



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 & 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> <i>(select all that apply)</i> <input type="checkbox"/> Graft versus Host Disease <input type="checkbox"/> Non-infectious complication <input type="checkbox"/> Infectious complication:
<input type="checkbox"/> HCT-related	<i>(select all that apply)</i> <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"/> GT-related	
<input type="checkbox"/> IST-related	
<input type="checkbox"/> Unknown	
<input type="checkbox"/> Other; specify: _____	

**Was an autopsy performed?**

- No
- Yes
- Unknown

### BEST RESPONSE

*Complete only once at one of the assessment periods: 100 days, 6 months or 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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**BEST RESPONSE continued**

If the indication was the treatment of complication derived from a previous transplant/cellular therapy:

<b>GvHD</b>	<input type="checkbox"/> Resolved	<input type="checkbox"/> Improved	<input type="checkbox"/> No response	<input type="checkbox"/> Progressed	<input type="checkbox"/> Not evaluated
<b>Graft failure</b>	<input type="checkbox"/> Resolved	<input type="checkbox"/> Improved	<input type="checkbox"/> No response	<input type="checkbox"/> Progressed	<input type="checkbox"/> Not evaluated
<b>Immune reconstitution</b>	<input type="checkbox"/> Resolved	<input type="checkbox"/> Improved	<input type="checkbox"/> No response	<input type="checkbox"/> Progressed	<input type="checkbox"/> Not evaluated
<b>Infection</b>	<input type="checkbox"/> Resolved	<input type="checkbox"/> Improved	<input type="checkbox"/> No response	<input type="checkbox"/> Progressed	<input type="checkbox"/> Not evaluated



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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

### 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: **Was there a B-cell recovery?**
- No: **Date of the last assessment:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)
- Yes: **Date of the first B-cell recovery:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD) *(If the recovery was reported on the last follow-up, this question can be skipped.)*
- Unknown

## CURRENT HAEMATOLOGICAL FINDINGS

Hb	_____ g/dL	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> Unknown
Platelets	_____ $10^9 / L$	<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	_____ $10^9 / L$	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> Unknown
Lymphocytes	_____ %	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> Unknown
Neutrophils	_____ %	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> Unknown

Extended dataset

**Antimicrobial prophylaxis**

Did the patient receive prophylaxis for bacterial, viral or fungal infection during this follow-up period?  No  Yes

If yes, what type of prophylaxis?  Antibacterial  Antifungal  Antiviral  
 (select all that apply and complete the relevant section)

**Antibacterial**

Antibiotic <i>(select all that were administered)</i>	Phase <i>Day 100 Only</i>	Responses for > 100 days only
<input type="checkbox"/> Ciprofloxacin	<input type="checkbox"/> Pre-engraftment <input type="checkbox"/> Post-engraftment; specify: <input type="checkbox"/> Only post-engraftment <input type="checkbox"/> Started pre-engraftment and continued into post-engraftment <input type="checkbox"/> Started and stopped in pre-engraftment phase and restarted in post-engraftment phase <input type="checkbox"/> Unknown	<input type="checkbox"/> Started in this follow-up period; <b>Start date:</b> ____/____/____ (YYYY/MM/DD) <input type="checkbox"/> Unknown <input type="checkbox"/> Ongoing since previous follow-up <input type="checkbox"/> Unknown
<input type="checkbox"/> Levofloxacin	<input type="checkbox"/> Pre-engraftment <input type="checkbox"/> Post-engraftment; specify: <input type="checkbox"/> Only post-engraftment <input type="checkbox"/> Started pre-engraftment and continued into post-engraftment <input type="checkbox"/> Started and stopped in pre-engraftment phase and restarted in post-engraftment phase <input type="checkbox"/> Unknown	<input type="checkbox"/> Started in this follow-up period; <b>Start date:</b> ____/____/____ (YYYY/MM/DD) <input type="checkbox"/> Unknown <input type="checkbox"/> Ongoing since previous follow-up <input type="checkbox"/> Unknown
<input type="checkbox"/> Moxifloxacin	<input type="checkbox"/> Pre-engraftment <input type="checkbox"/> Post-engraftment; specify: <input type="checkbox"/> Only post-engraftment <input type="checkbox"/> Started pre-engraftment and continued into post-engraftment <input type="checkbox"/> Started and stopped in pre-engraftment phase and restarted in post-engraftment phase <input type="checkbox"/> Unknown	<input type="checkbox"/> Started in this follow-up period; <b>Start date:</b> ____/____/____ (YYYY/MM/DD) <input type="checkbox"/> Unknown <input type="checkbox"/> Ongoing since previous follow-up <input type="checkbox"/> Unknown
<input type="checkbox"/> Penicillin	<input type="checkbox"/> Pre-engraftment <input type="checkbox"/> Post-engraftment; specify: <input type="checkbox"/> Only post-engraftment <input type="checkbox"/> Started pre-engraftment and continued into post-engraftment <input type="checkbox"/> Started and stopped in pre-engraftment phase and restarted in post-engraftment phase <input type="checkbox"/> Unknown	<input type="checkbox"/> Started in this follow-up period; <b>Start date:</b> ____/____/____ (YYYY/MM/DD) <input type="checkbox"/> Unknown <input type="checkbox"/> Ongoing since previous follow-up <input type="checkbox"/> Unknown

