# Change Summary of all Information Collection Data Element and Response Changes

| Information Collection Domain Sub-Type | Information Collection Domain Additional Sub Domain | Response required if Additional Sub Domain applies | Information Collection may be requested multiple times | Current Information Collection Data Element (if applicable) | Current Information Collection Data Element Response Option(s) | Information Collection update: | Proposed Information Collection Data Element (if applicable) | Proposed Information Collection Data Element Response Option(s) | Rationale for Information Collection Update |
|---|---|---|---|---|---|---|---|---|---|
| Pre-Transplant Essential Data | Clinical Trial Participants | yes | no | Study Sponsor | BMT CTN,COG,Other,PIDTC,RCI BMT,USIDNET | Change/Clarification of Response Options | Study Sponsor | BMT CTN,COG,Other,PIDTC,RCI BMT,USIDNET, PedAL | Be consistent with current clinical landscape, improve transplant outcome data |
| Pre-Transplant Essential Data | Allogeneic Donors | yes | yes | Non-NMDP unrelated donor ID: | open text | Change/Clarification of Information Requested | ~~Non-NMDP unrelated donor ID:~~Registry donor ID: | open text | Capture data accurately |
| Pre-Transplant Essential Data | Autologous Transplant | yes | yes | What agents were used to mobilize the autologous recipient for this HCT? (check all that apply) | G-CSF (filgrastim, Neupogen), Pegylated G-CSF (pegfilgrastim, Neulasta), Plerixafor (Mozobil), Combined with chemotherapy, Anti-CD20 (rituximab, Rituxan), Other agent | Change/Clarification of Response Options | What agents were used to mobilize the autologous recipient for this HCT? (check all that apply) | G-CSF (TBO-filgrastim, filgrastim, Granix, Neupogen) ,GM-CSF (sargramostim, Leukine), Pegylated G-CSF (pegfilgrastim, Neulasta), Plerixafor (Mozobil), Combined with chemotherapy, Anti-CD20 (rituximab, Rituxan), Other agent | Be consistent with current clinical landscape, improve transplant outcome data |
| Pre-Transplant Essential Data | | | | Was mechanical ventilation used for COVID-19 (SARS-CoV-2) infection? | No,Yes | Change/Clarification of Information Requested | Was mechanical ventilation ~~used~~ given for COVID-19 (SARS-CoV-2) infection? | No,Yes | Examples added or typographical errors corrected for clarification |

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|---|---|---|---|---|---|---|---|---|---|
| Pre-Transplant Essential Data | Comorbid Conditions | Yes | no | Specify prior malignancy (check all that apply) | Breast cancer<br>Central nervous system (CNS) malignancy (e.g., glioblastoma, astrocytoma)<br>Gastrointestinal malignancy (e.g., colon, rectum, stomach, pancreas, intestine, esophageal)<br>Genitourinary malignancy (e.g., kidney, bladder, ovary, testicle, genitalia, uterus, cervix, prostate)<br>Leukemia<br>Lung cancer<br>Lymphoma (includes Hodgkin & non-Hodgkin lymphoma)<br>MDS / MPN<br>Melanoma<br>Multiple myeloma / plasma cell disorder (PCD)<br>Oropharyngeal cancer | Change/Clarification of Response Options | Specify prior malignancy (check all that apply) | Breast cancer<br>Central nervous system (CNS) malignancy (e.g., glioblastoma, astrocytoma)<br>Gastrointestinal malignancy (e.g., colon, rectum, stomach, pancreas, intestine, esophageal)<br>Genitourinary malignancy (e.g., kidney, bladder, ovary, testicle, genitalia, uterus, cervix, prostate)<br>~~Leukemia~~ Acute myeloid leukemia<br>Chronic myeloid leukemia<br>Acute lymphoblastic leukemia<br>Chronic lymphoblastic leukemia<br>Lung cancer<br>Lymphoma (includes Hodgkin & non-Hodgkin lymphoma)<br>MDS / MPN<br>Melanoma<br>Multiple myeloma / plasma cell disorder (PCD)<br>Oropharyngeal cancer (e.g., | Be consistent with current clinical landscape, improve transplant outcome data |
| Pre-Transplant Essential Data | Comorbid Conditions | Yes | no | Specify other skin malignancy: (prior) | open text | Deletion of Information Requested | ~~Specify other skin malignancy: (prior)~~ | ~~open text~~ | Reduce redundancy in data capture |
| Pre-Transplant Essential Data | | no | no | Height at initiation of pre-HCT preparative regimen: | ___ ___ ___ inches<br>___ ___ ___ cms | Change/Clarification of Response Options | Height at initiation of pre-HCT preparative regimen: | ___ ___ ___ inches<br>___ ___ ___ cms | Capture data accurately |

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|---|---|---|---|---|---|---|---|---|---|
| Pre-HCT Preparative Regimen | | no | no | Drug (drop down list) | Bendamustine,Busulfan,Carboplatin,Carmustine,Clofarabine,Cyclophosphamide,Cytarabine,Etoposide,Fludarabine,Gemcitabine,Ibritumomab tiuxetan,Ifosfamide,Lomustine,Melphalan,Methylprednisolone,Other,Pentostatin,Propylene glycol-free melphalan,Rituximab,Thiotepa,Tositumomab,Treosulfan | Change/Clarification of Response Options | Drug (drop down list) | Bendamustine,Busulfan,Carboplatin,Carmustine,Clofarabine,Cyclophosphamide,Cytarabine,Etoposide,Fludarabine,Gemcitabine,Ibritumomab tiuxetan,Ifosfamide,Lomustine,Melphalan,Methylprednisolone,Other,Pentostatin,Propylene glycol-free melphalan,Rituximab,Thiotepa,Tositumomab,Treosulfan, Azathioprine, Bortezomib, Cisplatin, Hydroxyurea, and Vincristine. | Be consistent with current clinical landscape, improve transplant outcome data |
| Additional Drugs Given In the Peri-Transplant Period | | no | no | ALG, ALS, ATG, ATS | no,yes | Change/Clarification of Information Requested and Response Option | ALG, ALS, ATG, ATS, Alemtuzumab, Defibrotide, KGF, Ursodiol | ~~no,yes~~ (check all that apply) | Reduce burden: expanded response options to include responses previously reported manually or created a "check all that apply" |
| Additional Drugs Given In the Peri-Transplant Period | | no | no | Alemtuzumab (Campath) | no,yes | Deletion of Information: Merged to Check all that Apply | ~~Alemtuzumab (Campath)~~ | ~~no,yes~~ | Reduce burden: expanded response options to include responses previously reported manually or created a "check all that apply" |
| Additional Drugs Given In the Peri-Transplant Period | | no | no | Defibrotide | No,Yes | Deletion of Information: Merged to Check all that Apply | ~~Defibrotide~~ | ~~No,Yes~~ | Reduce burden: expanded response options to include responses previously reported manually or created a "check all that apply" |
| Additional Drugs Given In the Peri-Transplant Period | | no | no | KGF | No,Yes | Deletion of Information: Merged to Check all that Apply | ~~KGF~~ | ~~No,Yes~~ | Reduce burden: expanded response options to include responses previously reported manually or created a "check all that apply" |

