Error Correction Form

Sequence Number: CIBMTR Recipient ID: Initials:

Today's date: Month Day Year

Infusion Date: Month Day Year

CIBMTR Center Number5:

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 (circle)*: **A H O P** Other, specify: ________________

*Abbreviations, see Pre-TED, pg 2

Contact person: ______________________________________

Phone #: ____________________ Fax #: _________________

Email:____

Date of this Report:___ ___ ___ ___ - ___ ___ - ___ ___ (YYYY MM DD) ❑ Changed

❑Day 100 ❑6 months ❑Annual ❑FU visit (___ ___ yr post-HSCT)

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:

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

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:

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

Main **cause of death** (check only one main cause):

❑ Relapse/Progression/Persistent disease

❑ HSCT related causes (check as many as appropriate):

- ❑ GVHD
- ❑ Cardiac toxicity
- ❑ Infection
- ❑ Pulmonary toxicity
- ❑ Rejection/Poor graft function
- ❑ 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

CIBMTR CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH · EBMT · eurocord · fact · NATIONAL MARROW DONOR PROGRAM

Error Correction Form

Sequence Number: | CIBMTR Recipient ID: | Initials:

Today's date: Month Day Year | Infusion Date: Month Day Year | CIBMTR Center Number5:

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*	❑	❑	❑
Cytogenetic/FISH*	❑	❑	❑
Clinical/Hematologic	❑	❑	❑

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.