



EBMT Centre Identification Code (CIC): \_\_\_\_\_

Hospital Unique Patient Number (UPN): \_\_\_\_\_

Patient Number in EBMT Registry: \_\_\_\_\_

Treatment Type  CT

Treatment Date \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)

**CELLULAR THERAPIES**

--- Day 100, 6 Months, Annual &amp; Unscheduled Follow-Up ---

**SURVIVAL STATUS****Date of follow-up** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)

(if died: date of death, if lost to follow up: date last seen)

**Survival status:**

- Alive
- Dead
- Lost to follow-up

**Assessment period covered by this report:**

- Day 100
- 6 Months
- Annual or unscheduled follow-up

**Main cause of death:**

(check only one main cause)

<input type="checkbox"/> Relapse or progression/persistent disease	
<input type="checkbox"/> Secondary malignancy	
<input type="checkbox"/> CT-related	<b>Select treatment related cause:</b> (select all that apply) <input type="checkbox"/> Graft versus Host Disease <input type="checkbox"/> Non-infectious complication <input type="checkbox"/> Infectious complication: (select all that apply) <input type="checkbox"/> Bacterial infection <input type="checkbox"/> Viral infection <input type="checkbox"/> Fungal infection <input type="checkbox"/> Parasitic infection <input type="checkbox"/> Infection with unknown pathogen <input type="checkbox"/> Other treatment related cause of death; specify: _____
<input type="checkbox"/> HCT-related	
<input type="checkbox"/> GT-related	
<input type="checkbox"/> IST-related	
<input type="checkbox"/> Unknown	
<input type="checkbox"/> Other cause of death; specify: _____	

**BEST RESPONSE**

Complete only for Day 100, 6 Months and first annual Follow-Up.  
 Not applicable for Inborn Errors

**Best clinical/biological response after this CT\*** (observed before any subsequent treatment): \_\_\_\_\_**Date best response first observed:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown

\* Indicate the best clinical/biological response after CT corresponding to indication diagnosis for CT was given by selecting from the list provided in Appendix 1



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## RECOVERY

Complete only for Day 100 Follow-Up and 6 Months Follow-up.

If the recovery occurred before 100 days and was reported at Day 100 Follow-up the section can be skipped at 6 Months Follow-up.

**Absolute neutrophil count (ANC) recovery** (*neutrophils  $\geq 0.5 \times 10^9/L$* ):

- No: **Date of the last assessment:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)
- Yes: **Date of ANC recovery:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  
*(first of 3 consecutive values after 7 days without transfusion containing neutrophils)*
- Never below
- Not evaluated
- Unknown

**Did the patient receive granulocyte colony-stimulating factor (G-CSF) or pegulated G-CSF during this follow-up period?**

- No
- Yes: **Start date:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)     Unknown  
**Stop date:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)     Therapy ongoing     Unknown
- Unknown

**Platelet reconstitution** (*platelets  $\geq 20 \times 10^9/L$* ):

- No: **Date of the last assessment:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)     Unknown
- Yes: **Date of platelet reconstitution:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)     Unknown  
*(first of 3 consecutive values after 7 days without platelet transfusion)*
- Never below
- Not evaluated
- Unknown

**Date of the last platelet transfusion:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)     Not applicable (not transfused)     Unknown

**Was B-cell count monitored during this follow-up period ?**

- No
- Yes: **Please provide the absolute total immune cell count:** \_\_\_\_\_   $10^9/L$       $10^6/L$  (cells/ $\mu L$ )  
**Please provide the absolute B-cell count:** \_\_\_\_\_   $10^9/L$       $10^6/L$  (cells/ $\mu L$ )  
**Date of immune cell assessment:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)
- Unknown



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### CURRENT HAEMATOLOGICAL FINDINGS

Hb ( g/dL)	_____	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> Unknown
Platelets (10 <sup>9</sup> /L)	_____	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> Unknown
Were platelets transfused within 7 days before assessment?		<input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> Unknown
White blood cells (10 <sup>9</sup> /L)	_____	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> Unknown
Lymphocytes	_____ % <b>OR</b> Absolute count: _____ 10 <sup>9</sup> /L	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> Unknown
Neutrophils	_____ % <b>OR</b> Absolute count: _____ 10 <sup>9</sup> /L	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> Unknown

### Preventive therapies

**Were any immunoglobulins administered during this follow-up period?**

- No
- Yes: **Start date:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown
- Stop date:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Ongoing  Unknown



EBMT Centre Identification Code (CIC): \_\_\_\_\_

Treatment Type  CT

Hospital Unique Patient Number (UPN): \_\_\_\_\_

Patient Number in EBMT Registry: \_\_\_\_\_

Treatment Date \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)

**COMPLICATIONS SINCE THE LAST REPORT**

-- GvHD --

Do not report complications that were resolved before this cellular therapy.

Do not report complications that were previously reported as resolved, unless they recurred.

**Did graft versus host disease (GvHD) occur during this follow-up period?** No (proceed to 'Complications since the last report - Non-infectious complications') Yes: **Did the patient receive a systemic/immunosuppressive treatment for GvHD during this follow-up period?** No Yes:  Started in this follow-up period; **Date treatment started:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown Ongoing since previous follow-up**Treatment stopped:**  No Yes; **Stop date of treatment:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown Unknown Unknown Unknown (proceed to 'Complications since the last report - Non-infectious complications')**Did acute GvHD occur during this follow-up period?** No Yes:  Started in this follow-up period; **Date of onset:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown Ongoing since previous follow-up**Maximum observed organ severity score during this period:**

Skin:	<input type="checkbox"/> 0 (none)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> Unknown
Liver:	<input type="checkbox"/> 0 (none)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> Unknown
Lower GI tract:	<input type="checkbox"/> 0 (none)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> Unknown
Upper GI tract:	<input type="checkbox"/> 0 (none)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> Unknown
Other site affected:	<input type="checkbox"/> No		<input type="checkbox"/> Yes; specify: _____				

**Overall maximum grade observed during this period:**  1  2  3  4  Not evaluated  Unknown**Steroid-refractory acute GvHD:**  No Yes:  Started in this follow-up period;**Date of onset:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD) Unknown Ongoing since previous follow-up Unknown Unknown

**COMPLICATIONS SINCE THE LAST REPORT continued**

-- GvHD --

**Did chronic GvHD occur during this follow-up period?**

- No
- Yes:  Started in this follow-up period; **Date of onset:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown  
 Ongoing since previous follow-up

- Maximum NIH score during this period:**  Mild  
 Moderate  
 Severe  
 Unknown  
 Not evaluated

**Date of maximum NIH score:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown

**Maximum observed organ severity score during this period:**

Skin:	<input type="checkbox"/> 0 (none)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> Unknown
Oral:	<input type="checkbox"/> 0 (none)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> Unknown
Gastrointestinal:	<input type="checkbox"/> 0 (none)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> Unknown
Eyes:	<input type="checkbox"/> 0 (none)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> Unknown
Liver:	<input type="checkbox"/> 0 (none)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> Unknown
Joints and fascia:	<input type="checkbox"/> 0 (none)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> Unknown
Lungs:	<input type="checkbox"/> 0 (none)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> Unknown
Genitalia:	<input type="checkbox"/> 0 (none)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> Unknown
Other site affected:	<input type="checkbox"/> No <input type="checkbox"/> Yes; specify: _____						

- Steroid-refractory chronic GvHD:**  No  
 Yes:  Started in this follow-up period; **Date of onset:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown  
 Ongoing since previous follow-up  
 Unknown

**Was overlap syndrome observed:**  No  Yes  Unknown  
 (features of both chronic and acute GvHD)

Unknown



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**COMPLICATIONS SINCE THE LAST REPORT**

-- Non-infectious complications --

Do not report complications that were resolved before this cellular therapy.  
 Do not report complications that were previously reported as resolved, unless they recurred.

