Registration Forms for All Teams

CIBMTR® CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

Two Types of Forms

- **Pre-TED**
- **Post-TED**

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Pre-TED

- **Replaces Pre-Registration Form and part of the TED Form**
- **Deals with Conditioning Regimen, GVHD prophylaxis, and all things up to the date of transplant**

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What do I use the Pre-TED for?

- **Use to register all HSCTs for all patients**
- **Not used for DCIs (go ahead and cheer)**

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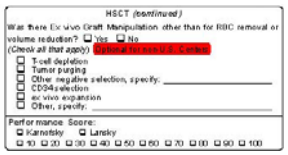
Pre-TED: Non-US Centers


HSCT *(continued)*

Was there Ex vivo Graft Manipulation other than for RBC removal or volume reduction? ☐ Yes ☐ No

(Check all that apply) Optional for non-U.S. Centers

- ☐ T-cell depletion
- ☐ Tumor purging
- ☐ Other negative selection, specify: _____
- ☐ CD34 selection
- ☐ ex vivo expansion
- ☐ Other, specify: _____

Performance Score:

☐ Karnofsky ☐ Lansky

☐ 10 ☐ 20 ☐ 30 ☐ 40 ☐ 50 ☐ 60 ☐ 70 ☐ 80 ☐ 90 ☐ 100

- **There are some items that are required for the SCTOD.**
- **Non-US Centers can submit this data if they wish.**

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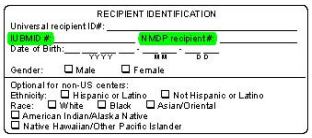
Pre-TED: Identification Numbers


RECIPIENT IDENTIFICATION

Universal recipient ID#: _____

IUBMID # _____ NMDP recipient# _____

Date of Birth: ____ (YYYY) - ____ (MM) - ____ (DD)

Gender: ☐ Male ☐ Female

Optional for non-US centers:

Ethnicity: ☐ Hispanic or Latino ☐ Not Hispanic or Latino

Race: ☐ White ☐ Black ☐ Asian/Oriental ☐ American Indian/Alaska Native ☐ Native Hawaiian/Other Pacific Islander

- **IUBMID # - the CIBMTR identification number**
- **NMDP recipient # - exactly what it says it is**
- **Universal recipient ID# - not sure what this is going to be exactly yet**

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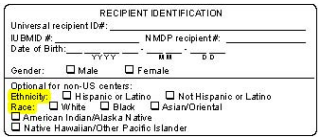
Pre-TED: Race and Ethnicity


RECIPIENT IDENTIFICATION

Universal recipient ID#: _____

IUBMID #: _____ NMDP recipient #: _____

Date of Birth: ____ ____ ____ - ____ - ____

YYYY MM DD

Gender: ☐ Male ☐ Female

Optional for non-US centers:

Ethnicity: ☐ Hispanic or Latino ☐ Not Hispanic or Latino

Race: ☐ White ☐ Black ☐ Asian/Oriental

☐ American Indian/Alaska Native

☐ Native Hawaiian/Other Pacific Islander

This now meets the U.S. government (OMB) classifications.

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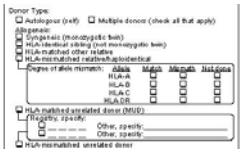
Pre-TED: Donor Type


Donor Type:

☐ Autologous (self) ☐ Multiple donors (check all that apply)

Allogeneic:

☐ Syngeneic (monozygotic twin)

☐ HLA-identical sibling (not monozygotic twin)

☐ HLA-matched other relative

☐ HLA-mismatched relative/haploidentical

Degree of allele mismatch: Allele Match Mismatch Not done

HLA-A

HLA-B

HLA-C

HLA-DR

☐ HLA-matched unrelated donor (MUD)

Registry, specify:

☐ ____ ____ ____ Other, specify: _____

☐ ____ ____ ____ Other, specify: _____

☐ HLA-mismatched unrelated donor

The HLA-mismatched section is a new setup.