*Extended dataset*

**Antibacterial**

<b>Antibiotic</b> <i>(select all that were administered)</i>	<b>Phase</b> <i>Day 100 only</i>	<b>Responses for &gt; 100 days only</b>
<input type="checkbox"/> Non-absorbable antibiotic	<input type="checkbox"/> Pre-engraftment <input type="checkbox"/> Post-engraftment; specify: <input type="checkbox"/> Only post-engraftment <input type="checkbox"/> Started pre-engraftment and continued into post-engraftment <input type="checkbox"/> Started and stopped in pre-engraftment phase and restarted in post-engraftment phase <input type="checkbox"/> Unknown	<input type="checkbox"/> Started in this follow-up period; <b>Start date:</b> ____/____/____ (YYYY/MM/DD) <input type="checkbox"/> Unknown <input type="checkbox"/> Ongoing since previous follow-up <input type="checkbox"/> Unknown

**Final date antibacterial prophylaxis was discontinued:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Ongoing  Unknown

Extended dataset

**Antiviral**

**Did the patient receive cytomegalovirus (CMV) prophylaxis during this follow-up period?**

- No
- Yes: **Which drugs were used?**  High-dose acyclovir  
*(select all that apply)*
- High-dose valacyclovir
  - Gancyclovir intravenous
  - Valgancyclovir
  - Foscarnet
  - Other drug

**Final date CMV prophylaxis was discontinued:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Ongoing  Unknown

**Did the patient receive prophylaxis for varicella-zoster virus (VZV) or herpes simplex virus (HSV) with either acyclovir or valacyclovir during this follow-up period?**

- No
- Yes: **Final date VZV or HSV prophylaxis was discontinued:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Ongoing  Unknown

**Did the patient receive rituximab or another anti-CD20 monoclonal drug as prophylaxis for Epstein-Barr virus post-transplant lymphoproliferative disorder (EBV-PTLD) during this follow-up period?**

- No
- Yes

**Did the patient receive prophylaxis for hepatitis B virus (HBV) during this follow-up period?**

- No
- Yes: **Which drugs were used?**  Lamivudine  
*(select all that apply)*
- Entecavir
  - Tenofovir
  - Other drug