**Did non-infectious complications occur or continue during this follow-up period?**

- No (proceed to 'Complications since the last report - Infectious complications')
- Yes (report in the table below)
- Unknown

**Cytokine release syndrome (CRS)**

- Complication observed during this follow-up period?**  No  
 Yes:  Newly developed  Ongoing since previous assessment  
 Unknown

**Maximum grade observed during this period:**  1  2  3  4  5 (fatal)  Unknown

- Grading system:**
- ASTCT consensus (Lee 2019)
  - Penn
  - CTCAE
  - Lee 2014
  - MDACC
  - Other; specify: \_\_\_\_\_

**Onset date (YYYY/MM/DD):** \_\_\_\_/\_\_\_\_/\_\_\_\_  Unknown *Only if newly developed*

- Was the CRS treated?**  No  
 Yes; specify treatment \_\_\_\_\_  
 Unknown

**Resolved:**  No  
 Yes; **Stop date (YYYY/MM/DD):** \_\_\_\_/\_\_\_\_/\_\_\_\_  Unknown  
 Unknown

**IEC-associated neurotoxicity syndrome (ICANS)**

- Complication observed during this follow-up period?**  No  
 Yes:  Newly developed  Ongoing since previous assessment  
 Unknown

**Maximum grade observed during this period:**  1  2  3  4  5 (fatal)  Unknown

- Grading system:**
- ASTCT consensus (Lee 2019)
  - CTCAE
  - Lee 2014
  - MDACC
  - Other; specify: \_\_\_\_\_

**Onset date (YYYY/MM/DD):** \_\_\_\_/\_\_\_\_/\_\_\_\_  Unknown *Only if newly developed*

- Was the ICANS treated?**  No  
 Yes; specify treatment \_\_\_\_\_  
 Unknown

**Resolved:**  No  
 Yes; **Stop date (YYYY/MM/DD):** \_\_\_\_/\_\_\_\_/\_\_\_\_  Unknown  
 Unknown

### COMPLICATIONS SINCE THE LAST REPORT

-- Non-infectious complications --

**Other neurotoxicity observed during this follow-up period?**  No\*  
 Yes:  Newly developed  Ongoing since previous assessment  
 Unknown

**Specify:** \_\_\_\_\_

**Maximum CTCAE grade observed during this period:**  3  4  5 (fatal)  Unknown

**Onset date (YYYY/MM/DD):** \_\_\_\_/\_\_\_\_/\_\_\_\_  Unknown *Only if newly developed*

**Resolved:**  No  
 Yes; **Stop date (YYYY/MM/DD):** \_\_\_\_/\_\_\_\_/\_\_\_\_  Unknown  
 Unknown

**Macrophage activation syndrome (MAS)**

**Complication observed during this follow-up period?**  No\*  
 Yes:  Newly developed  Ongoing since previous assessment  
 Unknown

**Maximum CTCAE grade observed during this period:**  3  4  5 (fatal)  Unknown

**Onset date (YYYY/MM/DD):** \_\_\_\_/\_\_\_\_/\_\_\_\_  Unknown *Only if newly developed*

**Resolved:**  No  
 Yes; **Stop date (YYYY/MM/DD):** \_\_\_\_/\_\_\_\_/\_\_\_\_  Unknown  
 Unknown

**Secondary haemophagocytic lymphohistiocytosis**

**Complication observed during this follow-up period?**  No  
 Yes:  Newly developed  Ongoing since previous assessment  
 Unknown

**Maximum CTCAE grade observed during this period:**  3  4  5 (fatal)  Unknown

**Onset date (YYYY/MM/DD):** \_\_\_\_/\_\_\_\_/\_\_\_\_  Unknown *Only if newly developed*

**Resolved:**  No  
 Yes; **Stop date (YYYY/MM/DD):** \_\_\_\_/\_\_\_\_/\_\_\_\_  Unknown  
 Unknown

**Organ toxicity: skin**

**Complication observed during this follow-up period?**  No  
 Yes:  Newly developed  Ongoing since previous assessment  
 Unknown

**Maximum CTCAE grade observed during this period:**  3  4  5 (fatal)  Unknown

**Onset date (YYYY/MM/DD):** \_\_\_\_/\_\_\_\_/\_\_\_\_  Unknown *Only if newly developed*

**Resolved:**  No  
 Yes; **Stop date (YYYY/MM/DD):** \_\_\_\_/\_\_\_\_/\_\_\_\_  Unknown  
 Unknown

\*Grade 0-2



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**COMPLICATIONS SINCE THE LAST REPORT**  
 -- Non-infectious complications --

**Organ toxicity: liver**

**Complication observed during this follow-up period?**  No\*  
 Yes:  Newly developed  Ongoing since previous assessment  
 Unknown

**Maximum CTCAE grade observed during this period:**  3  4  5 (fatal)  Unknown

**Onset date (YYYY/MM/DD):** \_\_\_\_/\_\_\_\_/\_\_\_\_  Unknown *Only if newly developed*

**Resolved:**  No  
 Yes; **Stop date (YYYY/MM/DD):** \_\_\_\_/\_\_\_\_/\_\_\_\_  Unknown  
 Unknown

**Organ toxicity: lung**

**Complication observed during this follow-up period?**  No\*  
 Yes:  Newly developed  Ongoing since previous assessment  
 Unknown

**Maximum CTCAE grade observed during this period:**  3  4  5 (fatal)  Unknown

**Onset date (YYYY/MM/DD):** \_\_\_\_/\_\_\_\_/\_\_\_\_  Unknown *Only if newly developed*

**Resolved:**  No  
 Yes; **Stop date (YYYY/MM/DD):** \_\_\_\_/\_\_\_\_/\_\_\_\_  Unknown  
 Unknown

**Organ toxicity: heart**

**Complication observed during this follow-up period?**  No\*  
 Yes:  Newly developed  Ongoing since previous assessment  
 Unknown

**Maximum CTCAE grade observed during this period:**  3  4  5 (fatal)  Unknown

**Onset date (YYYY/MM/DD):** \_\_\_\_/\_\_\_\_/\_\_\_\_  Unknown *Only if newly developed*

**Resolved:**  No  
 Yes; **Stop date (YYYY/MM/DD):** \_\_\_\_/\_\_\_\_/\_\_\_\_  Unknown  
 Unknown

**Organ toxicity: kidney**

**Complication observed during this follow-up period?**  No\*  
 Yes:  Newly developed  Ongoing since previous assessment  
 Unknown

**Maximum CTCAE grade observed during this period:**  3  4  5 (fatal)  Unknown

**Onset date (YYYY/MM/DD):** \_\_\_\_/\_\_\_\_/\_\_\_\_  Unknown *Only if newly developed*

**Resolved:**  No  
 Yes; **Stop date (YYYY/MM/DD):** \_\_\_\_/\_\_\_\_/\_\_\_\_  Unknown  
 Unknown

\* Grade 0-2

### COMPLICATIONS SINCE THE LAST REPORT

-- Non-infectious complications --

#### Organ toxicity: gastrointestinal

**Complication observed during this follow-up period?**  No\*  
 Yes:  Newly developed  Ongoing since previous assessment  
 Unknown