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Pre-TED: Graft Manipulation


HSCT *(continued)*

Was there Ex vivo Graft Manipulation other than for RBC removal or volume reduction? ☐ Yes ☐ No

(Check *all that apply*) Optional for non-U.S. Centers

☐ T-cell depletion

☐ Tumor purging

☐ Other negative selection, specify: _____

☐ CD34 selection

☐ ex vivo expansion

☐ Other, specify: _____

Performance Score:

☐ Karnofsky ☐ Lansky

☐ 10 ☐ 20 ☐ 30 ☐ 40 ☐ 50 ☐ 60 ☐ 70 ☐ 80 ☐ 90 ☐ 100

Graft Manipulation is now required by the SCTOD for all US transplant centers.

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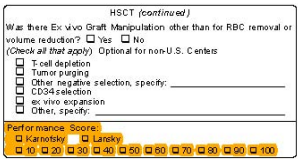
Pre-TED: Karnofsky and Lansky Scores


HSCT *(continued)*

Was there Ex vivo Graft Manipulation other than for RBC removal or volume reduction? ☐ Yes ☐ No

(Check all that apply) Optional for non-U.S. Centers

- ☐ T-cell depletion
- ☐ Tumor purging
- ☐ Other negative selection, specify: _____
- ☐ CD34 selection
- ☐ ex vivo expansion
- ☐ Other, specify: _____

Performance Score:

☐ Karnofsky ☐ Lansky

☐ 10 ☐ 20 ☐ 30 ☐ 40 ☐ 50 ☐ 60 ☐ 70 ☐ 80 ☐ 90 ☐ 100

Physicians will now need to document the precise Score in the medical record due to changes in auditing.

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Pre-TED: Preparative Regimen

- **"Total Drug Dose" means the overall total dose. Not dose per kilogram or daily dose.**
- **Doses must be in "mg". If your institution lists the doses differently, then you need to convert to "mg".**


PREPARATIVE REGIMEN

Was preparative regimen given? ☐ Yes ☐ No

(Check all that apply) Total Drug Dose RAD unit

- ☐ Total Body Irradiation (TBI) ____ ☐Gy ☐Gy
- ☐ Total Lymphoid/Nodal Radiation (TLI, TNI, TAI) ____ ☐Gy ☐Gy
- ☐ ALG, ALS, ATG, ATS ____ mg
- ☐ Anthracycline ____ mg
- ☐ Bleomycin ____ mg
- ☐ Busulfan ____ mg
  - ☐ Oral
  - ☐ IV
  - ☐ Both
- ☐ Carboplatin ____ mg
- ☐ Cisplatin ____ mg
- ☐ Corticosteroids ____ mg
- ☐ Cyclophosphamide ____ mg
- ☐ Cytarabine (Ara-C) ____ mg
- ☐ Etoposide (VP-16) ____ mg
- ☐ Fludarabine ____ mg
- ☐ Irinotecan ____ mg
- ☐ Inotuzumab ozogamicin ____ mg
- ☐ Melphalan (L-PAM) ____ mg
- ☐ Mitoxantrone ____ mg
- ☐ Monoclonal antibody (MAb) ____ mg
  - ☐ Campath ____ mg
  - ☐ Rituximab (Rituxan, anti-CD20) ____ mg
  - ☐ Ibritumomab (Mylotarg, anti-CD33) ____ mg
  - ☐ Other MAb ____ mg
  - specify: _____
- ☐ Nitrosoureas (BCNU, CCNU) ____ mg
- ☐ Paclitaxel (Taxol, Xyotax) ____ mg
- ☐ Radiolabeled MAb ____ unit ☐mCi ☐mBq
  - ☐ Tositumomab (Bexxar) ____ ____ ____
  - ☐ Ibritumomab (Zevalin) ____ ____ ____
  - ☐ Other mAb ____ ____ ____
  - specify: _____
- ☐ Teniposide (VM26) ____ mg
- ☐ Thiotepa ____ mg
- ☐ Other, specify: _____ ____ mg

The intent of the preparative regimen was *(allo only)*:

☐ Myeloablative ☐ NST ☐ RIC ☐ No prep regimen

Reason for NST/RIC *(check all that apply)*:

☐ Age of recipient

☐ Comorbid conditions

☐ Other, specify: _____

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Pre-TED: NST and RIC

The intent of the preparative regimen was *(allo only)*:

☐ Myeloablative ☐ NST ☐ RIC ☐ No prep regimen

Reason for NST/RIC (check all that apply):

☐ Age of recipient

☐ Comorbid conditions

☐ Other, specify: _____

- **Answer based on your institution's definition of NST and RIC.**
- **The "Reason for NST/RIC" is new.**