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|---|---|---|---|---|---|---|---|---|---|
| Additional Drugs Given In the Peri-Transplant Period | | no | no | Ursodiol | No,Yes | Deletion of Information: Merged to Check all that Apply | ~~Ursodiol~~ | ~~No,Yes~~ | Reduce burden: expanded response options to include responses previously reported manually or created a "check all that apply" |
| Covid-19 Impact | | no | no | | | Addition of Information Requested | Was the HCT impacted for a reason related to the COVID-19 (SARS-CoV-2) pandemic? | no,yes | Covid-19 Impact |
| Covid-19 Impact | | no | no | | | Addition of Information Requested | Is the HCT date different than the originally intended HCT date? | no,yes | Covid-19 Impact |
| Covid-19 Impact | | no | no | | | Addition of Information Requested | Original Date of HCT | YYYY/MM/DD | Covid-19 Impact |
| Covid-19 Impact | | no | no | | | Addition of Information Requested | Date estimated | checked | Covid-19 Impact |
| Covid-19 Impact | | no | no | | | Addition of Information Requested | Is the donor different than the originally intended donor? | no,yes | Covid-19 Impact |
| Covid-19 Impact | | no | no | | | Addition of Information Requested | Specify the originally intended donor | unrelated donor, syngeneic (monozygotic twin) , HLA-idential sibling (may include non-monozygotic twin) , HLA-matched other relative (does NOT include a haplo-identical donor), HLA-mismatched relative | Covid-19 Impact |
| Covid-19 Impact | | no | no | | | Addition of Information Requested | Is the product type (bone marrow, PBSC, cord blood unit) different than the originally intended product type? | no,yes | Covid-19 Impact |
| Covid-19 Impact | | no | no | | | Addition of Information Requested | Specify the originally intended product type | bone marrow,Other product,PBSC, cord blood unit | Covid-19 Impact |

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|---|---|---|---|---|---|---|---|---|---|
| Covid-19 Impact | | no | no | | | Addition of Information Requested | Specify other product type | open text | Covid-19 Impact |
| Covid-19 Impact | | no | no | | | Addition of Information Requested | Was the current product thawed from a cryopreserved state prior to infusion? | no,yes | Covid-19 Impact |
| Covid-19 Impact | | no | no | | | Addition of Information Requested | Did the preparative regimen change from the original plan? | no, yes | Covid-19 Impact |
| Covid-19 Impact | | no | no | | | Addition of Information Requested | Did the GVHD prophylaxis change from the original plan? | no,yes | Covid-19 Impact |

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|---|---|---|---|---|---|---|---|---|---|
| Disease Classification | | no | no | What was the primary disease for which the HCT / cellular therapy was performed? | diseases,Acute lymphoblastic leukemia (ALL),Acute myelogenous leukemia (AML or ANLL),Chronic myelogenous leukemia (CML),Hemoglobinopathies,Histiocytic disorders,Hodgkin lymphoma,Inherited Bone Marrow Failure Syndromes(If the recipient developed MDS or AML, indicate MDS or AML as the primary disease.)–,Disorders of the immune system,Inherited disorders of metabolism,Inherited abnormalities of platelets,Myelodysplastic syndrome (MDS) (If recipient has transformed to AML, | Change/Clarification of Response Options | What was the primary disease for which the HCT / cellular therapy was performed? | diseases,Acute lymphoblastic leukemia (ALL),Acute ~~myelogenous~~ myeloid leukemia (AML or ANLL),Chronic myelogenous leukemia (CML),Hemoglobinopathies,Histiocytic disorders,Hodgkin lymphoma,Inherited Bone Marrow Failure Syndromes(If the recipient developed MDS or AML, indicate MDS or AML as the primary disease.)–,Disorders of the immune system,Inherited disorders of metabolism,Inherited abnormalities of platelets,Myelodysplastic syndrome (MDS) (If recipient has transformed to AML, indicate AML as the primary disease.),Myeloproliferative neoplasms (MPN)(If recipient has transformed to AML, indicate AML as the | Capture data accurately |
| Disease Classification | Acute Myelogenous Leukemia (AML) | yes | yes | Were cytogenetics tested (karyotyping or FISH)? (at diagnosis) | no,Unknown,yes | Change/Clarification of Information Requested | Were cytogenetics tested (karyotyping or FISH)? (at diagnosis or relapse) | no,Unknown,yes | Reduce redundancy in data capture |
| Disease Classification | Acute Myelogenous Leukemia (AML) | yes | yes | Were tests for molecular markers performed? (at diagnosis) | no,Unknown,yes | Change/Clarification of Information Requested | Were tests for molecular markers performed? (at diagnosis or relapse) | no,Unknown,yes | Reduce redundancy in data capture |

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|---|---|---|---|---|---|---|---|---|---|
| Disease Classification | Acute Myelogenous Leukemia (AML) | yes | yes | Specify CEBPA mutation | Biallelic (homozygous),Monoallelic (heterozygous),Unknown | Change/Clarification of Response Options | Specify CEBPA mutation | Biallelic (double mutant),Monoallelic (single mutant),Unknown | Capture data accurately |
| Disease Classification | Acute Myelogenous Leukemia (AML) | yes | yes | Were cytogenetics tested (karyotyping or FISH)? (between diagnosis and last evaluation) | no,Unknown,yes | Change/Clarification of Information Requested | Were cytogenetics tested (karyotyping or FISH)? (between diagnosis or relapse and last evaluation) | no,Unknown,yes | Reduce redundancy in data capture |
| Disease Classification | Acute Myelogenous Leukemia (AML) | yes | yes | Were tests for molecular markers performed? (e.g. PCR, NGS) (between diagnosis and last evaluation) | no,Unknown,yes | Change/Clarification of Information Requested | Were tests for molecular markers performed? (e.g. PCR, NGS) (between diagnosis or relapse and last evaluation) | no,Unknown,yes | Reduce redundancy in data capture |
| Disease Classification | Acute Myelogenous Leukemia (AML) | yes | yes | Specify CEBPA mutation | Biallelic (homozygous),Monoallelic (heterozygous),Unknown | Change/Clarification of Response Options | Specify CEBPA mutation | Biallelic (double mutant),Monoallelic (single mutant),Unknown | Capture data accurately |
| Disease Classification | Acute Myelogenous Leukemia (AML) | yes | yes | Specify CEBPA mutation | Biallelic (homozygous),Monoallelic (heterozygous),Unknown | Change/Clarification of Response Options | Specify CEBPA mutation | Biallelic (double mutant),Monoallelic (single mutant),Unknown | Capture data accurately |
| Disease Classification | Acute Myelogenous Leukemia (AML) | yes | no | Was the recipient in remission by flow cytometry? | Not applicable,No,Unknown,Yes | Deletion of Information Requested | ~~Was the recipient in remission by flow cytometry?~~ | ~~Not applicable,No,Unknown,Yes~~ | Reduce redundancy in data capture |
| Disease Classification | Acute Myelogenous Leukemia (AML) | yes | no | | | Addition of Information Requested | Specify method(s) that was used to assess measurable residual disease status (check all that apply) | FISH, Karyotyping, Flow Cytometry, PCR, NGS, Not assessed | Be consistent with current clinical landscape, improve transplant outcome data |
| Disease Classification | Acute Myelogenous Leukemia (AML) | yes | no | | | Addition of Information Requested | Was measurable residual disease detected by FISH? | no,yes | Be consistent with current clinical landscape, improve transplant outcome data |

