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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

BEST RESPONSE

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

Best clinical/biological response after this CT *(observed before any subsequent treatment):*

If the indication was the treatment of a primary disease:

☐ Continued complete remission (CCR)
☐ Complete remission (CR)
☐ Partial remission
☐ No response / Stable disease / No change
☐ Disease progression
☐ Not evaluated
☐ Unknown

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

GvHD	☐ Resolved	☐ Improved	☐ No response	☐ Progressed	☐ Not evaluated
Graft failure	☐ Resolved	☐ Improved	☐ No response	☐ Progressed	☐ Not evaluated
Immune reconstitution	☐ Resolved	☐ Improved	☐ No response	☐ Progressed	☐ Not evaluated
Infection	☐ Resolved	☐ Improved	☐ No response	☐ Progressed	☐ Not evaluated

Date response evaluated: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*

RECOVERY

Absolute neutrophil count (ANC) recovery *(neutrophils ≥ 0.5x10^9 cells/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

☐ Unknown

Platelet reconstitution *(platelets ≥ 20x10^9 cells/L:)*:

☐ No: **Date of the last assessment:** _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*

☐ Yes: **Date of platelet reconstitution:** _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* ☐ Date unknown
(first of 3 consecutive values after 7 days without platelet transfusion)

☐ Never below

☐ Unknown

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

Was B-cell count monitored after CT?

☐ No

☐ Yes: Was there a B-cell recovery?

☐ No: **Date of the last assessment**: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*

☐ Yes: **Date of the <u>first</u> B-cell recovery**: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*

☐ Unknown

CURRENT HAEMATOLOGICAL FINDINGS

Hb	_____ g/dL	☐ Not evaluated	☐ Unknown
Platelets	_____ 10^9 cells/L	☐ Not evaluated	☐ Unknown
Were platelets transfused within 7 days before assessment?	☐ No ☐ Yes		☐ Unknown
White blood cells	_____ 10^9 cells/L	☐ Not evaluated	☐ Unknown
Lymphocytes	_____ %	☐ Not evaluated	☐ Unknown
Neutrophils	_____ %	☐ Not evaluated	☐ Unknown

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?

☐ No *(proceed to 'Complications since the last report - Non-infectious complications' on page 4)*

☐ Yes: **Did the patient receive a systemic/immunosuppressive treatment for GvHD?**

☐ No

☐ Yes; **Date treatment started:** _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*

Immunosuppression ongoing: ☐ No ☐ Yes ☐ Unknown

Acute GvHD: ☐ No

☐ Yes: **Date of onset:** _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*

Maximum observed organ severity score:

Skin:	☐ 0 *(none)*	☐ 1	☐ 2	☐ 3	☐ 4
Liver:	☐ 0 *(none)*	☐ 1	☐ 2	☐ 3	☐ 4
Lower GI tract:	☐ 0 *(none)*	☐ 1	☐ 2	☐ 3	☐ 4
Upper GI tract:	☐ 0 *(none)*	☐ 1			
Other site affected:	☐ No	☐ Yes; specify: _____			

Overall maximum grade observed: ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ Unknown

Steroid-refractory acute GvHD: ☐ No ☐ Yes

Date of aGvHD resolution: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* ☐ Ongoing

Chronic GvHD: ☐ No

☐ Yes: **Date of onset:** _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*

Maximum NIH score during this period: ☐ Mild ☐ Moderate ☐ Severe ☐ Unknown

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

Maximum observed organ severity score:

Skin:	☐ 0 *(none)*	☐ 1	☐ 2	☐ 3
Oral:	☐ 0 *(none)*	☐ 1	☐ 2	☐ 3
Gastrointestinal:	☐ 0 *(none)*	☐ 1	☐ 2	☐ 3
Eyes:	☐ 0 *(none)*	☐ 1	☐ 2	☐ 3
Liver:	☐ 0 *(none)*	☐ 1	☐ 2	☐ 3
Joints and fascia:	☐ 0 *(none)*	☐ 1	☐ 2	☐ 3
Lungs:	☐ 0 *(none)*	☐ 1	☐ 2	☐ 3
Genitalia:	☐ 0 *(none)*	☐ 1	☐ 2	☐ 3
Other site affected:	☐ No	☐ Yes; specify: _____		

Steroid-refractory chronic GvHD: ☐ No ☐ Yes

Date of cGvHD resolution: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* ☐ Ongoing

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

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

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

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

☐ No (*proceed to 'Complications since the last report - Infectious complications' on page 7)*
☐ Yes (report in the table below)