**Maximum CTCAE grade observed during this period:**  3  4  5 (fatal)  Unknown

**Onset date (YYYY/MM/DD):** \_\_\_\_/\_\_\_\_/\_\_\_\_  Unknown *Only if newly developed*

**Resolved:**  No  
 Yes; **Stop date (YYYY/MM/DD):** \_\_\_\_/\_\_\_\_/\_\_\_\_  Unknown  
 Unknown

**Other organ toxicity observed during this follow-up period?**  No\*  
 Yes:  Newly developed  Ongoing since previous assessment  
 Unknown

**Organ specify:** \_\_\_\_\_

**Maximum CTCAE grade observed during this period:**  3  4  5 (fatal)  Unknown

**Onset date (YYYY/MM/DD):** \_\_\_\_/\_\_\_\_/\_\_\_\_  Unknown *Only if newly developed*

**Resolved:**  No  
 Yes; **Stop date (YYYY/MM/DD):** \_\_\_\_/\_\_\_\_/\_\_\_\_  Unknown  
 Unknown

#### Tumour lysis syndrome

**Complication observed during this follow-up period?**  No\*  
 Yes:  Newly developed  Ongoing since previous assessment  
 Unknown

**Maximum CTCAE grade observed during this period:**  3  4  5 (fatal)  Unknown

**Onset date (YYYY/MM/DD):** \_\_\_\_/\_\_\_\_/\_\_\_\_  Unknown *Only if newly developed*

**Resolved:**  No  
 Yes; **Stop date (YYYY/MM/DD):** \_\_\_\_/\_\_\_\_/\_\_\_\_  Unknown  
 Unknown

#### B-cell aplasia

**Complication observed during this follow-up period?**  No  
 Yes:  Newly developed  Ongoing since previous assessment  
 Unknown

**% B-cells:** \_\_\_\_\_  Not evaluated

**Onset date (YYYY/MM/DD):** \_\_\_\_/\_\_\_\_/\_\_\_\_  Unknown *Only if newly developed*

**Resolved:**  No  
 Yes; **Stop date (YYYY/MM/DD):** \_\_\_\_/\_\_\_\_/\_\_\_\_  Unknown  
 Unknown

\* Grade 0-2

### COMPLICATIONS SINCE THE LAST REPORT

-- Non-infectious complications --

#### Bone marrow aplasia

Complication observed during this follow-up period?  No  
 Yes:  Newly developed  Ongoing since previous assessment  
 Unknown

Onset date (YYYY/MM/DD): \_\_\_\_/\_\_\_\_/\_\_\_\_  Unknown *Only if newly developed*

Resolved:  No  
 Yes; Stop date (YYYY/MM/DD): \_\_\_\_/\_\_\_\_/\_\_\_\_  Unknown  
 Unknown

#### Hypogammaglobulinemia

Complication observed during this follow-up period?  No\*  
 Yes:  Newly developed  Ongoing since previous assessment  
 Unknown

Was it also present at time of the cellular therapy?  No, occurred after the cellular therapy  
 Yes: Was it worsened by the cellular therapy?  No  Yes

Onset date (YYYY/MM/DD): \_\_\_\_/\_\_\_\_/\_\_\_\_  Unknown *Only if newly developed*

Resolved:  No  
 Yes; Stop date (YYYY/MM/DD): \_\_\_\_/\_\_\_\_/\_\_\_\_  Unknown  
 Unknown

Exacerbation of existing neurological disorder observed during this follow-up period?  No\*  
 Yes:  Newly developed  Ongoing since previous assessment  
 Unknown

Specify: \_\_\_\_\_  
 (Indicate CTCAE term)

Maximum CTCAE grade observed during this period:  3  4  5 (fatal)  Unknown

Onset date (YYYY/MM/DD): \_\_\_\_/\_\_\_\_/\_\_\_\_  Unknown *Only if newly developed*

Resolved:  No  
 Yes; Stop date (YYYY/MM/DD): \_\_\_\_/\_\_\_\_/\_\_\_\_  Unknown  
 Unknown

Other complication observed during this follow-up period?  No\*  
 Yes:  Newly developed  Ongoing since previous assessment  
 Unknown

Specify: \_\_\_\_\_ *Consult appendix 4 for a list of complications that should not be reported*  
 (Indicate CTCAE term)

Maximum CTCAE grade observed during this period:  3  4  5 (fatal)  Unknown

Onset date (YYYY/MM/DD): \_\_\_\_/\_\_\_\_/\_\_\_\_  Unknown *Only if newly developed*

Resolved:  No  
 Yes; Stop date (YYYY/MM/DD): \_\_\_\_/\_\_\_\_/\_\_\_\_  Unknown  
 Unknown

\*Grade 0-2

*If more other complications occurred, copy and fill-in this table as many times as necessary.*

## COMPLICATIONS SINCE THE LAST REPORT

### -- Infectious complications --

Do not report infections that were already reported as resolved on the previous assessment and did not reoccur.

**Did infectious complications occur during the follow-up period?**

- No *Consult appendix 4 for a list of complications that should not be reported*  
 Yes *(report all infection-related complications below)*  
 Unknown

**Bacterial infection:**  No  Yes  Unknown

1) **New or ongoing:**  Newly developed  Ongoing since previous assessment

**Start date:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD) *only if newly developed*  Unknown

Gram-positive  Gram-negative  Other

**Pathogen\*:** \_\_\_\_\_

**Infection with clinical implications:**  No

Yes: *(select all that apply during this period)*

Symptoms/signs of disease

Administration of pathogen-directed therapy

Unknown

*Indicate at least 1 location involved during this period:*

**Localisation 1 (CTCAE term)\*\*:** \_\_\_\_\_

**Localisation 2 (CTCAE term)\*\*:** \_\_\_\_\_

**Localisation 3 (CTCAE term)\*\*:** \_\_\_\_\_

*(if patient died)*

**Contributory cause of death:**  No  Yes  Unknown

*If more than 1 bacterial infections, copy and fill-in this table as many times as necessary.*

\* Indicate the pathogen and sub-type (if applicable) by choosing from the list of pathogens provided in Appendix 2

\*\* Indicate CTCAE term by choosing from the list provided in Appendix 3

### COMPLICATIONS SINCE THE LAST REPORT

-- Infectious complications -- continued

**Viral infection:**     No         Yes         Unknown

1) **New or ongoing:**  Newly developed     Ongoing since previous assessment

**Start date:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)    *only if newly developed*     Unknown

**Pathogen\*:** \_\_\_\_\_

**Infection with clinical implications:**  No

Yes\*\*\*: (select all that apply during this period)

Symptoms/signs of disease

Administration of pathogen-directed therapy (including pre-emptive therapy)

Unknown

*Indicate at least 1 location involved during this period:*

**Localisation 1 (CTCAE term)\*\*:** \_\_\_\_\_

**Localisation 2 (CTCAE term)\*\*:** \_\_\_\_\_

**Localisation 3 (CTCAE term)\*\*:** \_\_\_\_\_

*(if patient died)*

**Contributory cause of death:**     No         Yes         Unknown

*If more than 1 viral infections, copy and fill-in this table as many times as necessary.*

\* Indicate the pathogen and sub-type (if applicable) by choosing from the list of pathogens provided in Appendix 2