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|---|---|---|---|---|---|---|---|---|---|
| Disease Classification | Acute Myelogenous Leukemia (AML) | yes | no | | | Addition of Information Requested | Was measurable residual disease detected by karyotyping assay? | no,yes | Be consistent with current clinical landscape, improve transplant outcome data |
| Disease Classification | Acute Myelogenous Leukemia (AML) | yes | no | | | Addition of Information Requested | Which leukemia phenotype was used for detection (check all the apply) | original leukemia immunophenotype, aberrant phenotype | Be consistent with current clinical landscape, improve transplant outcome data |
| Disease Classification | Acute Myelogenous Leukemia (AML) | yes | no | | | Addition of Information Requested | What is the lower limit of detection (for the original leukemia immunophenotype) | open text | Be consistent with current clinical landscape, improve transplant outcome data |
| Disease Classification | Acute Myelogenous Leukemia (AML) | yes | no | | | Addition of Information Requested | What is the lower limit of detection (for the aberrant phenotype) | open text | Be consistent with current clinical landscape, improve transplant outcome data |
| Disease Classification | Acute Myelogenous Leukemia (AML) | yes | no | | | Addition of Information Requested | Was measurable residual disease detected by flow cytometry? | no,yes | Be consistent with current clinical landscape, improve transplant outcome data |
| Disease Classification | Acute Myelogenous Leukemia (AML) | yes | no | | | Addition of Information Requested | Was measurable residual disease detected by PCR? | no,yes | Be consistent with current clinical landscape, improve transplant outcome data |
| Disease Classification | Acute Myelogenous Leukemia (AML) | yes | no | | | Addition of Information Requested | Was measurable residual disease detected by NGS? | no,yes | Be consistent with current clinical landscape, improve transplant outcome data |
| Disease Classification | Acute Lymphoblastic Leukemia (ALL) | yes | yes | Were cytogenetics tested (karyotyping or FISH)? (at diagnosis) | no,Unknown,yes | Change/Clarification of Information Requested | Were cytogenetics tested (karyotyping or FISH)? (at diagnosis or relapse) | no,Unknown,yes | Reduce redundancy in data capture |
| Disease Classification | Acute Lymphoblastic Leukemia (ALL) | yes | yes | Were tests for molecular markers performed? (at diagnosis) | no,Unknown,yes | Change/Clarification of Information Requested | Were tests for molecular markers performed? (at diagnosis or relapse) | no,Unknown,yes | Reduce redundancy in data capture |
| Disease Classification | Acute Lymphoblastic Leukemia (ALL) | yes | yes | Were cytogenetics tested (karyotyping or FISH)? (between diagnosis and last evaluation) | no,Unknown,yes | Change/Clarification of Information Requested | Were cytogenetics tested (karyotyping or FISH)? (between diagnosis or at relapse and last evaluation) | no,Unknown,yes | Reduce redundancy in data capture |

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|---|---|---|---|---|---|---|---|---|---|
| Disease Classification | Acute Lymphoblastic Leukemia (ALL) | yes | yes | Were tests for molecular markers performed? (e.g. PCR, NGS) (between diagnosis and last evaluation) | no,Unknown,yes | Change/Clarification of Information Requested | Were tests for molecular markers performed? (e.g. PCR, NGS) (between diagnosis or relapse and last evaluation) | no,Unknown,yes | Reduce redundancy in data capture |
| Disease Classification | Acute Lymphoblastic Leukemia (ALL) | yes | no | Was the recipient in remission by flow cytometry? | Not applicable,No,Unknown,Yes | Deletion of Information Requested | ~~Was the recipient in remission by flow cytometry?~~ | ~~Not applicable,No,Unknown,Yes~~ | Reduce redundancy in data capture |
| Disease Classification | Acute Lymphoblastic Leukemia (ALL) | yes | no | | | Addition of Information Requested | Specify method(s) that was used to assess measurable residual disease status (check all that apply) | FISH, Karyotyping, Flow Cytometry, PCR, NGS, Not assessed | Be consistent with current clinical landscape, improve transplant outcome data |
| Disease Classification | Acute Lymphoblastic Leukemia (ALL) | yes | no | | | Addition of Information Requested | Was measurable residual disease detected by FISH? | no,yes | Be consistent with current clinical landscape, improve transplant outcome data |
| Disease Classification | Acute Lymphoblastic Leukemia (ALL) | yes | no | | | Addition of Information Requested | Was measurable residual disease detected by karyotyping assay? | no,yes | Be consistent with current clinical landscape, improve transplant outcome data |
| Disease Classification | Acute Lymphoblastic Leukemia (ALL) | yes | no | | | Addition of Information Requested | Which leukemia phenotype was used for detection (check all the apply) | original leukemia immunophenotype, aberrant phenotype | Be consistent with current clinical landscape, improve transplant outcome data |
| Disease Classification | Acute Lymphoblastic Leukemia (ALL) | yes | no | | | Addition of Information Requested | What is the lower limit of detection (for the original leukemia immunophenotype) | open text | Be consistent with current clinical landscape, improve transplant outcome data |
| Disease Classification | Acute Lymphoblastic Leukemia (ALL) | yes | no | | | Addition of Information Requested | What is the lower limit of detection (for the aberrant phenotype) | open text | Be consistent with current clinical landscape, improve transplant outcome data |
| Disease Classification | Acute Lymphoblastic Leukemia (ALL) | yes | no | | | Addition of Information Requested | Was measurable residual disease detected by flow cytometry? | no,yes | Be consistent with current clinical landscape, improve transplant outcome data |
| Disease Classification | Acute Lymphoblastic Leukemia (ALL) | yes | no | | | Addition of Information Requested | Was measurable residual disease detected by PCR? | no,yes | Be consistent with current clinical landscape, improve transplant outcome data |

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|---|---|---|---|---|---|---|---|---|---|
| Disease Classification | Acute Lymphoblastic Leukemia (ALL) | yes | no | | | Addition of Information Requested | Was measurable residual disease detected by NGS? | no,yes | Be consistent with current clinical landscape, improve transplant outcome data |
| Disease Classification | Myelodysplastic Syndrome (MDS) | yes | no | Specify the cell line examined to determine HI status | HI-E,HI-N,HI-P | Change/Clarification of Information Requested | Specify the cell lines examined to determine HI status | HI-E,HI-N,HI-P | Examples added or typographical errors corrected for clarification |
| Disease Classification | Hodgkin and Non-Hodgkin Lymphoma | yes | no | Specify the lymphoma histology | Hodgkin lymphoma, not otherwise specified (150)<br>Lymphocyte depleted (154)<br>Lymphocyte-rich (151)<br>Mixed cellularity (153)<br>Nodular lymphocyte predominant Hodgkin lymphoma (155)<br>Nodular sclerosis (152)<br>**Non-Hodgkin Lymphoma**<br>**B-cell Neoplasms**<br>ALK+ large B-cell lymphoma (1833)<br>B-cell lymphoma, unclassifiable, with features intermediate between DLBCL and classical Hodgkin lymphoma (149)<br>Burkitt lymphoma (111)<br>Burkitt-like lymphoma with 11q aberration | Change/Clarification of Response Options | Specify the lymphoma histology | **Lymphoma**<br>Lymphocyte depleted (154)<br>Lymphocyte-rich (151)<br>Mixed cellularity (153)<br>Nodular sclerosis (152)<br>**Other Classical Hodgkin Lymphoma**<br>Hodgkin lymphoma, not otherwise specified (150)<br>Nodular lymphocyte predominant Hodgkin lymphoma<br>**Non-Hodgkin Lymphoma**<br>**B-cell Neoplasms**<br>ALK+ large B-cell lymphoma (1833)<br>B-cell lymphoma, unclassifiable, with features intermediate between DLBCL and classical Hodgkin lymphoma (149)<br>Burkitt lymphoma (111)<br>Burkitt-like lymphoma with 11q aberration (1834)<br>Diffuse, large B-cell lymphoma- Activated B-cell type (non-GCB) (1821)<br>Diffuse, large B-cell | Be consistent with current clinical landscape, improve transplant outcome data |

