

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	Select treatment related cause: <i>(select all that apply)</i> <input type="checkbox"/> Graft versus Host Disease <input type="checkbox"/> Non-infectious complication <input type="checkbox"/> Infectious complication: <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"/> HCT-related	
<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 for Day 100 and 6 Months 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



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

Treatment Type CT
 Treatment Date ____/____/____ (YYYY/MM/DD)

BEST RESPONSE continued

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

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



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

Treatment Type CT
 Treatment Date ____/____/____ (YYYY/MM/DD)

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
- 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 (select all that were administered)	Phase Day 100 Only	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; Start date: ____/____/____ (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; Start date: ____/____/____ (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; Start date: ____/____/____ (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; Start date: ____/____/____ (YYYY/MM/DD) <input type="checkbox"/> Unknown <input type="checkbox"/> Ongoing since previous follow-up <input type="checkbox"/> Unknown

Extended dataset

Antibacterial

Antibiotic <i>(select all that were administered)</i>	Phase <i>Day 100 only</i>	Responses for > 100 days only
<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; Start date: ____/____/____ (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; Start date: ____/____/____ (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; Start date: ____/____/____ (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; Start date: ____/____/____ (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; Start date: ____/____/____ (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; Start date: ____/____/____ (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; Start date: ____/____/____ (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; Start date: ____/____/____ (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; Start date: ____/____/____ (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



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**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)

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

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*

Organ 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

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)

Bacterial infection: No Yes

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

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

Fungal infection: No Yes

1) **New or ongoing:** Newly developed Ongoing since previous assessment
Start date: ____/____/____ (YYYY/MM/DD) *only if newly developed*
 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):** _____

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*
 Yeasts Moulds
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):** _____

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 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
*** 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

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:
 (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:

- No
 Yes
 Unknown

Concomitant PBMCs preserved:

- No
 Yes
 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; complete the "Treatment — non-HCT/CT/GT/IST" form
 Ongoing since previous follow-up
- Unknown

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)

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.

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					

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); Number: <input type="checkbox"/> 1 st <input type="checkbox"/> 2 nd <input type="checkbox"/> 3 rd or higher <input type="checkbox"/> Unknown Haematological remission: <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Not evaluated <input type="checkbox"/> Unknown Cytogenetic remission: <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Not evaluated <input type="checkbox"/> Unknown Molecular remission: <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Not evaluated <input type="checkbox"/> Unknown
<input type="checkbox"/> Accelerated phase; Number: <input type="checkbox"/> 1 st <input type="checkbox"/> 2 nd <input type="checkbox"/> 3 rd or higher <input type="checkbox"/> Unknown
<input type="checkbox"/> Blast crisis; Number: <input type="checkbox"/> 1 st <input type="checkbox"/> 2 nd <input type="checkbox"/> 3 rd 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)	Number: <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?	<input type="checkbox"/> Patient was never transfusion dependent <input type="checkbox"/> No <input type="checkbox"/> Yes; Did the patient return to transfusion dependency afterwards? <input type="checkbox"/> No <input type="checkbox"/> Yes; First transfusion date: ____/____/____ (YYYY/MM/DD) <input type="checkbox"/> Unknown (after transfusion free period) <input type="checkbox"/> Unknown <input type="checkbox"/> Ongoing transfusion independence since last follow-up <input type="checkbox"/> 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; Date of last transfusion: ____/____/____ (YYYY/MM/DD) <input type="checkbox"/> Unknown <i>(after cellular therapy)</i>
<input type="checkbox"/> Transfusions required; Date of first transfusion: ____/____/____ (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;	Date of first episode: ____/____/____ (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	Date of first episode : ____/____/____ (YYYY/MM/DD) <input type="checkbox"/> Unknown (after cellular therapy)
<input type="checkbox"/> Ongoing presence of sickling episodes	
Number of SCD episodes: ____ <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

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 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:
 (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