\*\* Indicate CTCAE term by choosing from the list provided in Appendix 3

\*\*\* Also answer 'Yes' in case of pre-emptive therapy

### COMPLICATIONS SINCE THE LAST REPORT

-- Infectious complications -- continued

**Invasive fungal infection:**    No       Yes       Unknown

1) **New or ongoing:**    Newly developed    Ongoing since previous assessment

**Start date:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)   *only if newly developed*    Unknown

Yeasts               Moulds

**Pathogen\*:** \_\_\_\_\_

**Infection with clinical implications:**    No

Yes: *(select all that apply during this period)*

Symptoms/signs of disease

Administration of pathogen-directed therapy

Unknown

*Indicate at least 1 location involved during this period:*

**Localisation 1 (CTCAE term)\*\*:** \_\_\_\_\_

**Localisation 2 (CTCAE term)\*\*:** \_\_\_\_\_

**Localisation 3 (CTCAE term)\*\*:** \_\_\_\_\_

*(if patient died)*

**Contributory cause of death:**    No       Yes       Unknown

*If more than 1 fungal infections, copy and fill-in this table as many times as necessary.*

\* Indicate the pathogen and sub-type (if applicable) by choosing from the list of pathogens provided in Appendix 2

\*\* Indicate CTCAE term by choosing from the list provided in Appendix 3

**COMPLICATIONS SINCE THE LAST REPORT**

-- Infectious complications -- continued

**Parasitic infection:**  No  Yes  Unknown1) **New or ongoing:**  Newly developed  Ongoing since previous assessment**Start date:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD) *only if newly developed*  Unknown Protozoa  Helminths**Pathogen\*:** \_\_\_\_\_**Infection with clinical implications:**  No Yes: *(select all that apply during this period)* Symptoms/signs or disease Administration of pathogen-directed therapy Unknown*Indicate at least 1 location involved during this period:***Localisation 1 (CTCAE term)\*\*:** \_\_\_\_\_**Localisation 2 (CTCAE term)\*\*:** \_\_\_\_\_**Localisation 3 (CTCAE term)\*\*:** \_\_\_\_\_*(if patient died)***Contributory cause of death:**  No  Yes  Unknown*If more than 1 parasitic infections, copy and fill-in this table as many times as necessary.*

\* Indicate the pathogen and sub-type (if applicable) by choosing from the list of pathogens provided in Appendix 2

\*\* Indicate CTCAE term by choosing from the list provided in Appendix 3

### COMPLICATIONS SINCE THE LAST REPORT

-- Infectious complications -- continued

**Infection with unknown pathogen:**  No  Yes  Unknown

(for clinical infections without microbiological documentation, like pneumonia, cellulitis, etc.)

1) **New or ongoing:**  Newly developed  Ongoing since previous assessment

**Start date:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD) *only if newly developed*  Unknown

**Infection with clinical implications:**

No

(select all that apply)

Yes:

Symptoms/signs or disease

Administration of pathogen-directed therapy

Unknown

*Indicate at least 1 location:*

**Localisation 1 (CTCAE term)\*:** \_\_\_\_\_

**Localisation 2 (CTCAE term)\*:** \_\_\_\_\_

**Localisation 3 (CTCAE term)\*:** \_\_\_\_\_

*(if patient died)*

**Contributory cause of death:**  No  Yes  Unknown

*If more than 1 infections with unknown pathogen, copy and fill-in this table as many times as necessary.*

\* Indicate CTCAE term by choosing from the list provided in Appendix 3 at page 25

## SECONDARY MALIGNANCIES AND AUTOIMMUNE DISORDERS

**Did a secondary malignancy or autoimmune disorder occur during this follow-up period?**

- No
- Yes: **Was it a secondary malignancy or autoimmune disorder?**
- Secondary malignancy
  - Autoimmune disorder

**Date of diagnosis:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)

**Further details on secondary malignancy and autoimmune disorder:** \_\_\_\_\_  
 (Both for secondary malignancy and autoimmune disorder)

**Was this disease an indication for a subsequent HCT/CT/IST/GT?**

- No (complete the relevant non-indication diagnosis form)
- Yes (complete the relevant indication diagnosis form)
- Unknown

**Secondary malignancies only:**

**Histologic type (if applicable):** \_\_\_\_\_

**Location (if applicable):** \_\_\_\_\_

**Secondary malignancy material preserved:**

*(If a secondary malignancy occurred)*

- No
- Yes
- Unknown

**Concomitant PBMCs preserved:**

- No
- Yes
- Unknown

**Was a test on the secondary malignancy material performed?**

- No
- Yes: **Specify:**  PCR
- Flow cytometry
- Other specify: \_\_\_\_\_
- Unknown

*If material tested is 'yes':*

- What was the outcome of the test?**  CAR not detected
- CAR detected: please specify: \_\_\_\_\_
- Other specify: \_\_\_\_\_
- Unknown

- Is the secondary malignancy of T-cell origin?**  No
- Yes: please specify: \_\_\_\_\_
- Unknown

**Please specify the type of secondary malignancy:**

- Iatrogenic disease in relation with treatments administered prior to cellular therapy cells indication and administration (i.e. cytotoxic agents, targeted therapies, immunotherapies, radiation therapy, etc. Please provide more details below)
- Transformation of engineered immune effector cells through insertional mutagenesis or other mechanisms (please provide more details below)

**Has an investigation to assess the detection of replication competent retrovirus (RCR) in samples of secondary malignancy been conducted? (If PCR test was performed)**

- No
- Yes: **What was the outcome?**  RCR undetected
- RCR detected: please specify RCR details: \_\_\_\_\_
- Other: please specify: \_\_\_\_\_

**PERSISTENCE OF THE INFUSED CELLS**

**Was persistence of the infused cellular products assessed since the last follow-up?**

- No  
 Yes: **Date of the last assessment:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown

- Source of cells used for testing:  Bone marrow  
 Peripheral blood  
 Tumour  
 Other; specify: \_\_\_\_\_

- Technique used for testing:  Molecular (PCR)  
 Flow cytometry  
 Chimaerism  
 Imaging  
 Immunohistochemistry  
 Other; specify: \_\_\_\_\_

- Were immune effector cells (IEC) detected:  No  Yes  
 Unknown

**LAST DISEASE STATUS**  
 Additional Assessments

**Disease burden:**

LDH level:

- Normal  
 Elevated  
 Not evaluated  
 Unknown

Inflammatory state (C-reactive protein [CRP] concentration):

- Normal  
 Elevated: **Maximum CRP concentration:** \_\_\_\_\_ Unit (*check only one*):  mg/dL  mg/L  
 Not evaluated  
 Unknown

Date of C-reactive protein level assessment: \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown

**ADDITIONAL TREATMENTS**

*Include only systemic treatments designed to consolidate the anti-tumour activity of CT cells, prevent relapse (i.e. administration of immune checkpoint inhibitors). Indicate only treatments that have not been reported at previous follow-up(s).*

**Did the patient undergo additional treatment during this follow-up period?**

- No
- Yes;  Started in this follow-up period;  
 Ongoing since previous follow-up
- Unknown

**complete the "Treatment — non-HCT/CT/GT/IST form and /or the Cell infusion sheet before continuing with 'Additional Cell Infusions'**

**ADDITIONAL CELL INFUSIONS**

**Did the patient receive additional cell infusions (excluding a new HCT and CT) during this follow-up period?**

- No
- Yes: **Is this cell infusion an allogeneic boost\* ?**  No  Yes

*\* An allogeneic boost is an infusion of cells from the same donor without conditioning, with no evidence of graft rejection.*

**Date of the allogeneic boost:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)

**Is this cell infusion an autologous boost?**  No  Yes

**Date of the autologous boost:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)

- Unknown

*If this cell infusion is not a boost, attach the Cell Infusion (CI) sheet available in Appendix 6, completing as many sheets as episodes of cell infusion that took place during this interval; then continue below.*