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|---|---|---|---|---|---|---|---|---|---|
| Disease Classification | Hodgkin and Non-Hodgkin Lymphoma | yes | no | Is the lymphoma histology reported at transplant a transformation from CLL? | no,yes | Change/Clarification of Response Options | Is the lymphoma histology reported at transplant a transformation from CLL? | no,yes (Also complete Chronic Lymphocytic Leukemia (CLL) ) | Capture additional relevent disease information |
| Disease Classification | Multiple Myeloma / Plasma Cell Disorder (PCD) | yes | no | Plasma cells in blood by flow cytometry | Known,Unknown | Change/Clarification of Information Requested | Plasma cells in peripheral blood by flow cytometry | Known,Unknown | Capture data accurately |
| Disease Classification | Multiple Myeloma / Plasma Cell Disorder (PCD) | yes | no | Plasma cells in blood by morphologic assessment | Known,Unknown | Change/Clarification of Information Requested | Plasma cells in peripheral blood by morphologic assessment | Known,Unknown | Capture data accurately |
| Disease Classification | Inherited Bone Marrow Failure Syndromes | yes | no | Specify the inherited bone marrow failure syndrome classification | Dyskeratosis congenita,Fanconi anemia,Severe congenital neutropenia,Diamond-Blackfan anemia,Shwachman-Diamond | Change/Clarification of Response Options | Specify the inherited bone marrow failure syndrome classification | Dyskeratosis congenita,Fanconi anemia,Severe congenital neutropenia,Diamond-Blackfan anemia,Shwachman-Diamond, Other inherited bone failure syndromes | Be consistent with current clinical landscape, improve transplant outcome data |
| Disease Classification | Inherited Bone Marrow Failure Syndromes | yes | no | Did the recipient receive gene therapy to treat the inherited bone marrow failure syndrome? | No,Yes | Deletion of Information Requested | ~~Did the recipient receive gene therapy to treat the inherited bone marrow failure syndrome?~~ | ~~No,Yes~~ | Reduce redundancy in data capture |
| Disease Classification | Hemoglobinopathies | yes | no | Did the recipient receive gene therapy to treat the hemoglobinopathy? | No,Yes | Deletion of Information Requested | ~~Did the recipient receive gene therapy to treat the hemoglobinopathy?~~ | ~~No,Yes~~ | Reduce redundancy in data capture |

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|---|---|---|---|---|---|---|---|---|---|
| Disease Classification | Inherited Disorders of Metabolism | yes | no | Specify inherited disorders of metabolism classification | y (ALD) (543),Aspartyl glucosaminidase (561),ß-glucuronidase deficiency (VII) (537),Fucosidosis (562),Gaucher disease (541),Glucose storage disease (548),Hunter syndrome (II) (533),Hurler syndrome (IH) (531),I-cell disease (546),Krabbe disease (globoid leukodystrophy) (544),Lesch-Nyhan (HGPRT deficiency) (522),Mannosidosis (563),Maroteaux-Lamy (VI) (536),Metachromatic leukodystrophy (MLD) (542),Mucolipidoses, not otherwise specified (540),Morquio (IV) (535),Mucopolysaccharidosis (V) | Change/Clarification of Response Options | Specify inherited disorders of metabolism classification | leukoencephalopathy with spheroids, Adrenoleukodystrophy (ALD) (543),Aspartyl glucosaminidase (561),ß-glucuronidase deficiency (VII) (537),Fucosidosis (562),Gaucher disease (541),Glucose storage disease (548),Hunter syndrome (II) (533),Hurler syndrome (IH) (531),I-cell disease (546),Krabbe disease (globoid leukodystrophy) (544),Lesch-Nyhan (HGPRT deficiency) (522),Mannosidosis (563),Maroteaux-Lamy (VI) (536),Metachromatic leukodystrophy (MLD) (542),Mucolipidoses, not otherwise specified (540),Morquio (IV) (535),Mucopolysaccharidosis (V) (538),Mucopolysaccharidosis, not otherwise specified (530),Niemann-Pick disease | Be consistent with current clinical landscape, improve transplant outcome data |
| Hematopoietic Cellular Transplant (HCT) Infusion Product | | no | no | Specify the shipping environment of the product(s) | Room temperature, Cooled (refrigerator temperature, not frozen), Frozen (cyropreserved), Other shipping enfivronment | Change/Clarification of Response Options | Specify the shipping environment of the product(s) | Room temperature, Cooled (refrigerated gel pack, refrigerator temperature, not frozen), Frozen (cyropreserved), Other shipping enfivronment | Examples added or typographical errors corrected for clarification |

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| Hematopoietic Cellular Transplant (HCT) Infusion Product | | no | yes | Method of testing TNC viability | Flow cytometry based,Other method,Trypan blue | Change/Clarification of Response Options | Method of testing TNC viability | Flow cytometry based (7AAD, AOPI, AOEB),Other method,Trypan blue | Examples added or typographical errors corrected for clarification |
| Hematopoietic Cellular Transplant (HCT) Infusion Product | | no | yes | Method of testing CD34+ cell viability | Flow cytometry based,Other method,Trypan blue | Change/Clarification of Response Options | Method of testing CD34+ cell viability | Flow cytometry based (7AAD, AOPI, AOEB), Other method,Trypan blue | Examples added or typographical errors corrected for clarification |
| Hematopoietic Cellular Transplant (HCT) Infusion Product | | no | yes | Method of testing CD3+ cell viability | Flow cytometry based,Other method,Trypan blue | Change/Clarification of Response Options | Method of testing CD3+ cell viability | Flow cytometry based (7AAD, AOPI, AOEB), Other method,Trypan blue | Examples added or typographical errors corrected for clarification |
| Hematopoietic Cellular Transplant (HCT) Infusion Product | | no | yes | Method of testing CD3+CD4+ cell viability | Flow cytometry based,Other method,Trypan blue | Change/Clarification of Response Options | Method of testing CD3+CD4+ cell viability | Flow cytometry based (7AAD, AOPI, AOEB), Other method,Trypan blue | Examples added or typographical errors corrected for clarification |
| Hematopoietic Cellular Transplant (HCT) Infusion Product | | no | yes | Method of testing CD3+CD8+ cell viability | Flow cytometry based,Other method,Trypan blue | Change/Clarification of Response Options | Method of testing CD3+CD8+ cell viability | Flow cytometry based (7AAD, AOPI, AOEB), Other method,Trypan blue | Examples added or typographical errors corrected for clarification |
| Hematopoietic Cellular Transplant (HCT) Product Infusion | Cord Blood Product Infusion | yes | yes | Total CFU-GM | Done,Not done | Merged to Check all that Apply | Indicate which Assessments were Carried out (Check all that apply) | Total CFU-GM, Total CFU-GEMM, Total BFU-E | Reduce burden: expanded response options to include responses previously reported manually or created a "check all that apply" |

| Information Collection Domain Sub-Type | Information Collection Domain Additional Sub Domain | Response required if Additional Sub Domain applies | Information Collection may be requested multiple times | Current Information Collection Data Element (if applicable) | Current Information Collection Data Element Response Option(s) | Information Collection update: | Proposed Information Collection Data Element (if applicable) | Proposed Information Collection Data Element Response Option(s) | Rationale for Information Collection Update |
|---|---|---|---|---|---|---|---|---|---|
| Hematopoietic Cellular Transplant (HCT) Product Infusion | Cord Blood Product Infusion | yes | yes | Total CFU-GEMM | Done,Not done | Merged to Check all that Apply | ~~Total CFU-GEMM~~ | ~~Done,Not done~~ | Reduce burden: expanded response options to include responses previously reported manually or created a "check all that apply" |
| Hematopoietic Cellular Transplant (HCT) Product Infusion | Cord Blood Product Infusion | yes | yes | Total BFU-E | Done,Not done | Merged to Check all that Apply | ~~Total BFU-E~~ | ~~Done,Not done~~ | Reduce burden: expanded response options to include responses previously reported manually or created a "check all that apply" |