**Final date HBV prophylaxis was discontinued:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Ongoing  Unknown

## Extended dataset

## Antifungal

Antifungal (select all that were administered)	Phase Day 100 Only	Responses for > 100 days only
<input type="checkbox"/> Fluconazole	<input type="checkbox"/> Pre-engraftment <input type="checkbox"/> Post-engraftment; specify: <input type="checkbox"/> Only post-engraftment <input type="checkbox"/> Started pre-engraftment and continued into post-engraftment <input type="checkbox"/> Started and stopped in pre-engraftment phase and restarted in post-engraftment phase <input type="checkbox"/> Unknown	<input type="checkbox"/> Started in this follow-up period; <b>Start date:</b> ____/____/____ (YYYY/MM/DD) <input type="checkbox"/> Unknown <input type="checkbox"/> Ongoing since previous follow-up <input type="checkbox"/> Unknown
<input type="checkbox"/> Voriconazole	<input type="checkbox"/> Pre-engraftment <input type="checkbox"/> Post-engraftment; specify: <input type="checkbox"/> Only post-engraftment <input type="checkbox"/> Started pre-engraftment and continued into post-engraftment <input type="checkbox"/> Started and stopped in pre-engraftment phase and restarted in post-engraftment phase <input type="checkbox"/> Unknown	<input type="checkbox"/> Started in this follow-up period; <b>Start date:</b> ____/____/____ (YYYY/MM/DD) <input type="checkbox"/> Unknown <input type="checkbox"/> Ongoing since previous follow-up <input type="checkbox"/> Unknown
<input type="checkbox"/> Posaconazole	<input type="checkbox"/> Pre-engraftment <input type="checkbox"/> Post-engraftment; specify: <input type="checkbox"/> Only post-engraftment <input type="checkbox"/> Started pre-engraftment and continued into post-engraftment <input type="checkbox"/> Started and stopped in pre-engraftment phase and restarted in post-engraftment phase <input type="checkbox"/> Unknown	<input type="checkbox"/> Started in this follow-up period; <b>Start date:</b> ____/____/____ (YYYY/MM/DD) <input type="checkbox"/> Unknown <input type="checkbox"/> Ongoing since previous follow-up <input type="checkbox"/> Unknown
<input type="checkbox"/> Itraconazole	<input type="checkbox"/> Pre-engraftment <input type="checkbox"/> Post-engraftment; specify: <input type="checkbox"/> Only post-engraftment <input type="checkbox"/> Started pre-engraftment and continued into post-engraftment <input type="checkbox"/> Started and stopped in pre-engraftment phase and restarted in post-engraftment phase <input type="checkbox"/> Unknown	<input type="checkbox"/> Started in this follow-up period; <b>Start date:</b> ____/____/____ (YYYY/MM/DD) <input type="checkbox"/> Unknown <input type="checkbox"/> Ongoing since previous follow-up <input type="checkbox"/> Unknown

