

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

## 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)*

- Planned/protocol     Treatment for disease  
 Prophylactic     Mixed chimaerism  
 Treatment of GvHD     Treatment viral infection  
 Loss/decreased chimaerism  
 Treatment PTLN, EBV lymphoma  
 Other, specify: \_\_\_\_\_

Number of infusions within 10 weeks \_\_\_\_\_

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

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### 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

## Relapse/Progression

### First Relapse or Progression after HSCT (detected by any method)

- No:
- Yes: Date first seen .....  
yyyy - mm - dd
- Continuous progression since HSCT

## Relapse of Leukaemias

If Yes or Continuous **and** diagnosis is acute or chronic leukaemia, fill in the section below:

### Method of detection of the first relapse or progression after HSCT

Fill in only for acute and chronic leukaemias

Relapse/progression detected by **clinical/haematological** method:

- No: Date assessed .....
- Yes: Date first seen .....  
yyyy - mm - dd
- Not evaluated

Relapse/progression detected by **cytogenetic** method:

- No: Date assessed .....
- Yes: Date first seen .....  
yyyy - mm - dd
- Not evaluated

Relapse/progression detected by **molecular** method:

- No: Date assessed .....
- Yes: Date first seen .....  
yyyy - mm - dd
- Not evaluated

## Disease assessment at 100 days (All diseases)

### Disease status when the patient was last seen before day 100 or date of death

(record the most recent status and date for each method, depending on the disease)

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

- No  Yes

Last date assessed .....  
yyyy - mm - dd

- Not evaluated since HSCT was done

## 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 chroni **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 .....