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Pre-TED: KGF and FGF Questions

OTHER TOXICITY MODIFYING REGIMEN

Was KGF (palifermin, Kepivance) started or is there a plan to use it?
☐ Yes ☐ No

Was FGF (velafermin) started or is there a plan to use it?
☐ Yes ☐ No ☐ Marked trial

- **These questions are present because of a long-term study that is being done with the CIBMTR.**
- **KGF and FGF sound similar, but are quite different. Please do not confuse them.**

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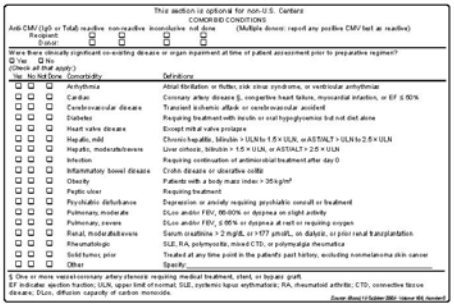
Pre-TED: Comorbid Conditions



This section is optional for non-U.S. Centers

COMORBID CONDITIONS

Anti-CMV (IgG or Total) reactive non-reactive inconclusive not done (Multiple donors: report any positive CMV test as reactive)
Recipient: ☐ ☐ ☐ ☐
Donor: ☐ ☐ ☐ ☐

Were there clinically significant co-existing disease or organ impairment at time of patient assessment prior to preparative regimen?
☐ Yes ☐ No
(Check all that apply):

Yes	No	Not Done	Comorbidity	Definitions
☐	☐	☐	Arrhythmia	Atrial fibrillation or flutter, sick sinus syndrome, or ventricular arrhythmias
☐	☐	☐	Cardiac	Coronary artery disease §, congestive heart failure, myocardial infarction, or EF ≤ 50%
☐	☐	☐	Cerebrovascular disease	Transient ischemic attack or cerebrovascular accident
☐	☐	☐	Diabetes	Requiring treatment with insulin or oral hypoglycemics but not diet alone
☐	☐	☐	Heart valve disease	Except mitral valve prolapse
☐	☐	☐	Hepatic, mild	Chronic hepatitis, bilirubin > ULN to 1.5 × ULN, or AST/ALT > ULN to 2.5 × ULN
☐	☐	☐	Hepatic, moderate/severe	Liver cirrhosis, bilirubin > 1.5 × ULN, or AST/ALT > 2.5 × ULN
☐	☐	☐	Infection	Requiring continuation of antimicrobial treatment after day 0
☐	☐	☐	Inflammatory bowel disease	Crohn disease or ulcerative colitis
☐	☐	☐	Obesity	Patients with a body mass index > 35 kg/m²
☐	☐	☐	Peptic ulcer	Requiring treatment
☐	☐	☐	Psychiatric disturbance	Depression or anxiety requiring psychiatric consult or treatment
☐	☐	☐	Pulmonary, moderate	DLco and/or FEV, 66-80% or dyspnea on slight activity
☐	☐	☐	Pulmonary, severe	DLco and/or FEV, ≤ 65% or dyspnea at rest or requiring oxygen
☐	☐	☐	Renal, moderate/severe	Serum creatinine > 2 mg/dL or > 177 µmol/L, on dialysis, or prior renal transplantation
☐	☐	☐	Rheumatologic	SLE, RA, polymyositis, mixed CTD, or polymyalgia rheumatica
☐	☐	☐	Solid tumor, prior	Treated at any time point in the patient's past history, excluding nonmelanoma skin cancer
☐	☐	☐	Other	Specify:

§ One or more vessel coronary artery stenosis requiring medical treatment, stent, or bypass graft.
EF indicates ejection fraction; ULN, upper limit of normal; SLE, systemic lupus erythematosis; RA, rheumatoid arthritis; CTD, connective tissue disease; DLco, diffusion capacity of carbon monoxide.

Please put only what is significant to the HSCT.