## Extended dataset

**Antifungal**

Antifungal (select all that were administered)	Phase Day 100 Only	Responses for > 100 days only
<input type="checkbox"/> Caspofungin	<input type="checkbox"/> Pre-engraftment <input type="checkbox"/> Post-engraftment; specify: <input type="checkbox"/> Only post-engraftment <input type="checkbox"/> Started pre-engraftment and continued into post-engraftment <input type="checkbox"/> Started and stopped in pre-engraftment phase and restarted in post-engraftment phase <input type="checkbox"/> Unknown	<input type="checkbox"/> Started in this follow-up period; <b>Start date:</b> ____/____/____ (YYYY/MM/DD) <input type="checkbox"/> Unknown <input type="checkbox"/> Ongoing since previous follow-up <input type="checkbox"/> Unknown
<input type="checkbox"/> Micafungin	<input type="checkbox"/> Pre-engraftment <input type="checkbox"/> Post-engraftment; specify: <input type="checkbox"/> Only post-engraftment <input type="checkbox"/> Started pre-engraftment and continued into post-engraftment <input type="checkbox"/> Started and stopped in pre-engraftment phase and restarted in post-engraftment phase <input type="checkbox"/> Unknown	<input type="checkbox"/> Started in this follow-up period; <b>Start date:</b> ____/____/____ (YYYY/MM/DD) <input type="checkbox"/> Unknown <input type="checkbox"/> Ongoing since previous follow-up <input type="checkbox"/> Unknown
<input type="checkbox"/> Anidulafungin	<input type="checkbox"/> Pre-engraftment <input type="checkbox"/> Post-engraftment; specify: <input type="checkbox"/> Only post-engraftment <input type="checkbox"/> Started pre-engraftment and continued into post-engraftment <input type="checkbox"/> Started and stopped in pre-engraftment phase and restarted in post-engraftment phase <input type="checkbox"/> Unknown	<input type="checkbox"/> Started in this follow-up period; <b>Start date:</b> ____/____/____ (YYYY/MM/DD) <input type="checkbox"/> Unknown <input type="checkbox"/> Ongoing since previous follow-up <input type="checkbox"/> Unknown
<input type="checkbox"/> Ambisome (IV or inhalations)	<input type="checkbox"/> Pre-engraftment <input type="checkbox"/> Post-engraftment; specify: <input type="checkbox"/> Only post-engraftment <input type="checkbox"/> Started pre-engraftment and continued into post-engraftment <input type="checkbox"/> Started and stopped in pre-engraftment phase and restarted in post-engraftment phase <input type="checkbox"/> Unknown	<input type="checkbox"/> Started in this follow-up period; <b>Start date:</b> ____/____/____ (YYYY/MM/DD) <input type="checkbox"/> Unknown <input type="checkbox"/> Ongoing since previous follow-up <input type="checkbox"/> Unknown

 Final date antifungal prophylaxis was discontinued: \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Ongoing  Unknown

*Extended dataset*

**Did the patient receive prophylaxis for *Pneumocystis jirovecii* pneumonia (PJP) during this follow-up period?**

- No
- Yes: **Which drugs were used?**  Trimethoprim-sulfamethoxazole  
*(select all that apply)*
- Dapsone
  - Atovaquone
  - Pentamidine inhaled
  - Pentamidine intravenous
  - Other drug

**Final date prophylaxis was discontinued:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Ongoing  Unknown

Unknown

**Pre-emptive viral therapy**

**Did the patient receive pre-emptive therapy for a viral infection during this follow-up period?**  No  Yes

**If yes, for what virus?**  CMV  EBV  
*(select all that apply)*

**Specify the pre-emptive therapy for each CMV episode that occurred during this follow-up period**

**CMV treatment start date:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown

**Antiviral(s) used:**  
*(Select all that apply)*

- Valgancyclovir
- Gancyclovir intravenous
- Foscarnet
- Cidofovir
- Maribavir
- Specific CMV T-cell
- Other drug

**Was this episode of CMV infection due to a resistant CMV strain?**

- No  Yes  Unknown

*Copy as often as necessary to reflect all episodes that occurred*

**Specify the pre-emptive therapy for each EBV episode that occurred during this follow-up period**

**EBV treatment start date:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown

**Antiviral(s) used:**  
*(Select all that apply)*

- Rituximab
- Specific EBV T-cells
- Other drug

*Copy as often as necessary to reflect all episodes that occurred*



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**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**aGvHD resolved:**  No Yes; **Date of aGvHD resolution:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown 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 ( <i>none</i> )	<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 ( <i>none</i> )	<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 ( <i>none</i> )	<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 ( <i>none</i> )	<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 ( <i>none</i> )	<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 ( <i>none</i> )	<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 ( <i>none</i> )	<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 ( <i>none</i> )	<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

- cGvHD resolved:**  No
- Yes; **Date of cGvHD resolution:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown
- Unknown

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

Unknown

### 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 during the 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*

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*

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

\* Grade 0-2

### COMPLICATIONS SINCE THE LAST REPORT

-- Non-infectious complications --

**Other neurotoxicity observed during this follow-up period?**  No\*  
 Specify: \_\_\_\_\_  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