| Information Collection Domain Sub-Type | Information Collection Domain Additional Sub Domain | Response required if Additional Sub Domain applies | Information Collection may be requested multiple times | Current Information Collection Data Element (if applicable) | Current Information Collection Data Element Response Option(s) | Information Collection update: | Proposed Information Collection Data Element (if applicable) | Proposed Information Collection Data Element Response Option(s) | Rationale for Information Collection Update |
|---|---|---|---|---|---|---|---|---|---|
| Hematopoietic Cellular Transplant (HCT) Product Infusion | Product Analysis | yes | yes | Specify Organism Code(s): | 121 inetobacter (all species), 125 Bordetella pertussis (whooping cough), 128 Campylobacter (all species), 129 Capnocytophaga (all species), 171 Chlamydia (pneumoniae), 130 Citrobacter (freundii, other species), 131 Clostridium (all species except difficile), 132 Clostridium difficile, 173 Corynebacterium jeikeium, 134 Enterobacter (all species), 135 Enterococcus (all species), 177 Enterococcus, vancomycin resistant (VRE), 136 Escherichia (also E. coli), 139 Fusobacterium (all species), 187 | Change/Clarification of Response Options | Specify Organism Code(s): | inetobacter (all species), 125 Bordetella pertussis (whooping cough), 128 Campylobacter (all species), 129 Capnocytophaga (all species), 171 Chlamydia (pneumoniae), 130 Citrobacter (freundii, other species), 131 Clostridium (all species except difficile), 132 Clostridium difficile, 173 Corynebacterium jeikeium, 134 Enterobacter (all species), 135 Enterococcus (all species), 177 Enterococcus, vancomycin resistant (VRE), 136 Escherichia (also E. coli), 139 Fusobacterium (all species), 187 Haemophilus influenzae, 188 Haemophilus non-influenzae, 146 Klebsiella (all species), 147 Lactobacillus (bulgaricus, acidophilus, other species), 189 Legionella pneumophila, 190 | Examples added or typographical errors corrected for clarification |

| Information Collection Domain Sub-Type | Information Collection Domain Additional Sub Domain | Response required if Additional Sub Domain applies | Information Collection may be requested multiple times | Current Information Collection Data Element (if applicable) | Current Information Collection Data Element Response Option(s) | Information Collection update: | Proposed Information Collection Data Element (if applicable) | Proposed Information Collection Data Element Response Option(s) | Rationale for Information Collection Update |
|---|---|---|---|---|---|---|---|---|---|
| Hematopoietic Cellular Transplant (HCT) Product Infusion | Product Analysis | yes | yes | Specify Organism Code(s): | 121 inetobacter (all species), 125 Bordetella pertussis (whooping cough), 128 Campylobacter (all species), 129 Capnocytophaga (all species), 171 Chlamydia (pneumoniae), 130 Citrobacter (freundii, other species), 131 Clostridium (all species except difficile), 132 Clostridium difficile, 173 Corynebacterium jeikeium, 134 Enterobacter (all species), 135 Enterococcus (all species), 177 Enterococcus, vancomycin resistant (VRE), 136 Escherichia (also E. coli), 139 Fusobacterium (all species), 187 | Change/Clarification of Response Options | Specify Organism Code(s): | inetobacter (all species), 125 Bordetella pertussis (whooping cough), 128 Campylobacter (all species), 129 Capnocytophaga (all species), 171 Chlamydia (pneumoniae), 130 Citrobacter (freundii, other species), 131 Clostridium (all species except difficile), 132 Clostridium difficile, 173 Corynebacterium jeikeium, 134 Enterobacter (all species), 135 Enterococcus (all species), 177 Enterococcus, vancomycin resistant (VRE), 136 Escherichia (also E. coli), 139 Fusobacterium (all species), 187 Haemophilus influenzae, 188 Haemophilus non-influenzae, 146 Klebsiella (all species), 147 Lactobacillus (bulgaricus, acidophilus, other species), 189 Legionella pneumophila, 190 | Examples added or typographical errors corrected for clarification |

| Information Collection Domain Sub-Type | Information Collection Domain Additional Sub Domain | Response required if Additional Sub Domain applies | Information Collection may be requested multiple times | Current Information Collection Data Element (if applicable) | Current Information Collection Data Element Response Option(s) | Information Collection update: | Proposed Information Collection Data Element (if applicable) | Proposed Information Collection Data Element Response Option(s) | Rationale for Information Collection Update |
|---|---|---|---|---|---|---|---|---|---|
| Hematopoietic Cellular Transplant (HCT) Product Infusion | Product Analysis | yes | yes | Specify Organism Code(s): | 121 inetobacter (all species), 125 Bordetella pertussis (whooping cough), 128 Campylobacter (all species), 129 Capnocytophaga (all species), 171 Chlamydia (pneumoniae), 130 Citrobacter (freundii, other species), 131 Clostridium (all species except difficile), 132 Clostridium difficile, 173 Corynebacterium jeikeium, 134 Enterobacter (all species), 135 Enterococcus (all species), 177 Enterococcus, vancomycin resistant (VRE), 136 Escherichia (also E. coli), 139 Fusobacterium (all species), 187 | Change/Clarification of Response Options | Specify Organism Code(s): | inetobacter (all species), 125 Bordetella pertussis (whooping cough), 128 Campylobacter (all species), 129 Capnocytophaga (all species), 171 Chlamydia (pneumoniae), 130 Citrobacter (freundii, other species), 131 Clostridium (all species except difficile), 132 Clostridium difficile, 173 Corynebacterium jeikeium, 134 Enterobacter (all species), 135 Enterococcus (all species), 177 Enterococcus, vancomycin resistant (VRE), 136 Escherichia (also E. coli), 139 Fusobacterium (all species), 187 Haemophilus influenzae, 188 Haemophilus non-influenzae, 146 Klebsiella (all species), 147 Lactobacillus (bulgaricus, acidophilus, other species), 189 Legionella pneumophila, 190 | Examples added or typographical errors corrected for clarification |

| Information Collection Domain Sub-Type | Information Collection Domain Additional Sub Domain | Response required if Additional Sub Domain applies | Information Collection may be requested multiple times | Current Information Collection Data Element (if applicable) | Current Information Collection Data Element Response Option(s) | Information Collection update: | Proposed Information Collection Data Element (if applicable) | Proposed Information Collection Data Element Response Option(s) | Rationale for Information Collection Update |
|---|---|---|---|---|---|---|---|---|---|
| Hematopoietic Cellular Transplant (HCT) Product Infusion | Product Analysis | yes | yes | Specify Organism Code(s): | 121 inetobacter (all species), 125 Bordetella pertussis (whooping cough), 128 Campylobacter (all species), 129 Capnocytophaga (all species), 171 Chlamydia (pneumoniae), 130 Citrobacter (freundii, other species), 131 Clostridium (all species except difficile), 132 Clostridium difficile, 173 Corynebacterium jeikeium, 134 Enterobacter (all species), 135 Enterococcus (all species), 177 Enterococcus, vancomycin resistant (VRE), 136 Escherichia (also E. coli), 139 Fusobacterium (all species), 187 | Change/Clarification of Response Options | Specify Organism Code(s): | inetobacter (all species), 125 Bordetella pertussis (whooping cough), 128 Campylobacter (all species), 129 Capnocytophaga (all species), 171 Chlamydia (pneumoniae), 130 Citrobacter (freundii, other species), 131 Clostridium (all species except difficile), 132 Clostridium difficile, 173 Corynebacterium jeikeium, 134 Enterobacter (all species), 135 Enterococcus (all species), 177 Enterococcus, vancomycin resistant (VRE), 136 Escherichia (also E. coli), 139 Fusobacterium (all species), 187 Haemophilus influenzae, 188 Haemophilus non-influenzae, 146 Klebsiella (all species), 147 Lactobacillus (bulgaricus, acidophilus, other species), 189 Legionella pneumophila, 190 | Examples added or typographical errors corrected for clarification |
| Post-Transplant Essential Data | | no | yes | Specify the recipient's survival status at the date of last contact | Alive,Dead | Change/Clarification of Response Options | Specify the recipient's survival status at the date of last contact | Alive,Dead (Complete recipient death data) | Capture additional relevent disease information |
| Post-Transplant Essential Data | Subsequent Transplant | yes | yes | | | Addition of Information Requested | Was this infusion a donor lymphocyte infusion (DLI)? | no,yes | Capture additional relevent disease information |