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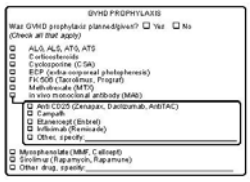
Pre-TED: GVHD Prophylaxis



GVHD PROPHYLAXIS

Was GVHD prophylaxis planned/given? ☐ Yes ☐ No
(Check all that apply)

☐ ALG, ALS, ATG, ATS
☐ Corticosteroids
☐ Cyclosporine (CSA)
☐ ECP (extra-corporeal photopheresis)
☐ FK 506 (Tacrolimus, Prograf)
☐ Methotrexate (MTX)
☐ In vivo monoclonal antibody (MAb)
  ☐ Anti CD25 (Zenapax, Daclizumab, AntiTAC)
  ☐ Campath
  ☐ Etanercept (Enbrel)
  ☐ Infliximab (Remicade)
  ☐ Other, specify:
☐ Mycophenolate (MMF, Cellcept)
☐ Sirolimus (Rapamycin, Rapamune)
☐ Other drug, specify:

This is almost exactly identical to the Day 100 Form.

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Pre-TED: Post-HSCT Therapy


POST-HSCT DISEASE THERAPY PLANNED AS OF DAY 0

Is the HSCT part of a planned multiple (sequential) graft/HSCT program? ☐ Yes ☐ No

Is additional post-HSCT therapy planned?

☐ Yes ☐ No

(Check all that apply) Optional for non-U.S. centers

- ☐ Anti CD 20 (Rituxan; Mabthera)
- ☐ Bortezomib (Velcade)
- ☐ Cellular therapy (e.g. DLI)
- ☐ Intrathecal Chemotherapy
- ☐ Imatinib mesylate (Gleevec, Glivec)
- ☐ Lenalidomide (Revlimid)
- ☐ Local radiotherapy
- ☐ Thalidomide
- ☐ Other, specify: _____

This refers to subsequent therapy that is documented as "planned" before the transplant even occurs.

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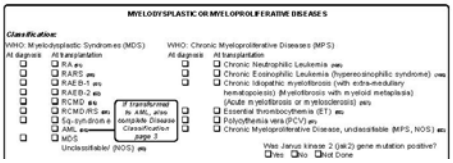
Pre-TED: New WHO Classifications


MYELODYSPLASTIC OR MYELOPROLIFERATIVE DISEASES

Classification:

WHO: Myelodysplastic Syndromes (MDS)

At diagnosis / At transplantation

- ☐ ☐ RA
- ☐ ☐ RARS
- ☐ ☐ RAEB-1
- ☐ ☐ RAEB-2
- ☐ ☐ RCMD
- ☐ ☐ RCMD-RS
- ☐ ☐ 5q- syndrome
- ☐ ☐ AML
- ☐ ☐ MDS Unclassifiable (NOS)

If transformed to AML, also complete Disease Classification page 3

WHO: Chronic Myeloproliferative Diseases (MPS)

At diagnosis / At transplantation

- ☐ ☐ Chronic Neutrophilic Leukemia
- ☐ ☐ Chronic Eosinophilic Leukemia (hypereosinophilic syndrome)
- ☐ ☐ Chronic Idiopathic myelofibrosis (with extra-medullary hematopoiesis) (Myelofibrosis with myeloid metaplasia) (Acute myelofibrosis or myelosclerosis)
- ☐ ☐ Essential thrombocythemia (ET)
- ☐ ☐ Polycythemia vera (PCV)
- ☐ ☐ Chronic Myeloproliferative Disease, unclassifiable (MPS, NOS)

Was Janus kinase 2 (jak2) gene mutation positive?

☐ Yes ☐ No ☐ Not Done

The WHO classifications will be used on these new forms.

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Fax a reply to team

- **Yes,** a Day 100 Report Form and Annual Follow-up Report Form is required

OR

- **No,** Post-TED is required at Day 100, 6 month, and annually. A Report Form is not required


REGISTRY USE ONLY

☐ Report Form due ☐ No Report Form due Date Received: _____

CIBMTR/EBMT/JFA CT/NMDP Transplant Essential Data Pre-TED (1/07v0) Page 1 of 10

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Form Submission Sequence

Modified TED (MTED)
Only due if you are unable to submit the Day 100 Report Form in a timely manner

↓

Day 100 Report Form

↓

TED-Follow-Up (TEDFU)
Only due if you are unable to submit the Follow-Up Report Form in a timely manner.