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

### 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

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

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*

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)\*\*:** \_\_\_\_\_

**Intravascular catheter-related infection:**  No

Yes; specify\*\*\*: \_\_\_\_\_

Unknown

**Resolved:**  No  Yes  Unknown

*(if patient died)*

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

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

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

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)\*\*:** \_\_\_\_\_

**Intravascular catheter-related infection:**  No

Yes; specify\*\*\*: \_\_\_\_\_

Unknown

**Resolved:**  No  Yes  Unknown

*(if patient died)*

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

*If more than 2 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

\*\*\* If intravascular catheter-related infection, specify it by choosing from the list provided in Appendix 5

**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*

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

If the pathogen was CMV/EBV: **Was this infection a reactivation?**  No  
 Yes

**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)\*\*:** \_\_\_\_\_

**Resolved:**  No  Yes  Unknown

*(if patient died)*

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

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

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

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

If the pathogen was CMV/EBV: **Was this infection a reactivation?**  No  
 Yes

**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)\*\*:** \_\_\_\_\_

**Resolved:**  No  Yes  Unknown

*(if patient died)*

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

*If more than 2 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

\*\*\* If intravascular catheter-related infection, specify it by choosing from the list provided in Appendix 5



### COMPLICATIONS SINCE THE LAST REPORT

-- Infectious complications -- continued

**Parasitic infection:**  No  Yes  Unknown

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

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

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)\*\*:** \_\_\_\_\_

**Resolved:**  No  Yes  Unknown

*(if patient died)*

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

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

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

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)\*\*:** \_\_\_\_\_

**Resolved:**  No  Yes  Unknown

*(if patient died)*

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

*If more than 2 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

\*\*\* If intravascular catheter-related infection, specify it by choosing from the list provided in Appendix 5

**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*

**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)\*:** \_\_\_\_\_

**Intravascular catheter-related infection:**  No  
 Yes; specify\*\*:  
 Unknown

**Resolved:**  No  Yes  Unknown

*(if patient died)*

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

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

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

**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)\*:** \_\_\_\_\_

**Intravascular catheter-related infection:**  No  
 Yes; specify\*\*:  
 Unknown

**Resolved:**  No  Yes  Unknown

*(if patient died)*

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

*If more than 2 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

\*\* If intravascular catheter-related infection, specify it by choosing from the list provided in Appendix 5

Extended dataset

**SARS-CoV-2 RELATED QUESTION**

**Did the patient receive a vaccination against SARS-CoV-2 during this follow-up period?**

- No
- Yes:      **Number of doses during this follow-up period:** \_\_\_\_\_  Unknown
- Date of the last dose:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown
- Unknown

**SECONDARY MALIGNANCIES AND AUTOIMMUNE DISORDERS**

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

- No
- Yes:       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)

Further details on secondary malignancy or autoimmune disorder: \_\_\_\_\_

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

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

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

- |  |                                  |
|--|----------------------------------|
| Secondary malignancy material preserved: | Concomitant PBMCs preserved:     |
| <input type="checkbox"/> No              | <input type="checkbox"/> No      |
| <input type="checkbox"/> Yes             | <input type="checkbox"/> Yes     |
| <input type="checkbox"/> Unknown         | <input type="checkbox"/> Unknown |

**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

### 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"**

### 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)*

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

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

Unknown

**CD19 expression at relapse after CT** *(only for Precursor lymphoid neoplasms):*

- Absent
- Present
- Unknown

### PATIENT STATUS

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

Type of scale used:

Score:

<input type="checkbox"/> Karnofsky	<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"/> Lansky										
<input type="checkbox"/> ECOG	<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										

### PREGNANCY AFTER CELLULAR THERAPY

*Complete only after 6 Months*

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

No;