| Information Collection Domain Sub-Type | Information Collection Domain Additional Sub Domain | Response required if Additional Sub Domain applies | Information Collection may be requested multiple times | Current Information Collection Data Element (if applicable) | Current Information Collection Data Element Response Option(s) | Information Collection update: | Proposed Information Collection Data Element (if applicable) | Proposed Information Collection Data Element Response Option(s) | Rationale for Information Collection Update |
|---|---|---|---|---|---|---|---|---|---|
| Post-Transplant Essential Data | Subsequent Transplant | yes | yes | | | Addition of Information Requested | Number of DLIs in this reporting period | — — | Capture additional relevent disease information |
| Post-Transplant Essential Data | Subsequent Transplant | yes | yes | | | Addition of Information Requested | Are any of the products, associated with this course of cellular therapy, genetically modified? | no, yes | Capture additional relevent disease information |
| Post-Transplant Essential Data | Graft vs. Host Disease | yes | yes | Date maximum overall grade of acute GVHD: | YYYY/MM/DD | Change/Clarification of Information Requested | First date maximum overall grade of acute GVHD: | YYYY/MM/DD | Capture data accurately |
| Post-Transplant Essential Data | Graft vs. Host Disease | yes | yes | Date estimated | checked | Deletion of Information: Merged to Check all that Apply | ~~Date estimated~~ | ~~checked~~ | Reduce burden: expanded response options to include responses previously reported manually or created a "check all that apply" |
| Post-Transplant Essential Data | | no | yes | Specify therapy (check all that apply) | Defibrotide,N-acetylcysteine,Other therapy,Tissue plasminogen activator (TPA),Ursodiol | Change/Clarification of Response Options | Specify therapy (check all that apply) | Defibrotide,N-acetylcysteine,Other therapy,Tissue plasminogen activator (TPA),Ursodiol, Enoxaparin (Lovenox), Heparin | Be consistent with current clinical landscape, improve transplant outcome data |
| Post-Transplant Essential Data | | no | yes | Did a new malignancy, myelodysplastic, myeloproliferative, or lymphoproliferative disease / disorder occur that is different from the disease / disorder for which the HCT or cellular therapy was performed? | No,Yes | Change/Clarification of Response Options | Did a new malignancy, myelodysplastic, myeloproliferative, or lymphoproliferative disease / disorder occur that is different from the disease / disorder for which the HCT or cellular therapy was performed? | No,Yes (Also complete Subsequent Neoplasms) , previosly reported | Capture additional relevent disease information |

| Information Collection Domain Sub-Type | Information Collection Domain Additional Sub Domain | Response required if Additional Sub Domain applies | Information Collection may be requested multiple times | Current Information Collection Data Element (if applicable) | Current Information Collection Data Element Response Option(s) | Information Collection update: | Proposed Information Collection Data Element (if applicable) | Proposed Information Collection Data Element Response Option(s) | Rationale for Information Collection Update |
|---|---|---|---|---|---|---|---|---|---|
| Post-Transplant Essential Data | Chimerism Study Performed | yes | yes | Date of birth: | YYYY/MM/DD | Change/Clarification of Information Requested | Donor Date of birth: | YYYY/MM/DD | Capture data accurately |
| Post-Transplant Essential Data | Chimerism Study Performed | yes | yes | Sex | female,male | Change/Clarification of Information Requested | Donor Sex | female,male | Capture data accurately |
| Post-Transplant Essential Data | Chimerism Study Performed | yes | yes | Method | Fluorescent in situ hybridization (FISH) for XX/XY,Karyotyping for XX/XY,Other,Restriction fragment-length polymorphisms (RFLP),VNTR or STR, micro or mini satellite | Change/Clarification of Response Options | Method | PCR(includes quantitative, real time, and fluorescent multiplex), Fluorescent in situ hybridization (FISH) for XX/XY,Karyotyping for XX/XY,Other,Restriction fragment-length polymorphisms (RFLP),VNTR or STR, micro or mini satellite | Examples added or typographical errors corrected for clarification |
| Post-Transplant Essential Data | Chimerism Study Performed | yes | yes | Were donor cells detected? | No,Yes | Deletion of Information Requested | ~~Were donor cells detected?~~ | ~~No,Yes~~ | Reduce redundancy in data capture |

| Information Collection Domain Sub-Type | Information Collection Domain Additional Sub Domain | Response required if Additional Sub Domain applies | Information Collection may be requested multiple times | Current Information Collection Data Element (if applicable) | Current Information Collection Data Element Response Option(s) | Information Collection update: | Proposed Information Collection Data Element (if applicable) | Proposed Information Collection Data Element Response Option(s) | Rationale for Information Collection Update |
|---|---|---|---|---|---|---|---|---|---|
| Post-HCT Therapy | | no | yes | Specify systemic therapy (check all that apply) | Alemtuzumab,Azacytidine,Blinatumomab,Bortezomib,Bosutinib,Carfilzomib,Chemotherapy,Dasatinib,Decitabine,Gemtuzumab,Gilteritinib,Ibrutinib,Imatinib mesylate,Ixazomib,Lenalidomide,Lestaurtinib,Midostaurin,Nilotinib,Nivolumab,Other systemic therapy,Pembrolizumab,Pomalidomide,Quizartinib,Rituximab,Sorafenib,Sunitinib,Thalidomide | Change/Clarification of Response Options | Specify systemic therapy (check all that apply) | Alemtuzumab,Azacytidine,Blinatumomab,Bortezomib,Bosutinib,Carfilzomib,~~Chemotherapy~~,Dasatinib,Decitabine,Gemtuzumab,Gilteritinib,Ibrutinib,Imatinib mesylate,Ixazomib,Lenalidomide,Lestaurtinib,Midostaurin,Nilotinib,Nivolumab,Other systemic therapy,Pembrolizumab,Pomalidomide,Quizartinib,Rituximab,Sorafenib,Sunitinib,Thalidomide, Brentuximab vendotin, Daratumumab (Darzalex) | Be consistent with current clinical landscape, improve transplant outcome data |
| Post-HCT Therapy | | no | yes | | | Addition of Information Requested | Did a fecal microbiota transplant (FMT) occur since the date of last report? | No, Yes | Be consistent with current clinical landscape, improve transplant outcome data |
| Post-HCT Therapy | | no | yes | | | Addition of Information Requested | Date of FMT | DD/MM/YY | Be consistent with current clinical landscape, improve transplant outcome data |
| Post-HCT Therapy | | no | yes | | | Addition of Information Requested | Specify the indication for the FMT | Graft versus host disease (GVHD), Clostridium difficle, Other | Be consistent with current clinical landscape, improve transplant outcome data |
| Post-HCT Therapy | | no | yes | | | Addition of Information Requested | Specify other indication: | open text | Be consistent with current clinical landscape, improve transplant outcome data |