**Did the patient receive subsequent HCT (either at your or another centre)?**

- No  
 Yes

**Did the patient receive subsequent cellular therapy (either at your or another centre)?**

- No
- Yes; **Reason for subsequent CT:**  Primary failure  
 Consolidation  
 Mitigation of side effects

*If the patient had a subsequent HCT/CT, please, make sure that this subsequent treatment is registered using the appropriate treatment form before proceeding.*



EBMT Centre Identification Code (CIC): \_\_\_\_  
Hospital Unique Patient Number (UPN): \_\_\_\_\_  
Patient Number in EBMT Registry: \_\_\_\_\_

Treatment Type  CT  
Treatment Date \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)

**HOSPITAL ADMISSION**  
*Complete only for Day 100 and 6 Months Follow-Up.*

**Was inpatient admission and care needed since the last follow-up?**

- No
- Yes; **Number of days in hospital:** \_\_\_\_\_
- Unknown

**Was the patient transferred to the intensive care unit (ICU) since the last follow-up?**

- No
- Yes; **Number of days in ICU:** \_\_\_\_\_
- Unknown

**RELAPSE/PROGRESSION, RECURRENCE OF DISEASE OR SIGNIFICANT WORSENING**

*(not relevant for Inborn Errors)*

**MRD detectable (with any method):** (only for Acute leukaemia)

- No  
 Yes: **Date of first detectable MRD:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown  
 Unknown

**Was there a relapse, progression, recurrence of disease or significant worsening of organ function related to the primary disease since last follow-up?** *(detected by any method)*

- No  
 Yes; *for every relapse, progression, recurrence, significant worsening complete the questions below*

**Type:**  Relapse / Recurrence of disease

(Continuous) progression / Significant worsening

**Date of relapse/progression/recurrence/worsening:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown

**Malignant disorders only:**

**Type of relapse/progression:**

**Medullary:**  No  Yes  Unknown

**Extramedullary:**  No  Yes  Unknown

*If the relapse/progression was extramedullary or both medullary and extramedullary:*

**Involvement at time of relapse/progression:**

**Skin:**  No  Yes  Not evaluated

**CNS:**  No  Yes  Not evaluated

**Testes/Ovaries:**  No  Yes  Not evaluated

**Other:**  No  Yes; specify: \_\_\_\_\_

Unknown

*copy and fill-in this table as many times as necessary.*

**Target expression at relapse after CT:**

- Absent  
 Present  
 Unknown

**PATIENT STATUS**

**Performance status at the last assessment** *(check only one):*

Type of scale used: \_\_\_\_\_ Score: \_\_\_\_\_

<b>Karnofsky/Lansky</b>	<input type="checkbox"/> 10	<input type="checkbox"/> 20	<input type="checkbox"/> 30	<input type="checkbox"/> 40	<input type="checkbox"/> 50	<input type="checkbox"/> 60	<input type="checkbox"/> 70	<input type="checkbox"/> 80	<input type="checkbox"/> 90	<input type="checkbox"/> 100	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> Unknown
<b>ECOG</b>	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> Unknown					



EBMT Centre Identification Code (CIC): \_\_\_\_  
 Hospital Unique Patient Number (UPN): \_\_\_\_\_  
 Patient Number in EBMT Registry: \_\_\_\_\_

Treatment Type  CT  
 Treatment Date \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)

### PREGNANCY AFTER CELLULAR THERAPY

*Complete only after 6 Months*

Has patient become pregnant or impregnated another person since last follow-up?

No;

Yes: **Did the pregnancy result in a live birth?**

No; **Date of spontaneous or induced termination:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown

Yes; **Year of birth:** \_\_\_\_ (YYYY) **Month of birth:** \_\_ (MM)  Unknown

Still pregnant at time of follow-up

Unknown

Unknown

### DISEASE STATUS

*Disease specific*

*Not applicable for Inborn Errors*

Disease status at this follow-up or at time of death\*: \_\_\_\_\_

\* Indicate the disease status at this follow-up or at time of death corresponding to indication diagnosis by selecting from the list provided in Appendix 1

**Appendix 1**  
Best Response and Disease Status (Disease Specific)

*Complete only one section with the main indication diagnosis for which CT was given.*

ACUTE LEUKAEMIAS	Go to page 23
CHRONIC LEUKAEMIAS	Go to page 23
PLASMA CELL NEOPLASMS (PCN)	Go to page 23
MPN, MDS, MDS / MPN OVERLAP SYNDROMES	Go to page 24
LYMPHOMAS	Go to page 25
SOLID TUMOURS	Go to page 25
BONE MARROW FAILURE SYNDROMES (BMF) including APLASTIC ANAEMIA (AA)	Go to page 25
AUTOIMMUNE DISORDERS	Go to page 26
HAEMOGLOBINOPATHIES	Go to page 26
OTHER DIAGNOSIS	Go to page 27

**Appendix 1**  
**Best Response and Disease Status (Disease Specific)**
**Acute leukaemias (AML, PLN, Other)**

<input type="checkbox"/> Complete remission (CR)
<input type="checkbox"/> Not in complete remission
<input type="checkbox"/> Not evaluated
<input type="checkbox"/> Unknown

*Proceed to next page for Diseases Status section*

**Chronic leukaemias (CML, CLL, PLL, Other)**
Chronic Myeloid Leukaemia (CML):

<input type="checkbox"/> Chronic phase (CP); <b>Number:</b> <input type="checkbox"/> 1 <sup>st</sup> <input type="checkbox"/> 2 <sup>nd</sup> <input type="checkbox"/> 3 <sup>rd</sup> or higher <input type="checkbox"/> Unknown <b>Haematological remission:</b> <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Not evaluated <input type="checkbox"/> Unknown <b>Cytogenetic remission:</b> <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Not evaluated <input type="checkbox"/> Unknown <b>Molecular remission:</b> <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Not evaluated <input type="checkbox"/> Unknown
<input type="checkbox"/> Accelerated phase; <b>Number:</b> <input type="checkbox"/> 1 <sup>st</sup> <input type="checkbox"/> 2 <sup>nd</sup> <input type="checkbox"/> 3 <sup>rd</sup> or higher <input type="checkbox"/> Unknown
<input type="checkbox"/> Blast crisis; <b>Number:</b> <input type="checkbox"/> 1 <sup>st</sup> <input type="checkbox"/> 2 <sup>nd</sup> <input type="checkbox"/> 3 <sup>rd</sup> or higher <input type="checkbox"/> Unknown
<input type="checkbox"/> Not evaluated
<input type="checkbox"/> Unknown

*Proceed to next page for Diseases Status section*

Chronic Lymphocytic Leukaemia (CLL), Prolymphocytic Leukaemia (PLL) and other chronic leukaemias:

<input type="checkbox"/> Complete remission (CR)
<input type="checkbox"/> Partial remission (PR)
<input type="checkbox"/> Progression: <input type="checkbox"/> Resistant to last regimen <input type="checkbox"/> Sensitive to last regimen <input type="checkbox"/> Unknown
<input type="checkbox"/> Stable disease (no change, no response/loss of response)
<input type="checkbox"/> Relapse
<input type="checkbox"/> Not evaluated
<input type="checkbox"/> Unknown