*Extended dataset*

**Was there an attempted pregnancy since last follow-up?**  No  Yes  Unknown

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

*Extended dataset*

**Conception method:**  Natural  Assisted  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	<i>Go to page 29</i>
CHRONIC LEUKAEMIAS	<i>Go to page 29</i>
PLASMA CELL NEOPLASMS (PCN)	<i>Go to page 29</i>
MPN, MDS, MDS / MPN OVERLAP SYNDROMES	<i>Go to page 30</i>
LYMPHOMAS	<i>Go to page 31</i>
SOLID TUMOURS	<i>Go to page 31</i>
BONE MARROW FAILURE SYNDROMES (BMF) including APLASTIC ANAEMIA (AA)	<i>Go to page 31</i>
AUTOIMMUNE DISORDERS	<i>Go to page 32</i>
HAEMOGLOBINOPATHIES	<i>Go to page 32</i>
OTHER DIAGNOSIS	<i>Go to page 33</i>

**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
- No
- 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"/> Confirmed <input type="checkbox"/> Unconfirmed (CRU*) <input type="checkbox"/> Unknown
<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

\* CRU: Complete response with persistent scan abnormalities of unknown significance

**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 (after cellular therapy)
<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 (after cellular therapy)
<input type="checkbox"/> Ongoing presence of sickling episodes	
<b>Number of SCD episodes:</b> ____ <input type="checkbox"/> Unknown (during follow-up)	
<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:

- Clostridioides difficile
- Enterococcus faecalis (vancomycin-susceptible)
- Enterococcus faecalis (vancomycin-resistant)
- Enterococcus faecium (vancomycin-susceptible)
- Enterococcus faecium (vancomycin-resistant)
- Listeria monocytogenes
- Nocardia spp (specify)
- Staphylococcus aureus MSSA (methicillin-susceptible)
- Staphylococcus aureus MRSA (methicillin-resistant) vancomycin-susceptible
- Staphylococcus aureus MRSA (methicillin-resistant) vancomycin not tested
- Staphylococcus aureus MRSA and VISA (vancomycin-intermediate, MIC 4-8 µg/ml)
- Staphylococcus aureus MRSA and VRSA (vancomycin-resistant, MIC ≥ 16 µg/ml)
- Staphylococcus coagulase-negative spp (at least two positive blood cultures)
- Streptococcus pneumoniae
- Streptococcus viridans
- Streptococcus other spp (specify)
- Gram-positive bacteria other spp (specify)

Gram-negative:

- Acinetobacter baumannii
- Campylobacter jejuni
- Citrobacter freundii
- Enterobacter cloacae
- Enterobacter other spp (specify)
- Escherichia coli
- Haemophilus influenzae
- Helicobacter pylori
- Klebsiella aerogenes (carbapenem-susceptible)
- Klebsiella pneumoniae (carbapenem-susceptible)
- Klebsiella (any species) (carbapenem-resistant) (specify)
- Legionella pneumophila
- Morganella morganii
- Neisseria gonorrhoeae
- Neisseria meningitidis
- Proteus vulgaris
- Providencia spp
- Pseudomonas aeruginosa (carbapenem-susceptible)
- Pseudomonas aeruginosa (carbapenem-resistant)
- Salmonella spp (specify)
- Serratia marcescens
- Shigella spp
- Stenotrophomonas maltophilia
- Treponema pallidum
- Gram-negative bacteria other spp (specify)

Other bacteria:

- Chlamydia spp
- Chlamydophila
- Mycobacterium other spp (specify)
- Mycobacterium tuberculosis
- Mycoplasma pneumoniae
- Rickettsia spp
- Bacteria other (specify)

**Viral infections:**

- Adenovirus
- Gastrointestinal viruses:
  - o Norovirus
  - o Rotavirus
- Hepatotropic viruses:
  - o HAV
  - o HBV
  - o HCV
  - o HEV
- Herpes group:
  - o CMV
  - o EBV
  - o HHV6
  - o HHV7
  - o HHV8
  - o HS
  - o VZ
- HIV
- Human papilloma viruses (HPV)
- Parvovirus
- Polyomaviruses:
  - o BK
  - o JC
  - o Merkel cell
  - o Other polyomavirus (specify)
- Respiratory viruses:
  - o Enterovirus
  - o Human coronavirus
  - o Influenza A
  - o Influenza B
  - o Metapneumovirus
  - o Parainfluenza
  - o Rhinovirus
  - o RSV
  - o SARS-CoV-2
  - o Respiratory virus other (specify)
- Viruses other (specify)