| Information Collection Domain Sub-Type | Information Collection Domain Additional Sub Domain | Response required if Additional Sub Domain applies | Information Collection may be requested multiple times | Current Information Collection Data Element (if applicable) | Current Information Collection Data Element Response Option(s) | Information Collection update: | Proposed Information Collection Data Element (if applicable) | Proposed Information Collection Data Element Response Option(s) | Rationale for Information Collection Update |
|---|---|---|---|---|---|---|---|---|---|
| Relapse or Progression Post-HCT | | no | yes | Specify systemic therapy (check all that apply) | Alemtuzumab,Azacytidine,Blinatumomab,Bortezomib,Bosutinib,Carfilzomib,Chemotherapy,Dasatinib,Decitabine,Gemtuzumab,Gilteritinib,Ibrutinib,Imatinib mesylate,Ixazomib,Lenalidomide,Lestaurtinib,Midostaurin,Nilotinib,Nivolumab,Other systemic therapy,Pembrolizumab,Pomalidomide,Quizartinib,Rituximab,Sorafenib,Sunitinib,Thalidomide | Change/Clarification of Response Options | Specify systemic therapy (check all that apply) | Alemtuzumab,Azacytidine,Blinatumomab,Bortezomib,Bosutinib,Carfilzomib,Chemotherapy,Dasatinib,Decitabine,Gemtuzumab,Gilteritinib,Ibrutinib,Imatinib mesylate,Ixazomib,Lenalidomide,Lestaurtinib,Midostaurin,Nilotinib,Nivolumab,Other systemic therapy,Pembrolizumab,Pomalidomide,Quizartinib,Rituximab,Sorafenib,Sunitinib,Thalidomide, Daratumumb (Darzalex), Venetoclax | Be consistent with current clinical landscape, improve transplant outcome data |
| Current Disease Status | | no | yes | Date of most recent disease assessment | Known,Unknown | Deletion of Information Requested | ~~Date of most recent disease assessment~~ | ~~Known,Unknown~~ | Reduce redundancy in data capture |
| Current Disease Status | | no | yes | Date of most recent disease assessment: | YYYY/MM/DD | Change/Clarification of Information Requested | ~~Date of most recent disease assessment~~ Date of -assesment of current disease status | YYYY/MM/DD | Reduce redundancy in data capture |
| Recipient Death Data | Recipient Death | yes | no | | | Addition of Information Requested | Date of death: | YYYY/MM/DD | Reduce redundancy in data capture |
| Recipient Death Data | Recipient Death | yes | no | | | Addition of Information Requested | Date estimated | checked | Reduce redundancy in data capture |
| Recipient Death Data | Recipient Death | yes | no | | | Addition of Information Requested | Was cause of death confirmed by autopsy? | Autopsy pending,No,Unknown,Yes | Reduce redundancy in data capture |

| Information Collection Domain Sub-Type | Information Collection Domain Additional Sub Domain | Response required if Additional Sub Domain applies | Information Collection may be requested multiple times | Current Information Collection Data Element (if applicable) | Current Information Collection Data Element Response Option(s) | Information Collection update: | Proposed Information Collection Data Element (if applicable) | Proposed Information Collection Data Element Response Option(s) | Rationale for Information Collection Update |
|---|---|---|---|---|---|---|---|---|---|
| Recipient Death Data | Recipient Death | yes | no | | | Addition of Information Requested | Was documentation submitted to the CIBMTR? | No,Yes | Reduce redundancy in data capture |
| Recipient Death Data | Recipient Death | yes | no | Primary cause of death | death,Acute GVHD,Adult respiratory distress syndrome (ARDS) (other than IPS),Bacterial infection,Cardiac failure,Chronic GVHD,Central nervous system (CNS) failure,COVID-19 (SARS-CoV-2),Cytokine release syndrome,Diffuse alveolar damage (without hemorrhage), Disseminated intravascular coagulation (DIC),Fungal infection, Gastrointestinal (GI) failure (not liver),Graft rejection or failure, Thrombotic microangiopathy (TMA) (Thrombotic thrombocytopenic | Change/Clarification of Response Options | Primary cause of death | GVHD,Adult respiratory distress syndrome (ARDS) (other than IPS),Bacterial infection,Cardiac failure,Chronic GVHD,Central nervous system (CNS) failure,COVID-19 (SARS-CoV-2),Cytokine release syndrome,Diffuse alveolar damage (without hemorrhage),Diffuse alveolar hemorrhage (DAH),Disseminated intravascular coagulation (DIC),Fungal infection,Gastrointestinal hemorrhage,Gastrointestinal (GI) failure (not liver),Graft rejection or failure,Hemorrhagic cystitis,Thrombotic microangiopathy (TMA) (Thrombotic thrombocytopenic purpura (TTP)/Hemolytic Uremic Syndrome (HUS)),Idiopathic pneumonia syndrome (IPS),Intracranial | Be consistent with current clinical landscape, improve transplant outcome data |

| Information Collection Domain Sub-Type | Information Collection Domain Additional Sub Domain | Response required if Additional Sub Domain applies | Information Collection may be requested multiple times | Current Information Collection Data Element (if applicable) | Current Information Collection Data Element Response Option(s) | Information Collection update: | Proposed Information Collection Data Element (if applicable) | Proposed Information Collection Data Element Response Option(s) | Rationale for Information Collection Update |
|---|---|---|---|---|---|---|---|---|---|
| Recipient Death Data | Recipient Death | yes | no | Contributing cause of death | death,Acute GVHD,Adult respiratory distress syndrome (ARDS) (other than IPS),Bacterial infection,Cardiac failure,Chronic GVHD,Central nervous system (CNS) failure,COVID-19 (SARS-CoV-2),Cytokine release syndrome,Diffuse alveolar damage (without hemorrhage), Disseminated intravascular coagulation (DIC),Fungal infection, Gastrointestinal (GI) failure (not liver),Graft rejection or failure, Thrombotic microangiopathy (TMA) (Thrombotic thrombocytopenic | Change/Clarification of Response Options | Contributing cause of death | GVHD,Adult respiratory distress syndrome (ARDS) (other than IPS),Bacterial infection,Cardiac failure,Chronic GVHD,Central nervous system (CNS) failure,COVID-19 (SARS-CoV-2),Cytokine release syndrome,Diffuse alveolar damage (without hemorrhage),Diffuse alveolar hemorrhage (DAH),Disseminated intravascular coagulation (DIC),Fungal infection,Gastrointestinal hemorrhage,Gastrointestinal (GI) failure (not liver),Graft rejection or failure,Hemorrhagic cystitis,Thrombotic microangiopathy (TMA) (Thrombotic thrombocytopenic purpura (TTP)/Hemolytic Uremic Syndrome (HUS)),Idiopathic pneumonia syndrome (IPS),Intracranial | Be consistent with current clinical landscape, improve transplant outcome data |