*Proceed to next page for Diseases Status section*

**Plasma cell neoplasms (PCN)**

<input type="checkbox"/> Complete remission (CR)	<b>Number:</b> <input type="checkbox"/> 1st <input type="checkbox"/> 2nd <input type="checkbox"/> 3rd or higher <input type="checkbox"/> Unknown
<input type="checkbox"/> Stringent complete remission (sCR)	
<input type="checkbox"/> Very good partial remission (VGPR)	
<input type="checkbox"/> Partial remission (PR)	
<input type="checkbox"/> Relapse	
<input type="checkbox"/> Progression	
<input type="checkbox"/> Stable disease (no change, no response/loss of response)	
<input type="checkbox"/> Not evaluated	
<input type="checkbox"/> Unknown	

*Proceed to next page for Diseases Status section*

**Appendix 1**  
**Best Response and Disease Status (Disease Specific)**  
**continued**

**Complete only for PCN Disease Status**

**Was the patient on dialysis during this follow-up period?**

- Yes;  Started in this follow-up period: **Start date:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown  
 Ongoing since previous follow-up  
**Did dialysis stop?**  No  
 Yes; **End date:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown  
 Unknown

**Complete only for AL, CLL and PCN Disease Status**

**Leukaemias (AL, CLL) and PCN (complete only for patient in CR or sCR)**

**Minimal residual disease (MRD):**

- Positive;  
 Increasing (>1log10 change)  Stable (<1log10 change)  Decreasing (>1log10 change)  Unknown  
 Negative  
 Not evaluated  
 Unknown

**Date MRD status evaluated:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown

**Sensitivity of MRD assay:**

- $\leq 10^{-6}$   
  $\leq 10^{-5}$   
  $\leq 10^{-4}$   
  $\leq 10^{-3}$   
 Other; specify: \_\_\_\_\_  
 Unknown

**Method used:**

- (select all that apply)*  
 PCR  
 Flow cytometry  
 NGS  
 Other; specify: \_\_\_\_\_  
 Unknown

**Myeloproliferative neoplasms (MPN), Myelodysplastic neoplasms (MDS), MDS/MPN overlap syndromes**

<input type="checkbox"/> Complete remission (CR)	<u>Number:</u> <input type="checkbox"/> 1st <input type="checkbox"/> 2nd <input type="checkbox"/> 3rd or higher <input type="checkbox"/> Unknown
<input type="checkbox"/> Improvement but no CR	
<input type="checkbox"/> Primary refractory phase (no change)	
<input type="checkbox"/> Relapse	<u>Number:</u> <input type="checkbox"/> 1st <input type="checkbox"/> 2nd <input type="checkbox"/> 3rd or higher <input type="checkbox"/> Unknown
<input type="checkbox"/> Progression/Worsening	
<input type="checkbox"/> Not evaluated	
<input type="checkbox"/> Unknown	

**Appendix 1**  
**Best Response and Disease Status (Disease Specific)**  
**continued**

**Lymphomas**

<input type="checkbox"/> Chemorefractory relapse or progression, including primary refractory disease
<input type="checkbox"/> Complete remission (CR)
<input type="checkbox"/> Partial remission (PR)
<input type="checkbox"/> Stable disease (no change, no response/loss of response)
<input type="checkbox"/> Untreated relapse (from a previous CR) or progression (from a previous PR)
<input type="checkbox"/> Not evaluated
<input type="checkbox"/> Unknown

**Technique used for disease assessment:**  CT scan  
 PET  
 MRI  
 Unknown

**Solid tumours**

<input type="checkbox"/> Complete remission (CR): <input type="checkbox"/> Confirmed <input type="checkbox"/> Unconfirmed <input type="checkbox"/> Unknown
<input type="checkbox"/> First partial remission
<input type="checkbox"/> Partial remission (PR)
<input type="checkbox"/> Progressive disease
<input type="checkbox"/> Relapse: <input type="checkbox"/> Resistant <input type="checkbox"/> Sensitive <input type="checkbox"/> Unknown
<input type="checkbox"/> Stable disease (no change, no response/loss of response)
<input type="checkbox"/> Not evaluated
<input type="checkbox"/> Unknown

**Bone marrow failures (incl. AA)**

<input type="checkbox"/> Complete remission (CR)
<input type="checkbox"/> Partial remission (PR)
<input type="checkbox"/> Haematological improvement (HI); <i>NIH partial response</i>
<input type="checkbox"/> Stable disease (no change, no response/loss of response)
<input type="checkbox"/> Relapse / Progression
<input type="checkbox"/> Not evaluated
<input type="checkbox"/> Unknown

**Complete only for Bone marrow failures (incl. AA) Disease Status**

**Did transfusions stop during the follow-up period?**  Patient was never transfusion dependent  
 No  
 Yes; **Did the patient return to transfusion dependency afterwards?**  
 No  
 Yes; **First transfusion date:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown (after transfusion free period)  
 Unknown  
 Ongoing transfusion independence since last follow-up  
 Unknown

**Appendix 1**  
**Best Response and Disease Status (Disease Specific)**  
**continued**

**Autoimmune disorders**

<input type="checkbox"/> No evidence of disease
<input type="checkbox"/> Improved
<input type="checkbox"/> Unchanged
<input type="checkbox"/> Worse
<input type="checkbox"/> Not evaluated
<input type="checkbox"/> Unknown

**Haemoglobinopathies**

Thalassaemia:

Complete only for Thalassemia Best Response

<input type="checkbox"/> Transfusion independent; <b>Date of last transfusion:</b> ____/____/____ (YYYY/MM/DD) <input type="checkbox"/> Unknown <i>(after cellular therapy)</i>
<input type="checkbox"/> Transfusions required; <b>Date of first transfusion:</b> ____/____/____ (YYYY/MM/DD) <input type="checkbox"/> Unknown <i>(after cellular therapy)</i>
<input type="checkbox"/> Not evaluated
<input type="checkbox"/> Unknown

Complete only for Thalassemia Disease Status

**Patient requires transfusions during follow-up period:**

No

Yes;  Return to transfusion dependence after **Date of first transfusion:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown  
*cellular therapy or transfusion free period; (after cellular therapy or transfusion free period)*

Ongoing transfusion dependence since previous assessment

**Number of units:** \_\_\_\_  Unknown  
*(during follow-up period)*

**Did transfusions stop?**  No  
 Yes; **Date of last transfusion:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown  
 Unknown

Unknown

**Appendix 1**  
**Best Response and Disease Status (Disease Specific)**  
**continued**

**Haemoglobinopathies**

Sickle cell disease:

**Complete only for Sickle cell disease Best Response**

<input type="checkbox"/> No return of sickling episodes	
<input type="checkbox"/> Return of sickling episodes;	<b>Date of first episode:</b> ____/____/____ (YYYY/MM/DD) <input type="checkbox"/> Unknown <i>(after cellular therapy)</i>
<input type="checkbox"/> Not evaluated	
<input type="checkbox"/> Unknown	

**Complete only for Sickle cell disease Disease Status**

**Sickling episodes occur during follow-up period:**

<input type="checkbox"/> No	
<input type="checkbox"/> Yes; <input type="checkbox"/> First return of sickling episodes after cellular therapy	<b>Date of first episode :</b> ____/____/____ (YYYY/MM/DD) <input type="checkbox"/> Unknown <i>(after cellular therapy)</i>
<input type="checkbox"/> Ongoing presence of sickling episodes	
<b>Number of SCD episodes:</b> ____ <input type="checkbox"/> Unknown <i>(during follow-up)</i>	
<input type="checkbox"/> Unknown	

