

CIC:

Hospital UPN:

Patient UIC

HSCT Date:
yyyy - mm - dd

HSCT - Minimum Essential Data - A

SECOND REPORT - 100 DAYS AFTER HSCT

Disease

PRIMARY DISEASE DIAGNOSIS.....

Centre Identification

EBMT Code (CIC):

Contact person:

Hospital: Unit:

Email:

Patient Data

Date of this report:
yyyy - mm - dd

Hospital Unique Patient Number/ Code:

(Compulsory, registrations will not be accepted without this item)

Initials: (first name(s) _family name(s))

Date of birth
yyyy - mm - dd

Sex Male Female
(at birth)

Date of the transplant:
yyyy - mm - dd

Recovery

Absolute neutrophil count (ANC) recovery (Neutrophils $\geq 0.5 \times 10^9/L$; first of 3 consecutive values after 7 days without any transfusion containing neutrophils)

No: Date of last assessment:
yyyy - mm - dd

Yes: Date of ANC recovery:
yyyy - mm - dd

Never below

Unknown

Platelet reconstitution (Platelets $\geq 20 \times 10^9/L$; first of 3 consecutive values after 7 days without transfusion)

No

Yes: Date Platelets $\geq 20 \times 10^9/l$
yyyy - mm - dd

Never below this level

Date unknown: patient discharged before levels reached

Date unknown: out-patient

Unknown

Early graft loss (Engraftment followed by loss of graft within the first 100 days)

No

Yes

Unknown

Acute GvHD (Allografts)

Acute Graft Versus Host Disease *(Allografts only)*

Maximum Grade:

- 0 (none)
 I
 II
 III
 IV
 Present but grade unknown
 Not evaluated

Date of onset

yyyy - mm - dd

Stage:

- | | | | | | |
|---------------------|-----------------------------------|------------------------------|----------------------------|----------------------------|----------------------------|
| Skin | <input type="checkbox"/> 0 (none) | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 |
| Liver | <input type="checkbox"/> 0 (none) | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 |
| Lower GI tract | <input type="checkbox"/> 0 (none) | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 |
| Upper GI tract | <input type="checkbox"/> 0 (none) | <input type="checkbox"/> 1 | | | |
| Other site affected | <input type="checkbox"/> No | <input type="checkbox"/> Yes | | | |

Additional Cell Infusions

Additional cell infusions *(excluding a new HSCT)*

 No Yes:
 Is this cell infusion an allogeneic boost? No Yes: - *Skip Cell therapy table below*
An allo boost is an infusion of cells from the same donor without conditioning, with no evidence of graft rejection.

 Is this cell infusion an autologous boost? No Yes: - *Skip Cell therapy table below*

 If the cell infusion is **not** a boost fill in the **Cell therapy** section below:

Cell therapy

 First date of the cell therapy infusion _____
yyyy - mm - dd

 Source of cell(s): Allo Auto

(check all that apply)

 Type of cell(s): *(check all that apply)*

- Lymphocyte (DLI)
 Mesenchymal
 Fibroblasts
 Dendritic cells
 NK cells
 Regulatory T-cells
 Gamma/delta cells
 Other, specify _____

Chronological number of the cell infusion episode for this patient _____

 Indication: *(check all that apply)*

- | | |
|---|--|
| <input type="checkbox"/> Planned/protocol | <input type="checkbox"/> Treatment for disease |
| <input type="checkbox"/> Prophylactic | <input type="checkbox"/> Mixed chimaerism |
| <input type="checkbox"/> Treatment of GvHD | <input type="checkbox"/> Treatment viral infection |
| <input type="checkbox"/> Loss/decreased chimaerism | |
| <input type="checkbox"/> Treatment PTLD, EBV lymphoma | |
| <input type="checkbox"/> Other, specify: _____ | |

 Number of infusions within 10 weeks _____

(count only infusions that are part of same regimen and given for the same indication)

Additional Disease Treatment

Additional disease treatment given *(excluding cell infusion)*

- No
- Yes: Reason for this additional treatment
- Prophylaxis / prevention *(planned before the transplant took place)*
- For relapse / progression or persistent disease *(not planned)*

Date started
yyyy - mm - dd

Chemo/drug

- No
- Yes:
- Imatinib mesylate (Gleevec, Glivec)
 - Dasatinib (Sprycel)
 - Nilotinib (Tasigna)
 - Bortezomib (Velcade)
 - Lenalidomide (Revlimid)
 - Rituximab (Rituxan, mabthera)
 - Velafermin (FGF)
 - Kepivance (KGF, palifermin)
 - Thalidomide
 - Eculizumab (Soliris)
 - Other drug/chemotherapy, specify Intrathecal: No Yes

Radiotherapy No Yes Unknown

Best response

Best disease status (response) after HSCT

(prior to any treatment modification in response to a post HSCT disease assessment)

This field is not mandatory for Inherited disorders

- Continued complete remission (CCR)
- CR achieved: Date achieved :
yyyy - mm - dd
- Never in CR: Date assessed:
yyyy - mm - dd
- Not evaluated

Last Contact Date for 100 day Assessment

If patient has died before this date, enter date of death, otherwise enter Date of HSCT + 100 DAYS APPROX.

Day 100 assessment :
yyyy - mm - dd

Date of death (if before day 100):
yyyy - mm - dd

Chronic GvHD at day 100 (Allografts)

Chronic Graft Versus Host Disease present between HSCT and 100 days or date of death

(allografts only)

- No *(never)*
- Yes: Date of diagnosis of cGvHD
yyyy - mm - dd

Maximum extent during this period

- Limited Extensive Unknown

Maximum NIH score during this period

- Mild Moderate Severe Not calculated

Disease Assessment at 100 days - Leukaemias

Was disease detected by cytogenetic/FISH method when the patient was last assessed before day 100 or date of death?

Fill in only for acute and chronic **leukaemias**

No Yes: Was the presence of the disease considered relapse/progression since HSCT? No Yes:

Last date assessed
yyyy - mm - dd

Not evaluated since HSCT was done

Was disease detected by molecular method when the patient was last assessed before day 100 or date of death?

Fill in only for acute and chronic **leukaemias**

No Yes: Was the presence of the disease considered relapse/progression since HSCT? No Yes:

Last date assessed
yyyy - mm - dd

Not evaluated since HSCT was done

Survival Status at 100 days – All diseases

Survival Status last contact date at 100 day assessment

Alive Dead

Main Cause of Death (check only one main cause)

- Relapse or Progression/Persistent disease
- Secondary malignancy
- HSCT Related Cause
- Unknown
- Other _____

Contributory Cause of Death (check as many as appropriate):

- GVHD
- Interstitial pneumonitis
- Pulmonary toxicity
- Infection:
 - bacterial
 - viral
 - Fungal
 - parasitic
 - Unknown
- Rejection/Poor graft function
- History of severe Veno occlusive disorder (VOD)
- Haemorrhage
- Cardiac toxicity
- Central nervous system (CNS) toxicity
- Gastrointestinal (GI) toxicity
- Skin toxicity
- Renal failure
- Multiple organ failure
- Other, specify