**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
- Trichosporon (specify)
- Pneumocytis jiroveci
- Yeasts other (specify)

**Moulds:**

- Aspergillus flavus
- Aspergillus fumigatus
- Aspergillus other spp (specify)
- Aspergillus terreus
- Fusarium other spp (specify)
- Fusarium solani
- Lomentospora prolificans (formerly Scedosporium prolificans)
- Order Mucorales (specify)
- Dematiaceous fungi (Phaeohyphomycosis) (specify)
- Scedosporium spp (specify)
- Moulds other spp (specify)
- Mould infection diagnosed based on positive galactomannan only, without microbiological confirmation
- Blastomyces spp
- Histoplasma spp (specify)
- Coccidioides spp
- Paracoccidioides spp

**Parasitic infections:****Protozoa:**

- Babesia spp (specify)
- Cryptosporidium
- Giardia spp
- Leishmania spp (specify)
- Plasmodium spp (specify)
- Toxoplasma gondii
- Trypanosoma cruzi
- Protozoa other spp (specify)

**Helminths:**

- Strongyloides stercoralis
- Other helminths

**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:

- Upper respiratory tract infection
- Tracheobronchitis
- Pleural infection

**Intra-abdominal infections**

- Esophagus or gastric infection
- Liver site infection (including biliary tract and gallbladder), please specify:

- Biliary tract or gallbladder infection
- Liver infection

- Lower gastrointestinal infection, please specify:

- Anorectal infection
- Appendicitis infective
- Duodenal infection
- Enterocolitis infective
- Small intestine infection
- Typhlitis infective

- Other intra-abdominal infection, please specify:

- Pancreas infection
- Peritoneal infection
- Splenic infection

**Skin, soft tissue and muscle infections**

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

- Breast infection
- Muscle infection
- Papulo/pustular rash
- Periorbital infection
- Skin infection (other than periorbital)
- Soft tissue infection (other than periorbital)

**Blood infections**

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

**Other infections**

- Device-related infection (other than intravascular catheter)

**Uro-genital tract infections**

- Genital infection, please specify:

- Deep genital infection( including cervicitis infective, ovarian/ pelvic/ prostate/ uterine infection)
- Superficial genital infection( including penile/ scrotal / vaginal / vulvai infection)

- Urinary tract infection, please specify:

- Cystitis or urethritis infective
- Upper urinary tract infection (e.g. kidney infection)

**Nervous system infection**

- Central nervous system infection, please specify:

- Encephalitis infective (including abscess)
- Isolated meningitis infective

- Other nervous system infection, please specify:

- Cranial nerve infection
- Myelitis infective

**Cardiovascular infections**

- Endocarditis infective
- Other cardiovascular infection, please specify:

- Arteritis infective
- Mediastinal infection

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

- Conjunctivitis infective
- Corneal infection
- Ear infection
- Endophthalmitis infective
- Oral cavity infection, please specify:

- Salivary gland infection
- Other oral cavity structure infection

- Retinitis infective
- Sinusitis infective

**Osteoarticular infections**

- Joint infection
- Bone infection

### Appendix 4

-- Non-infectious and 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
- Neutropenic fever and sepsis of unknown origin

### 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:**  
 (check all that apply)

- Allogeneic
- Autologous

**Type of cells:**  
 (check all that apply)

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

*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 |  |

**Acute GvHD -- maximum grade (after this infusion episode but before any subsequent cell infusion/HCT/CT):**

- 0 (none)
  - 1
  - 2
  - 3
  - 4
  - Present but grade unknown
- Date Acute GvHD onset after cell infusion:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)
- Unknown