**Other diagnosis**

<input type="checkbox"/> No evidence of disease
<input type="checkbox"/> Improved
<input type="checkbox"/> No response
<input type="checkbox"/> Worse
<input type="checkbox"/> Not evaluated
<input type="checkbox"/> Unknown

## Appendix 2

### -- Pathogens as per EBMT Registry database --

*\*As defined by the IDSA (Mermel LA, Allon M, Bouza E, Craven DE, Flynn P, O'Grady NP, et al. Clinical practice guidelines for the diagnosis and management of intravascular catheter-related infection: 2009 Update by the Infectious Diseases Society of America. Clin Infect Dis. 2009;49(1):1-45)*

#### Bacterial infections

##### Gram-positive:

- . Bacillus (in blood: report only if  $\geq 2$  positive separately taken cultures)
- . Clostridioides difficile (c difficile/CDT/CDI)
- . Clostridium other (NOT difficile)
- . Corynebacterium jeikeium
- . Corynebacterium other (NOT jeikeium) (in blood: report only if  $\geq 2$  positive separately taken cultures)
- . Enterococcus faecalis (vancomycin-susceptible)
- . Enterococcus faecalis (vancomycin-resistant)
- . Enterococcus faecium (vancomycin-susceptible)
- . Enterococcus faecium (vancomycin-resistant)
- . Listeria monocytogenes
- . Nocardia (specify)
- . Propionibacterium (in blood: report only if  $\geq 2$  positive separately taken cultures)
- . Rothia
- . Staphylococcus aureus (s aureus/staph aureus) MSSA (methicillin-susceptible)
- . Staphylococcus aureus (s aureus/staph aureus) MRSA (methicillin-resistant vancomycin-susceptible)
- . Staphylococcus coagulase-negative (in blood: report only if  $\geq 2$  positive separately taken cultures)
- . Staphylococcus lugdunensis
- . Streptococcus pneumoniae (pneumococcus)
- . Streptococcus viridans
- . Streptococcus other (specify)
- . Gram-positive bacteria other (specify)

##### Gram-negative:

- . Acinetobacter baumannii
- . Acinetobacter Iwoffii (in blood: report only if  $\geq 2$  positive separately taken cultures)
- . Acinetobacter other (NOT baumannii, NOT Iwoffii)
- . Bacteroides fragilis
- . Bordetella pertussis
- . Borrelia
- . Brucella
- . Campylobacter jejuni
- . Citrobacter freundii
- . Coxiella burnetii (Q fever)
- . Enterobacter cloacae
- . Enterobacter other
- . Escherichia coli (e coli)
- . Fusobacterium
- . Haemophilus influenzae (haemophilus influenzae type B/Hib/hemophilus influenzae)
- . Haemophilus other (hemophilus)
- . Helicobacter pylori
- . Klebsiella pneumoniae (carbapenem-susceptible)
- . Klebsiella other (NOT pneumoniae) (carbapenem-susceptible)
- . Klebsiella (any species) (carbapenem-susceptibility not checked)
- . Klebsiella (any species) (carbapenem-resistant)
- . Legionella pneumophila
- . Morganella morganii
- . Micrococcus (in blood: report only if  $\geq 2$  positive separately taken cultures)
- . Moraxella catarrhalis
- . Neisseria gonorrhoeae (gonococcus)
- . Neisseria meningitidis (meningococcus)
- . Proteus vulgaris
- . Providencia
- . Pseudomonas aeruginosa (PSA) (carbapenem-susceptible)
- . Pseudomonas aeruginosa (PSA) (carbapenem-resistant)
- . Pseudomonas aeruginosa (PSA) (carbapenem-susceptibility not checked)
- . Pseudomonas other (NOT aeruginosa)
- . Raoultella
- . Salmonella (specify)
- . Serratia marcescens
- . Shigella
- . Stenotrophomonas maltophilia
- . Treponema pallidum (syphilis/lues)
- . Yersinia
- . Gram-negative bacteria other (specify)

##### Other bacteria:

- . Chlamydia
- . Chlamydomphila
- . Mycobacterium other (specify)
- . Mycobacterium tuberculosis (TB)
- . Mycoplasma pneumoniae
- . Rickettsia
- . Ureoplasma
- . Bacteria other (specify)

##### Viral infections:

- . Adenovirus (ADV)
- . Chikungunya virus
- . Crimean-Congo haemorrhagic fever virus (CCHFV)
- . Dengue virus
- . Gastrointestinal viruses:
  - o Norovirus
  - o Rotavirus
  - o Sapovirus
  - o Astrovirus
- . Hepatotropic viruses:
  - o Hepatitis A virus (HAV)
  - o Hepatitis B virus (HBV)
  - o Hepatitis C virus (HCV)
  - o Hepatitis D virus (HDV)
  - o Hepatitis E virus (HEV)
- . Herpes group:
  - o Cytomegalovirus (CMV)
  - o Epstein-Barr virus (EBV)
  - o Herpes simplex virus (HS/HSV)
  - o Herpesvirus 6 (HHV6)
  - o Herpesvirus (HHV7)
  - o Herpesvirus 8 (HHV8/Kaposi's sarcoma-associated herpesvirus/KSHV/Kaposi)
  - o Varicella zoster virus (VZV/VZV/HZV/shingles/zoster/chickenpox)
- . Human immunodeficiency virus (HIV)
- . Human papilloma viruses (HPV)
- . Human T-lymphotropic virus 1 (HTLV-1)
- . Human T-lymphotropic virus 2 (HTLV-2)
- . Measles virus
- . Mumps virus
- . Parechovirus
- . Parvovirus (parvovirus B-19/B-19)
- . Poliovirus
- . Polyomaviruses:
  - o BK polyomavirus (BKV)
  - o JC virus (JCV)
  - o Merkel cell virus
- . Respiratory viruses:
  - o Bocavirus
  - o Enterovirus
  - o Human coronavirus (excluding SARS-CoV-2 or COVID-19)
  - o Influenza A virus (including birdflu)
  - o Influenza B virus
  - o Human metapneumovirus (hMPV)
  - o Parainfluenza
  - o Rhinovirus
  - o Respiratory syncytial virus (RSV)
  - o SARS-CoV-2 virus (COVID-19)
- . Rubella virus
- . Sandfly viruses (Naples virus/Sicilian virus/Toscana virus/Cyprus virus/Turkey virus/Tehran virus/phlebovirus)
- . Tick-borne encephalitis virus (TBE)
- . West Nile virus (WNV)
- . Yellow fever virus
- . Zika virus (ZIKV)

## Appendix 2

### -- Pathogens as per EBMT Registry database -- continued

*\*As defined by the IDSA (Mermel LA, Allon M, Bouza E, Craven DE, Flynn P, O'Grady NP, et al. Clinical practice guidelines for the diagnosis and management of intravascular catheter-related infection: 2009 Update by the Infectious Diseases Society of America. Clin Infect Dis. 2009;49(1):1-45)*

#### Fungal infections:

##### Yeasts:

- Candida albicans
- Candida auris
- Candida other (specify)
- Cryptococcus neoformans
- Geotrichum
- Magnusiomyces
- Pneumocystis jirovecii
- Saccharomyces
- Saprochaete
- Trichosporon
- Yeasts other (specify)

##### Moulds:

- Aspergillus flavus
- Aspergillus fumigatus
- Aspergillus other (NOT flavus, NOT fumigatus, NOT terreus)
- Aspergillus terreus
- Blastomyces
- Coccidioides
- Dematiaceous fungi / phaeohyphomycosis (specify)
- Fusarium solani
- Fusarium other (NOT solani)
- Galactomannan positive in blood or BAL, without microbiological confirmation of fungal infection
- Histoplasma
- Lomentospora prolificans / scedosporium prolificans
- Mucorales (mucor/rhizomucor/rhizopus/lichteinia) (specify)
- Paracoccidioides
- Scedosporium other (NOT prolificans) (specify)
- Moulds other (specify)

#### Parasitic infections:

##### Protozoa:

- Amoeba
- Babesia
- Cryptosporidium
- Giardia
- Leishmania
- Plasmodium (malaria)
- Toxoplasma gondii
- Trypanosoma cruzi
- Protozoa other

##### Helminths:

- Schistosoma
- Strongyloides stercoralis
- Helminths other

### Appendix 3

-- CTCAE term --

CTCAE terms related to infections and infestations (version 5.0.)