Adverse event *(check all that apply)*	**Maximum grade observed***	**Onset date** *(YYYY/MM/DD)*	**Treated**	**Resolved**
Cytokine release syndrome (CRS) ☐ Absent ☐ Present ☐ Unknown	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 (fatal) ☐ Unknown Grading system: ☐ ASTCT consensus (Lee 2019) ☐ Penn ☐ CTCAE ☐ Lee 2014 ☐ MDACC ☐ Other; specify: _____	_ _ _ _/ _ _/ _ _	☐ No ☐ Yes ☐ Unknown	☐ No ☐ Yes ☐ Unknown
IEC-associated neurotoxicity syndrome (ICANS) ☐ Absent ☐ Present ☐ Unknown	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 (fatal) ☐ Unknown Grading system: ☐ ASTCT consensus (Lee 2019) ☐ CTCAE ☐ Lee 2014 ☐ MDACC ☐ Other; specify: _____	_ _ _ _/ _ _/ _ _	☐ No ☐ Yes ☐ Unknown	☐ No ☐ Yes ☐ Unknown
Other neurotoxicity, specify: _____ ☐ Absent ☐ Present ☐ Unknown	☐ 2 ☐ 3 ☐ 4 ☐ 5 (fatal) ☐ Unknown	_ _ _ _/ _ _/ _ _	☐ No ☐ Yes ☐ Unknown	☐ No ☐ Yes ☐ Unknown
Macrophage activation syndrome (MAS) ☐ Absent ☐ Present ☐ Unknown	☐ 2 ☐ 3 ☐ 4 ☐ 5 (fatal) ☐ Unknown	_ _ _ _/ _ _/ _ _	☐ No ☐ Yes ☐ Unknown	☐ No ☐ Yes ☐ Unknown
Secondary haemophagocytic lymphohistiocytosis (HLH) ☐ Absent ☐ Present ☐ Unknown	☐ 2 ☐ 3 ☐ 4 ☐ 5 (fatal) ☐ Unknown	_ _ _ _/ _ _/ _ _	☐ No ☐ Yes ☐ Unknown	☐ No ☐ Yes ☐ Unknown

*If not otherwise specified, CTCAE grading system is to be used.

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

Adverse event *(check all that apply)*	**Maximum grade observed***	**Onset date** *(YYYY/MM/DD)*	**Treated**	**Resolved**
Organ toxicity: skin ☐ Absent ☐ Present ☐ Unknown	☐ 2 ☐ 3 ☐ 4 ☐ 5 (fatal) ☐ Unknown	_ _ _ _/ _ _/ _ _	☐ No ☐ Yes ☐ Unknown	☐ No ☐ Yes ☐ Unknown
Organ toxicity: liver ☐ Absent ☐ Present ☐ Unknown	☐ 2 ☐ 3 ☐ 4 ☐ 5 (fatal) ☐ Unknown	_ _ _ _/ _ _/ _ _	☐ No ☐ Yes ☐ Unknown	☐ No ☐ Yes ☐ Unknown
Organ toxicity: lung ☐ Absent ☐ Present ☐ Unknown	☐ 2 ☐ 3 ☐ 4 ☐ 5 (fatal) ☐ Unknown	_ _ _ _/ _ _/ _ _	☐ No ☐ Yes ☐ Unknown	☐ No ☐ Yes ☐ Unknown
Organ toxicity: heart ☐ Absent ☐ Present ☐ Unknown	☐ 2 ☐ 3 ☐ 4 ☐ 5 (fatal) ☐ Unknown	_ _ _ _/ _ _/ _ _	☐ No ☐ Yes ☐ Unknown	☐ No ☐ Yes ☐ Unknown
Organ toxicity: kidney ☐ Absent ☐ Present ☐ Unknown	☐ 2 ☐ 3 ☐ 4 ☐ 5 (fatal) ☐ Unknown	_ _ _ _/ _ _/ _ _	☐ No ☐ Yes ☐ Unknown	☐ No ☐ Yes ☐ Unknown
Organ toxicity: gastrointestinal ☐ Absent ☐ Present ☐ Unknown	☐ 2 ☐ 3 ☐ 4 ☐ 5 (fatal) ☐ Unknown	_ _ _ _/ _ _/ _ _	☐ No ☐ Yes ☐ Unknown	☐ No ☐ Yes ☐ Unknown
Organ toxicity: other; specify: _____ ☐ Absent ☐ Present ☐ Unknown	☐ 2 ☐ 3 ☐ 4 ☐ 5 (fatal) ☐ Unknown	_ _ _ _/ _ _/ _ _	☐ No ☐ Yes ☐ Unknown	☐ No ☐ Yes ☐ Unknown

*If not otherwise specified, CTCAE grading system is to be used.

