OMB No: 0915-
Expiration Date:

Public Burden Statement

Public Burden Statement: An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this project is _____. Public reporting burden for this collection of information is estimated to average 0.85 hours per response when collected at 100 days post transplant, 1.0 hours per response when collected at 6 and 12 months post transplant, and 1.5 hours per response annually thereafter, including the time for reviewing instructions, searching existing data sources, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to HRSA Reports Clearance Officer, 5600 Fishers Lane, Room 10-33, Rockville, Maryland, 20857.

Post-Transplant Essential Data

Note: ">100 Days Report" answer *since last report*

❍ = symbol for answer that is only valid on >d100 evaluation.

CENTER IDENTIFICATION

CIBMTR Center # _____ EBMT Code (CIC) _____

Hospital:_____

Unit:_____

Contact person:_____

Phone #: _____

Fax #:_____

Email:_____

Date of this Report:___ ___ ___ ___ - ___ ___ - ___ ___
YYYY MM DD

❑ Day 100 ❑ 6 months ❑ Annual

Did the recipient receive a subsequent HSCT since the date of contact from the last report? ❑ Yes ❑ No

REGISTRY USE ONLY

Date Received:_____ DE:_____

RECIPIENT IDENTIFICATION

CIBMTR recipient ID#:_____

Date of Birth:___ ___ ___ ___ - ___ ___ - ___ ___
YYYY MM DD

Gender: ❑ Male ❑ Female

Disease:_____

HSCT

Donor Type: ❑ Allogeneic ❑ Autologous

Chronological # of this: HSCT#: ___ ___ DCI#: ___ ___

Date of HSCT for this follow-up:___ ___ ___ ___ - ___ ___ - ___ ___
YYYY MM DD

Yes	No	100 Day Report Only
❑	❑	Is 'Date of HSCT' same as date given on Pre-TED?
❑	❑	Was HSCT Infusion given? If ***No***,:
❑	❑	At least 1 dose of the prep regimen was given? If ***Yes***,:
❑	❑	Patient died during prep regimen?
❑	❑	This HSCT is cancelled?
❑	❑	This HSCT is postponed?

New estimated date: ___ ___ ___ ___ - ___ ___ - ___ ___
YYYY MM DD

INITIAL ANC RECOVERY

Was ≥0.5 x 10^9/L achieved for 3 consecutive labs?

❑Yes, first date of 3 labs: ___ ___ ___ ___ - ___ ___ - ___ ___
YYYY MM DD

❑No, last assessment: ___ ___ ___ ___ - ___ ___ - ___ ___
YYYY MM DD

❑Never below ❍Previously reported ❑Unknown

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

INITIAL PLATELET RECOVERY

(Optional for Non-U.S. Centers)

❑Yes, date Platelet >20 x 10^9/L:

___ ___ ___ ___ - ___ ___ - ___ ___
YYYY MM DD

❑No, last assessment: ___ ___ ___ ___ - ___ ___ - ___ ___
YYYY MM DD

❑Never below ❍Previously reported ❑Unknown

GRAFT VERSUS HOST DISEASE (Allo only)

Maximum Grade of Acute GVHD

❑ 0 ❑ I ❑ II ❑ III ❑ IV ❑ Present, grade unknown

Maximum extent of Chronic GVHD during this period:

❑ None ❑ Limited ❑ Extensive ❑ Unknown

Date of diagnosis of chronic GVHD:

___ ___ ___ ___ - ___ ___ - ___ ___ ❍ Continued from last report
YYYY MM DD

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*

SURVIVAL

Survival status at latest follow-up:

❑ Alive ❑ Dead ❑ Lost To Follow-Up (LTF)

Latest follow-up: Last known date alive:

___ ___ ___ ___ - ___ ___ - ___ ___ ❑ Day of the month is estimated
YYYY MM DD

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

POST-HSCT THERAPY *(Optional for Non-U.S. Centers)*

	Yes	Masked Trial	No	Unk
FGF (velafermin)?	❑	❑	❑	❑
Imatinib mesylate (Gleevec, Glivec)?	❑	❑	❑	❑
KGF (palifermin, Kepivance)?	❑	❑	❑	❑

HSCT FOR NON-MALIGNANT DISEASE ***ONLY***

DCI given in this period?

❑ Yes, ***also complete 'DCI' section on pg 2***
❑ No, ***send only pg 1***

All Abbreviations on Pre-TED, pg 2

Post-Transplant Essential Data

Note: ">100 Days Report" answer *since last report*
❍ = symbol for answer that is only valid on >d100 evaluation.