↓

Follow-Up Report Form

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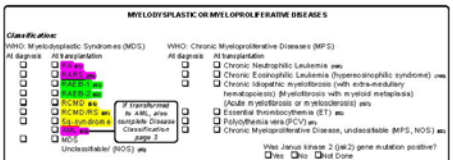
Pre-TED: New WHO Classifications



- **Purple – Same classification as before**
- **Green – This is a split in the old classification**
- **Yellow – New Classifications from WHO**

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Post-TED

- **Due at Day 100, 6 months, and annually**
- **Only 2 pages long**

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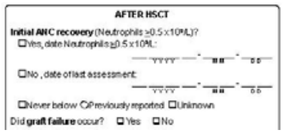
Post-TED: ANC Recovery



AFTER HSCT

Initial ANC recovery (Neutrophils ≥0.5 x 10⁹/L)?

☐ Yes, date Neutrophils ≥0.5 x 10⁹/L: ___ ___ ___ ___ - ___ ___ - ___ ___ (YYYY - MM - DD)

☐ No, date of last assessment: ___ ___ ___ ___ - ___ ___ - ___ ___ (YYYY - MM - DD)

☐ Never below ○ Previously reported ☐ Unknown

Did **graft failure** occur? ☐ Yes ☐ No

- ANC recovery does not equal Engraftment.
- Whether Engraftment occurs or not, we need to have the ANC recovery numbers.

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Post-TED: New Malignancy

Make sure this is a new disease and not recurrence or transformation of primary disease.

DID A NEW MALIGNANCY, LYMPHOPROLIFERATIVE OR MYELOPROLIFERATIVE DISORDER OCCUR?

Different from the disease for which HSCT performed (not recurrence or transformation).

☐ Yes ☐ No ☐ Unknown, If yes:

Date of diagnosis: ___ ___ ___ ___ - ___ ___ - ___ ___ (YYYY - MM - DD)

☐ Acute myeloid leukemia (AML/ANLL)
☐ Other leukemia (including ALL), specify: ______
☐ Breast cancer
☐ Central nervous system (CNS) malignancy (glioblastoma, astrocytoma)
☐ Clonal cytogenetic abnormality without leukemia or MDS
☐ Gastrointestinal malignancy (colon, rectum, stomach, pancreas, intestine)
☐ Genitourinary malignancy (kidney, bladder, ovary, testicle, genitalia, uterus, cervix)
☐ Hodgkin disease
☐ Lung cancer
☐ Lymphoma or lymphoproliferative disease
  Is the tumor EBV positive? ☐ Yes ☐ No ☐ Unknown
☐ Melanoma
☐ Other skin malignancy (basal cell, squamous)
☐ Myelodysplasia (MDS)/myeloproliferative (MPS) disorder
☐ Oropharyngeal cancer (tongue, buccal mucosa)
☐ Sarcoma
☐ Thyroid cancer
☐ Other malignancy, specify: ______

Copy of pathology report/documentation attached? ☐ Yes ☐ No

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Post-TED: Disease Response

New and easier way to fill out this section.

MALIGNANT DISEASE EVALUATION FOR THIS HSCT

(non-malignant disease skip disease evaluation)

Was a CR ever achieved in response to HSCT (including any therapy planned as of Day 0, not including any change in therapy in response to assessment)?

☐ Recipient already in CR at start of preparative regimen (N/Apl)
☐ Yes, post-HSCT CR achieved, date: ___ ___ ___ ___ - ___ ___ - ___ ___ (YYYY - MM - DD)
  ○ First CR date reported previously
☐ No, never in CR from HSCT

Did the patient ***first*** experience a relapse or progression as detected by any of the following methods during this period (complete all questions)?

Done	Not Done	Method	Relapse or Progression detected? Yes	No	
☐	☐	Molecular*	☐	☐	○ Detected Previous Period
		Date 1st detected: ___ ___ ___ ___ - ___ ___ - ___ ___			
☐	☐	Cytogenetic	☐	☐	○ Detected Previous Period
		Date 1st detected: ___ ___ ___ ___ - ___ ___ - ___ ___			
☐	☐	Clinical/Hematologic	☐	☐	○ Detected Previous Period
		Date 1st detected: ___ ___ ___ ___ - ___ ___ - ___ ___			

* In some circumstances, disease may be detected by molecular testing, but may not be considered a relapse or progression. It should still be reported.