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

Adverse event *(check all that apply)*	**Maximum grade observed***	**Onset date** *(YYYY/MM/DD)*	**Treated**	**Resolved**
Tumour lysis syndrome (TLS) ☐ Absent ☐ Present ☐ Unknown	☐ 2 ☐ 3 ☐ 4 ☐ 5 (fatal) ☐ Unknown	_ _ _ _/ _ _/ _ _	☐ No ☐ Yes ☐ Unknown	☐ No ☐ Yes ☐ Unknown
B-cell aplasia ☐ Absent ☐ Present ☐ Unknown	% B-cells: ____ ☐ Not evaluated	_ _ _ _/ _ _/ _ _	☐ No ☐ Yes ☐ Unknown	☐ No ☐ Yes ☐ Unknown
Bone marrow aplasia ☐ Absent ☐ Present ☐ Unknown		_ _ _ _/ _ _/ _ _	☐ No ☐ Yes ☐ Unknown	☐ No ☐ Yes ☐ Unknown
Hypogammaglobulinemia ☐ Absent ☐ Present: Was it also present at time of the cellular therapy? ☐ No, occurred after the cellular therapy ☐ Yes: Was it worsened by the cellular therapy? ☐ No ☐ Yes		_ _ _ _/ _ _/ _ _	☐ No ☐ Yes ☐ Unknown	☐ No ☐ Yes ☐ Unknown
Exacerbation of existing neurological disorder, specify: _____ ☐ Absent ☐ Present ☐ Unknown	☐ 2 ☐ 3 ☐ 4 ☐ 5 (fatal) ☐ Unknown	_ _ _ _/ _ _/ _ _	☐ No ☐ Yes ☐ Unknown	☐ No ☐ Yes ☐ Unknown
Other complication, specify: _____ ☐ Absent ☐ Present ☐ Unknown	☐ 2 ☐ 3 ☐ 4 ☐ 5 (fatal) ☐ Unknown	_ _ _ _/ _ _/ _ _	☐ No ☐ Yes ☐ Unknown	☐ No ☐ Yes ☐ Unknown

*If not otherwise specified, CTCAE grading system is to be used.

COMPLICATIONS SINCE THE LAST REPORT
-- 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 infectious complications occur during the follow-up period?

☐ No (*proceed to 'SARS-CoV2 related questions' on page 12*)
☐ Yes (*report all infectious complications below*)

Bacterial infection: ☐ No ☐ Yes

1) Start date: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*

☐ Gram-positive ☐ Gram-negative ☐ Other

Pathogen*: _____

Infection with clinical implications: ☐ No ☐ Yes:
- ☐ Symptoms/signs of disease
- ☐ Administration of pathogen-directed therapy
- ☐ Isolation precautions or surveillance

☐ Unknown

Localisation (CTCAE term)**: _____

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

Resolved: ☐ No ☐ Yes ☐ Unknown

2) Start date: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*

☐ Gram-positive ☐ Gram-negative ☐ Other

Pathogen*: _____

Infection with clinical implications: ☐ No ☐ Yes:
- ☐ Symptoms/signs of disease
- ☐ Administration of pathogen-directed therapy
- ☐ Isolation precautions or surveillance

☐ Unknown

Localisation (CTCAE term)**: _____

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

Resolved: ☐ No ☐ Yes ☐ Unknown

If more than 2 episodes, copy and fill-in this table as many times as necessary.

* Indicate the pathogen and sub-type (if applicable) from the list of pathogens provided in Appendix 1 at pages 27-28
** Indicate CTCAE term by choosing from the list provided in Appendix 2 at page 29
*** If intravascular catheter-related infection, specify it by choosing from the list provided in Appendix 3 at page 29

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COMPLICATIONS SINCE THE LAST REPORT
-- Infectious complications -- continued

Viral infection: ☐ No ☐ Yes

1) Start date: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*

Pathogen*: _____

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

Infection with clinical implications: ☐ No ☐ Yes:
- ☐ Symptoms/signs of disease
- ☐ Administration of pathogen-directed therapy
- ☐ Isolation precautions or surveillance

☐ Unknown

Localisation (CTCAE term)**: _____

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

Resolved: ☐ No ☐ Yes ☐ Unknown

---

2) Start date: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*

Pathogen*: _____

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

Infection with clinical implications: ☐ No ☐ Yes:
- ☐ Symptoms/signs of disease
- ☐ Administration of pathogen-directed therapy
- ☐ Isolation precautions or surveillance

☐ Unknown

Localisation (CTCAE term)**: _____

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

Resolved: ☐ No ☐ Yes ☐ Unknown

If more than 2 episodes, copy and fill-in this table as many times as necessary.