[https://ctep.cancer.gov/protocoldevelopment/electronic\\_applications/ctc.htm#ctc\\_50](https://ctep.cancer.gov/protocoldevelopment/electronic_applications/ctc.htm#ctc_50)

#### Respiratory tract infections

- Pneumonia
- Other respiratory tract infections, please specify:

#### Intra-abdominal infections

- Esophagus or gastric infection
- Liver site infection (including biliary tract and gallbladder), please specify:
- Lower gastrointestinal infection, please specify:
  - . Enteritis infective, please specify:
- Other intra-abdominal infection, please specify:

#### Skin, soft tissue and muscle infections

- . Lymph gland infection
- . Skin, soft tissue or muscle infection, please specify:

#### Blood infections

- Bacteremia
- Fungemia
- Viremia (including DNAemia)
- . DNAemia for parasitic infection

#### Other infections

- . Device-related infection (other than intravascular catheter)
- . Post-transplant lymphoproliferative disorder (PTLD)\*\*

#### Uro-genital tract infections

- Genital infection, please specify:
- Urinary tract infection, please specify:

#### Nervous system infection

- Central nervous system infection, please specify:
- Other nervous system infection, please specify:

#### Cardiovascular infections

- . Endocarditis infective
- . Other cardiovascular infection, please specify:

#### Head and neck infections (excluding lymph gland)

- . Ear infection
- Oral cavity infection, please specify:
- Retinitis infective
- Sinusitis infective
- Other eye infection, please specify:

#### Osteoarticular infections

- Joint infection
- Bone infection

\* Only if pathogen 'JC virus' is selected

\*\* Only if pathogen 'Epstein-Barr virus' is selected



EBMT Centre Identification Code (CIC): \_\_\_\_\_

Treatment Type  CT

Hospital Unique Patient Number (UPN): \_\_\_\_\_

Patient Number in EBMT Registry: \_\_\_\_\_

Treatment Date \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)

## Appendix 4

-- Non-infectious Complications CTCAE term -- **No Reporting Required****Non-infectious complications**

- Allergic reaction
- All laboratory abnormalities
- All types of pain
- Alopecia
- Blurred vision
- Diarrhoea (enteropathy)
- Dry mouth
- Dyspepsia
- Dysphagia
- Edema
- Esophageal stenosis
- Fatigue
- Flashes
- Gastritis
- Hematologic toxicities
- Hematoma
- Hypertension
- Injection site reaction
- Malaise
- Mucositis
- Sore throat
- Tinnitus
- Vertigo
- Weight loss

**Infectious complications**

- Minor ophthalmologic bacterial infections
- External otitis treated topically
- Otitis media treated with oral antibiotics
- Isolated lip herpes simplex
- Bacterial tonsillitis or pharyngitis treated orally
- Laryngitis without viral identification managed at home by inhalations or without any intervention
- URTI without viral/bacterial identification managed at home
- Bilateral cervical lymph node enlargement concurrent with URTI that resolved without specific treatment, together with the resolution of URTI
- Local superficial wound infection resolved under topical antibiotics (incl. impetigo)
- Minor skin bacterial infections
- Minor fungal skin infection
- Diaper rash treated with local antifungals
- Candidal balanitis treated topically
- Vaginal candidiasis treated topically or with a single oral dose
- Asymptomatic bacteriuria due to a pathogen not multi-resistant
- Single low urinary tract infection treated orally without need for hospitalisation
- Phlebitis following peripheral intravascular infusion that resolved after intravascular removal without treatment with antibiotics
- Any isolate that is considered part of the normal flora of the place (oral cavity, vagina, skin, stools) except if it carries an antimicrobial resistance that has clinical implications (induce isolation precautions or a pathogen-directed therapy)
- Positive culture without clinical implications

**Appendix 5**

## -- Intravascular catheter-related infections --

**CVC infections:**

- Catheter colonization
- Tunnel infection
- Phlebitis
- Pocket infection
- Exit site infection
- Bloodstream infection

## Appendix 6 Cell Infusion Sheet

**Chronological number of CI episode for this patient:** \_\_\_\_\_

**Date of the first infusion** (*within this episode*): \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)

**Number of infusions within this episode (10 weeks):** \_\_\_\_\_  
 (*Count only infusions that are part of the same regimen and given for the same indication*)

**Source of cells:**

- Allogeneic  
 Autologous

**Type of cells:**

- Lymphocytes (DLI)  
 Mesenchymal  
 Fibroblasts  
 Dendritic cells  
 NK cells  
 Regulatory T-cells  
 Gamma/delta cells  
 Virus-specific T-cells (VST)  
 Other; specify: \_\_\_\_\_

*(Only if 'Type of cells: = Virus-specific T-cells (VST))'*

**Specificity of VST product:**     Single-virus specific     Multi-virus specific

**If single-virus specific, to which virus?** (*Please register this virus in the Infectious complications - Viral infection part and fill in the VST in the 'Pre-emptive viral therapy' or 'Treatment of end-organ viral disease' section*)

- EBV  
 CMV  
 ADV  
 BKV or JCV  
 HHV-6

**If multi-virus specific, to which viruses?** (*Please register these viruses in the Infectious complications - Viral infection part and fill in the VST in the 'Pre-emptive viral therapy' or 'Treatment of end-organ viral disease' section*)

- (Select all that apply)**  EBV  
 CMV  
 ADV  
 BKV or JCV  
 HHV-6

**Appendix 6**  
Cell Infusion Sheet continued

*Not applicable for Inborn Errors*

**Disease status at time of this cell infusion\*:** \_\_\_\_\_

\* Indicate the disease status corresponding to indication diagnosis by selecting from the list provided in Appendix 1

**Indication:**

*(check all that apply)*

- |  |  |
|--|--|
| <input type="checkbox"/> Planned/protocol                            | <input type="checkbox"/> Poor graft function   |
| <input type="checkbox"/> Prophylactic                                | <input type="checkbox"/> Infection prophylaxis |
| <input type="checkbox"/> Treatment of acute GvHD                     | <input type="checkbox"/> Other; specify: _____ |
| <input type="checkbox"/> Treatment of chronic GvHD                   |  |
| <input type="checkbox"/> Treatment PTLD, EBV lymphoma                |  |
| <input type="checkbox"/> Treatment for primary disease               |  |
| <input type="checkbox"/> Mixed chimaerism                            |  |
| <input type="checkbox"/> Loss/decreased donor chimaerism             |  |
| <input type="checkbox"/> Treatment of viral infection other than EBV |  |

*Only for Acute leukemia donor lymphocyte infusions:*

**Response to DLI:**

- Complete remission (CR)    **MRD status:**  MRD negative    MRD positive    Not evaluated    Unknown
- Not in CR
- Not evaluated
- Unknown