Method of latest disease assessment (record most recent of each):

Done	Not Done	Method	Disease detected? Yes	No
☐	☐	Molecular	☐	☐
		Date latest assessed: ___ ___ ___ ___ - ___ ___ - ___ ___		
☐	☐	Cytogenetic	☐	☐
		Date latest assessed: ___ ___ ___ ___ - ___ ___ - ___ ___		
☐	☐	Clinical/Hematologic	☐	☐
		Date latest assessed: ___ ___ ___ ___ - ___ ___ - ___ ___		

Was any disease treatment initiated during this period? ☐ Yes ☐ No

If yes (check all that apply):

☐ Planned (given regardless of disease status/assessment post-HCT)
☐ Not planned (given for relapse, progression, or persistent disease)

Current disease status?

☐ CR ☐ Not CR
  ☐ Date determined: ___ ___ ___ ___ - ___ ___ - ___ ___ (YYYY - MM - DD)

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Post-TED: Capture of DCI Data


DONOR CELLULAR INFUSION (DCI)
For HSCT Anniversary answer since last report

Was **DCI** given? ☐No ☐Yes Total # in 28 days:_____

Date of **first** DCI: ____/____/____

Type of cell(s) (check all that apply):
☐Lymphocytes ☐Fibroblasts ☐Dendritic cells
☐Mesenchymal ☐Other, specify:_____

Indication: Chimerism:
☐Planned ☐Stable/Mixed
☐Treat disease ☐Loss/Worsened
☐Treat PTLD, EBV-lym ☐Other, specify:
☐Treat viral

Maximum Grade of Acute Graft Versus Host Disease
(GVHD): ☐0 ☐I ☐II ☐III ☐IV ☐Unknown

If another DCI was received in this reporting period, disease status before next DCI: ☐CR ☐Not in CR ☐Not assessed

Date of **second** DCI: ____/____/____

Total # in 28 days:_____

Type of cell(s) (check all that apply):
☐Lymphocytes ☐Fibroblasts ☐Dendritic cells
☐Mesenchymal ☐Other, specify:_____

Indication: Chimerism:
☐Planned ☐Stable/Mixed
☐Treat disease ☐Loss/Worsened
☐Treat PTLD, EBV-lym ☐Other, specify:
☐Treat viral

Maximum Grade of Acute Graft Versus Host Disease
(GVHD): ☐0 ☐I ☐II ☐III ☐IV ☐Unknown

If another DCI was received in this reporting period, disease status before next DCI: ☐CR ☐Not in CR ☐Not assessed

Up to three DCIs can be captured on one Post-TED form

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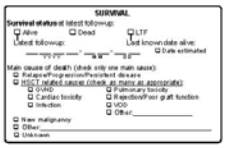
Post-TED: Cause of Death


SURVIVAL

Survival status at latest follow-up:
☐Alive ☐Dead ☐LTF
Latest follow-up: Last known date alive:
☐Date estimated

Main cause of death (check only one main cause):
☐Relapse/Progression/Persistent disease
☐HSCT related causes (check as many as appropriate)
☐GVHD ☐Pulmonary toxicity
☐Cardiac toxicity ☐Rejection/Poor graft function
☐Infection ☐VOD
☐Other:_____
☐New malignancy
☐Other:_____
☐Unknown

- **Only one (1) Primary Cause of Death can be chosen**
- **But as many contributing causes can be chosen as necessary**

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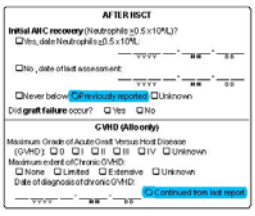
Post-TED: 1 Year Follow-up and Beyond


AFTER HSCT

Initial AHC recovery (Neutrophils ≥0.5 x10⁹/L)?
☐Yes, date Neutrophils ≥0.5 x10⁹/L:
☐No , date of last assessment:
☐Never below ☐Previously reported ☐Unknown
Did **graft failure** occur? ☐Yes ☐No

GVHD (All or only)
Maximum Grade of Acute Graft Versus Host Disease
(GVHD): ☐0 ☐I ☐II ☐III ☐IV ☐Unknown
Maximum extent of Chronic GVHD:
☐None ☐Limited ☐Extensive ☐Unknown
Date of diagnosis of chronic GVHD:
☐Continued from last report

A circle can only be filled in on or after the 1 year report.

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