CIBMTR Center #: ☐☐☐☐☐ CIBMTR Recipient ID#: ☐☐☐☐☐☐☐☐☐ Report represents: ❑Day 100 ❑6 months ❑Annual

MALIGNANT DISEASE EVALUATION FOR THIS HSCT
(*non-malignant disease skip disease evaluation*)

WAS A CR EVER ACHIEVED IN REPONSE TO HSCT (including any therapy planned as of Day 0, excluding any change in therapy in response to disease 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, date assessed: ___ ___ ___ ___ - ___ ___ - ___ ___ (YYYY - MM - DD)
❑ Not evaluated

FIRST RELAPSE OR PROGRESSION AFTER HSCT
(in this period, *any type,* not persistent disease)

❑ Yes, answer all 3 methods. If used, give the date used and the results.
❑ No—(*skip to 'Additional Treatment' below)*

Relapse/progression detected by **molecular method:**
❑ Yes, Date first seen: ___ ___ ___ ___ - ___ ___ - ___ ___ (YYYY - MM - DD)
❑ No, Date of Assessment: ___ ___ ___ ___ - ___ ___ - ___ ___ (YYYY - MM - DD)
❍ Previously reported ❑ Not evaluated

Relapse/progression detected by **cytogenetic/FISH method:**
❑ Yes, Date first seen: ___ ___ ___ ___ - ___ ___ - ___ ___ (YYYY - MM - DD)
❑ No, Date of Assessment: ___ ___ ___ ___ - ___ ___ - ___ ___ (YYYY - MM - DD)
❍ Previously reported ❑ Not evaluated

Relapse/progression detected by **clinical/hematological method:**
❑ Yes, Date first seen: ___ ___ ___ ___ - ___ ___ - ___ ___ (YYYY - MM - DD)
❑ No, Date of Assessment: ___ ___ ___ ___ - ___ ___ - ___ ___ (YYYY - MM - DD)
❍ Previously reported ❑ Not evaluated

ADDITIONAL TREATMENT?

❑ Yes ❑ No—(*skip to 'Method' below)*

Yes No
❑ ❑ **DCI (allo only)**
(also complete 'DCI' section)

❑ ❑ **Planned** (given regardless of disease status/assessment post-HSCT)

❑ ❑ **Not planned** (given for relapse, progression, or persistent disease)

METHOD OF LATEST DISEASE ASSESSMENT
(record most recent of each)

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

Method	Disease detected? No	Yes	Not evaluated
Molecular*	❑	❑	❑

If yes, was the status considered a disease relapse or progression? ❑ Yes ❑ No
Date latest assessed: ___ ___ ___ ___ - ___ ___ - ___ ___ (YYYY - MM - DD)

Cytogenetic/FISH*	❑	❑	❑

If yes, was the status considered a disease relapse or progression? ❑ Yes ❑ No
Date latest assessed: ___ ___ ___ ___ - ___ ___ - ___ ___ (YYYY - MM - DD)

Clinical/Hematologic	❑	❑	❑

Date latest assessed: ___ ___ ___ ___ - ___ ___ - ___ ___ (YYYY - MM - DD)

If a previous HSCT was performed for a different disease than this HSCT, give status of original disease and date determined:
❑ CR ❑ Not in CR Date: ___ ___ ___ ___ - ___ ___ - ___ ___ (YYYY - MM - DD)

DONOR CELLULAR INFUSION (DCI)

Date of **first** DCI: ___ ___ ___ ___ - ___ ___ - ___ ___ (YYYY - MM - DD)
Total # DCI in 10 weeks_____
Type of cell(s) (check all that apply):
❑ Lymphocytes ❑ Fibroblasts ❑ Dendritic cells
❑ Mesenchymal ❑ Other, specify:_____

Indication:
❑ Planned
❑ Treat disease
❑ Treat PTLD, EBV-Lym
❑ Treat viral
❑ Treat GVHD
❑ Mixed Chimerism
❑ Loss/Decreased Chimerism
❑ Other, specify: _____

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: ___ ___ ___ ___ - ___ ___ - ___ ___ (YYYY - MM - DD)
Total # DCI in 10 weeks_____
Type of cell(s) (check all that apply):
❑ Lymphocytes ❑ Fibroblasts ❑ Dendritic cells
❑ Mesenchymal ❑ Other, specify:_____

Indication:
❑ Planned
❑ Treat disease
❑ Treat PTLD, EBV-Lym
❑ Treat viral
❑ Treat GVHD
❑ Mixed Chimerism
❑ Loss/Decreased Chimerism
❑ Other, specify: _____

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 **third** DCI: ___ ___ ___ ___ - ___ ___ - ___ ___ (YYYY - MM - DD)
Total # DCI in 10 weeks_____
Type of cell(s) (check all that apply):
❑ Lymphocytes ❑ Fibroblasts ❑ Dendritic cells
❑ Mesenchymal ❑ Other, specify:_____

Indication:
❑ Planned
❑ Treat disease
❑ Treat PTLD, EBV-Lym
❑ Treat viral
❑ Treat GVHD
❑ Mixed Chimerism
❑ Loss/Decreased Chimerism
❑ Other, specify: _____

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

Were there more than 3 instances of DCI infusions in this reporting period? ❑ Yes ❑ No
If yes, copy this page and continue numbering fourth, fifth, etc.