (>50) |
| 3029114v1.0 | Hypodiploid (Less than 46) | Hypodiploid (< 46) | Hypodiploid (<46) |
| 3689264v1.0 | abnormal 1q | Any abnormality at 1q | Any abnormality at 1q |
| 3689265v1.0 | abnormal 1p | Any abnormality at 1p | Any abnormality at 1p |
| 3021310v1.0 | Other abnormality | Other abnormality | |

Module: Multiple Myeloma / Plasma Cell Disorder (PCD) - Part 3 of 3

Major:

- Added the following CDEs:

- 3308059v1.0 (Disease or Disorder Status Plasma Cell Myeloma Type)
- 2936618v1.0 (Disease or Disorder Status Date)

Module: Solid Tumors

Major:

- Added the following CDEs:
 - 3838571v1.0 (Solid Tumor Classification Type)
 - 3838579v1.0 (Solid Tumor Classification Specify Text)

Module: Severe Aplastic Anemia

Major:

- Added the following CDEs:
 - 3923927v1.0 (Severe Aplastic Anemia Classification Type)
 - 3923947v1.0 (Acquired Cytopenia Syndrome Classification Specify Text)

Module: Inherited Abnormalities of Erythrocyte Differentiation or Function

Major:

- Added the following CDEs:
 - 2912001v2.0 (Congenital Abnormalities of Erythrocyte Differentiation or Function Classification Anemia Hemoglobinopathy Type)
 - 2685390v1.0 (Other Genetic Anemia Classification Disease Diagnosis Specify)
 - 2686104v1.0 (Other Hemoglobinopathy Classification Disease Diagnosis Other Specify)
- Permissible Value Change to value names only for 2912001v2.0 (Congenital Abnormalities of Erythrocyte Differentiation or Function Classification Anemia Hemoglobinopathy Type)

| <u>PV ID & Version</u> | <u>Old PV Value</u> | <u>New PV Value</u> | <u>PV instruction text</u> |
|----------------------------|---|---|----------------------------|
| 2593267v1.0 | Paroxysmal nocturnal hemoglobinuria (PNH) | Paroxysmal nocturnal hemoglobinuria (PNH) | |

Module: Disorders of the Immune System

Major:

- Added the following CDEs:
 - 2689272v2.0 (Immune System Disorder Classification Type)
 - 3946671v1.0 (Severe Combined Immunodeficiency Classification Specify Text)
 - 2686127v1.0 (Immune System Disorder Other Classification Specify Text)

Module: Inherited Abnormalities of Platelets

Major:

- Added the following CDEs:
 - 3930503v1.0 (Congenital Platelets Abnormality Classification Type)
 - 2679790v1.0 (Congenital Platelets Abnormality Other Type Specify)

Module: Inherited Disorders of Metabolism

Major:

- Added the following CDEs:
 - 3930586v2.0 (Inherited Metabolic Disorder Classification Type)
 - 2679800v1.0 (Congenital Metabolic Disorder Other Type Specify)
- Permissible Value change for CDE 3930586v2.0 (Inherited Metabolic Disorder Classification Type)
 - Permissible Value change for: 3028420v1.0
 - Was: β -glucuronidase deficiency (VII)
 - Now: Beta-glucuronidase deficiency (VII)

Module: Histiocytic Disorders

Major:

- Added the following CDEs:
 - 2685158v1.0 (Histiocytic and Dendritic Cell Neoplasms Classification Type)
 - 2685162v1.0 (Histiocytic and Dendritic Cell Neoplasms Classification Disease Diagnosis Other Specify)

Module: Autoimmune Diseases

Major:

- Added the following CDEs:
 - 2679802v2.0 (Autoimmune Disease Type)
 - 2686147v1.0 (Arthritis Other Classification Disease Diagnosis Other Specify)
 - 3930655v1.0 (Juvenile Rheumatoid Arthritis Classification Specify Text)
 - 2685309v1.0 (Other Connective Tissue Disorder Type Disease Diagnosis Other Specify)
 - 2689395v1.0 (Vasculitis Other Classification Disease Diagnosis Other Specify)
 - 3930659v1.0 (Autoimmune Nervous System Disorder Classification Specify Text)
 - 3930663v1.0 (Autoimmune Cytopenia Classification Specify Text)
 - 3930667v1.0 (Inflammatory Bowel Disease Classification Specify Text)

Module: Other Disease

Major:

- Added the following CDEs:
 - 3945806v1.0 (Disease or Disorder Classification Specify Text)

Module: Author Information

Major:

- Added the following CDEs:
 - 2179589v2.0 (Person Given/First Name)
 - 2179591v2.0 (Person Family/Last Name)
 - 2517550v1.0 (Person Email Address Text)
 - 3771111v1.0 (Form Entry Date)