| Information Collection Domain Sub-Type | Information Collection Domain Additional Sub Domain | Response required if Additional Sub Domain applies | Information Collection may be requested multiple times | Current Information Collection Data Element (if applicable) | Current Information Collection Data Element Response Option(s) | Information Collection update: | Proposed Information Collection Data Element (if applicable) | Proposed Information Collection Data Element Response Option(s) | Rationale for Information Collection Update |
|---|---|---|---|---|---|---|---|---|---|
| Subsequent Neoplasms | New Malignancy, Lymphoproliferative or Myeloproliferative Disease / Disorder | yes | yes | Specify the new malignancy | **Hematologic Malignancy:** Acute myeloid leukemia (AML / ANLL), Other leukemia, Myelodysplastic syndrome (MDS), Myeloproliferative neoplasm (MPN), Overlapping myelodysplasia / myeloproliferative neoplasm (MDS / MPN), Hodgkin lymphoma, Non-Hodgkin lymphoma, Clonal cytogenetic abnormality without leukemia or MDS, Uncontrolled proliferation of donor cells without malignant transformation **Solid Tumors:** Oropharyngeal cancer (e.g. tongue, mouth, throat), | Change/Clarification of Response Options | Specify the new malignancy | **Hematologic Malignancy:** Acute myeloid leukemia (AML / ANLL), Acute lymphoblastic leukemia (ALL), Other leukemia, Myelodysplastic syndrome (MDS), Myeloproliferative neoplasm (MPN), Overlapping myelodysplasia / myeloproliferative neoplasm (MDS / MPN), Hodgkin lymphoma, Non-Hodgkin lymphoma, Multiple myeloma / plasma cell neoplasms, Clonal cytogenetic abnormality without leukemia or MDS, Uncontrolled proliferation of donor cells without malignant transformation. **Solid Tumors:** Bone sarcoma (regardless of site), Soft tissue sarcoma (regardless of site), Oropharyngeal cancer (e.g. tongue, mouth, throat), Gastrointestinal malignancy (e.g. | Be consistent with current clinical landscape, improve transplant outcome data |
| Subsequent Neoplasms | New Malignancy, Lymphoproliferative or Myeloproliferative Disease / Disorder | yes | yes | | | Addition of Information Requested | Was post-transplant lymphoproliferative disorder (PTLD) diagnosed? | No,Yes | Be consistent with current clinical landscape, improve transplant outcome data |

| Information Collection Domain Sub-Type | Information Collection Domain Additional Sub Domain | Response required if Additional Sub Domain applies | Information Collection may be requested multiple times | Current Information Collection Data Element (if applicable) | Current Information Collection Data Element Response Option(s) | Information Collection update: | Proposed Information Collection Data Element (if applicable) | Proposed Information Collection Data Element Response Option(s) | Rationale for Information Collection Update |
|---|---|---|---|---|---|---|---|---|---|
| Subsequent Neoplasms | New Malignancy, Lymphoproliferative or Myeloproliferative Disease / Disorder | yes | yes | | | Addition of Information Requested | Specify type of PTLD | Monomorphic,Polymorphic, Unknown | Be consistent with current clinical landscape, improve transplant outcome data |
| Subsequent Neoplasms | New Malignancy, Lymphoproliferative or Myeloproliferative Disease / Disorder | yes | yes | | | Addition of Information Requested | Specify oropharyngeal cancer | Mouth,Throat,Tongue, Other oropharyngeal cancer | Be consistent with current clinical landscape, improve transplant outcome data |
| Subsequent Neoplasms | New Malignancy, Lymphoproliferative or Myeloproliferative Disease / Disorder | yes | yes | | | Addition of Information Requested | Specify gastrointestinal malignancy | Anus,Colon,Esophagus,Liver,Pancreas,Rectum,Small intestine (DUODENUM, JEJUNUM, ILEUM),Stomach, Other gastrointestinall cancer | Be consistent with current clinical landscape, improve transplant outcome data |
| Subsequent Neoplasms | New Malignancy, Lymphoproliferative or Myeloproliferative Disease / Disorder | yes | yes | | | Addition of Information Requested | Specify genitourinary malignancy | Bladder,Cervix,Kidney,Ovary,Prostate,Testicle,Uterus, Other genitourary malignancy | Be consistent with current clinical landscape, improve transplant outcome data |
| Subsequent Neoplasms | New Malignancy, Lymphoproliferative or Myeloproliferative Disease / Disorder | yes | yes | | | Addition of Information Requested | Specify CNS malignancy | Glioma,Meningioma,Other CNS malignancy | Be consistent with current clinical landscape, improve transplant outcome data |
| Subsequent Neoplasms | New Malignancy, Lymphoproliferative or Myeloproliferative Disease / Disorder | yes | yes | | | Addition of Information Requested | Was PTLD confirmed by biopsy? | No,Yes | Be consistent with current clinical landscape, improve transplant outcome data |

| Information Collection Domain Sub-Type | Information Collection Domain Additional Sub Domain | Response required if Additional Sub Domain applies | Information Collection may be requested multiple times | Current Information Collection Data Element (if applicable) | Current Information Collection Data Element Response Option(s) | Information Collection update: | Proposed Information Collection Data Element (if applicable) | Proposed Information Collection Data Element Response Option(s) | Rationale for Information Collection Update |
|---|---|---|---|---|---|---|---|---|---|
| Subsequent Neoplasms | New Malignancy, Lymphoproliferative or Myeloproliferative Disease / Disorder | yes | yes | | | Addition of Information Requested | Was documentation submitted to the CIBMTR? (e.g. pathology report) | No,Yes | Be consistent with current clinical landscape, improve transplant outcome data |
| Subsequent Neoplasms | New Malignancy, Lymphoproliferative or Myeloproliferative Disease / Disorder | yes | yes | | | Addition of Information Requested | Was there EBV reactivation in the blood? | No,Not Done,Yes | Be consistent with current clinical landscape, improve transplant outcome data |
| Subsequent Neoplasms | New Malignancy, Lymphoproliferative or Myeloproliferative Disease / Disorder | yes | yes | | | Addition of Information Requested | How was EBV reactivation diagnosed? | Other method,Qualitative PCR of blood,Quantitative PCR of blood | Be consistent with current clinical landscape, improve transplant outcome data |
| Subsequent Neoplasms | New Malignancy, Lymphoproliferative or Myeloproliferative Disease / Disorder | yes | yes | | | Addition of Information Requested | Specify other method: | open text | Be consistent with current clinical landscape, improve transplant outcome data |
| Subsequent Neoplasms | New Malignancy, Lymphoproliferative or Myeloproliferative Disease / Disorder | yes | yes | | | Addition of Information Requested | Quantitative EBV viral load of blood: At diagnosis | _____ copies/ml | Be consistent with current clinical landscape, improve transplant outcome data |
| Subsequent Neoplasms | New Malignancy, Lymphoproliferative or Myeloproliferative Disease / Disorder | yes | yes | | | Addition of Information Requested | Was a quantitative PCR of blood performed again after diagnosis? | No,Yes | Be consistent with current clinical landscape, improve transplant outcome data |

| Information Collection Domain Sub-Type | Information Collection Domain Additional Sub Domain | Response required if Additional Sub Domain applies | Information Collection may be requested multiple times | Current Information Collection Data Element (if applicable) | Current Information Collection Data Element Response Option(s) | Information Collection update: | Proposed Information Collection Data Element (if applicable) | Proposed Information Collection Data Element Response Option(s) | Rationale for Information Collection Update |
|---|---|---|---|---|---|---|---|---|---|
| Subsequent Neoplasms | New Malignancy, Lymphoproliferative or Myeloproliferative Disease / Disorder | yes | yes | | | Addition of Information Requested | Highest EBV viral load of blood: | _____copies/ml | Be consistent with current clinical landscape, improve transplant outcome data |
| Subsequent Neoplasms | New Malignancy, Lymphoproliferative or Myeloproliferative Disease / Disorder | yes | yes | | | Addition of Information Requested | Was there lymphomatous involvement? | No,Yes | Be consistent with current clinical landscape, improve transplant outcome data |
| Subsequent Neoplasms | New Malignancy, Lymphoproliferative or Myeloproliferative Disease / Disorder | yes | yes | | | Addition of Information Requested | Specify sites of PTLD involvement (check all that apply) | Bone marrow,Central nervous system (brain or cerebrospinal fluid),Liver,Lung,Lymph node(s),Other,Spleen | Be consistent with current clinical landscape, improve transplant outcome data |
| Subsequent Neoplasms | New Malignancy, Lymphoproliferative or Myeloproliferative Disease / Disorder | yes | yes | | | Addition of Information Requested | Specify other site: | open text | Be consistent with current clinical landscape, improve transplant outcome data |