* Indicate the pathogen and sub-type (if applicable) from the list of pathogens provided in Appendix 1 at pages 27-28
** Indicate CTCAE term by choosing from the list provided in Appendix 2 at page 29
*** If intravascular catheter-related infection, specify it by choosing from the list provided in Appendix 3 at page 29

COMPLICATIONS SINCE THE LAST REPORT
-- Infectious complications -- continued

Fungal infection: ☐ No ☐ Yes

1) Start date: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*

☐ Yeasts ☐ Moulds

Pathogen*: _____

Infection with clinical implications: ☐ No
☐ Yes:
- ☐ Symptoms/signs of disease
- ☐ Administration of pathogen-directed therapy
- ☐ Isolation precautions or surveillance

☐ Unknown

Localisation (CTCAE term)**: _____

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

Resolved: ☐ No ☐ Yes ☐ Unknown

2) Start date: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*

☐ Yeasts ☐ Moulds

Pathogen*: _____

Infection with clinical implications: ☐ No
☐ Yes:
- ☐ Symptoms/signs or disease
- ☐ Administration of pathogen-directed therapy
- ☐ Isolation precautions or surveillance

☐ Unknown

Localisation (CTCAE term)**: _____

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

Resolved: ☐ No ☐ Yes ☐ Unknown

If more than 2 episodes, copy and fill-in this table as many times as necessary.

* Indicate the pathogen and sub-type (if applicable) from the list of pathogens provided in Appendix 1 at pages 27-28
** Indicate CTCAE term by choosing from the list provided in Appendix 2 at page 29
*** If intravascular catheter-related infection, specify it by choosing from the list provided in Appendix 3 at page 29

COMPLICATIONS SINCE THE LAST REPORT
-- Infectious complications -- continued

Parasitic infection: ☐ No ☐ Yes

1) Start date: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*

☐ Protozoa ☐ Helminths

Pathogen*: _____

Infection with clinical implications: ☐ No
☐ Yes:
- ☐ Symptoms/signs or disease
- ☐ Administration of pathogen-directed therapy
- ☐ Isolation precautions or surveillance

☐ Unknown

Localisation (CTCAE term)**: _____

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

Resolved: ☐ No ☐ Yes ☐ Unknown

2) Start date: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*

☐ Protozoa ☐ Helminths

Pathogen*: _____

Infection with clinical implications: ☐ No
☐ Yes:
- ☐ Symptoms/signs or disease
- ☐ Administration of pathogen-directed therapy
- ☐ Isolation precautions or surveillance

☐ Unknown

Localisation (CTCAE term)**: _____

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

Resolved: ☐ No ☐ Yes ☐ Unknown

If more than 2 episodes, copy and fill-in this table as many times as necessary.

* Indicate the pathogen and sub-type (if applicable) from the list of pathogens provided in Appendix 1 at pages 27-28
** Indicate CTCAE term by choosing from the list provided in Appendix 2 at page 29
*** If intravascular catheter-related infection, specify it by choosing from the list provided in Appendix 3 at page 29

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) Start date: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*
Infection with clinical implications: ☐ No
☐ Yes:
- ☐ Symptoms/signs or disease
- ☐ Administration of pathogen-directed therapy
- ☐ Isolation precautions or surveillance

☐ Unknown

Localisation (CTCAE term):** _____

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

Resolved: ☐ No ☐ Yes ☐ Unknown

2) Start date: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*
Infection with clinical implications: ☐ No
☐ Yes:
- ☐ Symptoms/signs or disease
- ☐ Administration of pathogen-directed therapy
- ☐ Isolation precautions or surveillance

☐ Unknown

Localisation (CTCAE term):** _____

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

Resolved: ☐ No ☐ Yes ☐ Unknown

If more than 2 episodes, copy and fill-in this table as many times as necessary.

* Indicate the pathogen and sub-type (if applicable) from the list of pathogens provided in Appendix 1 at pages 27-28
** Indicate CTCAE term by choosing from the list provided in Appendix 2 at page 29
*** If intravascular catheter-related infection, specify it by choosing from the list provided in Appendix 3 at page 29

SARS-CoV-2 RELATED QUESTIONS

Did the patient receive a vaccination against SARS-CoV-2 after CT?

☐ No

☐ Yes: Number of doses: _____

Date of the last dose: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*

Did the patient have a SARS-CoV-2 infection after CT *(positive PCR or antigen test)***:**

☐ No

☐ Yes: Date: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*

If more than one episode *(new confirmed infection at least ≥ 90 days after the clearance of the previous one or at any time if evidence of a different variant):*

Date: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*

Date: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*

SECONDARY MALIGNANCIES AND AUTOIMMUNE DISORDERS

Did a secondary malignancy or autoimmune disorder occur?

☐ 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:
☐ No	☐ No
☐ Yes	☐ Yes
☐ Unknown	☐ Unknown

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

☐ No (*complete the relevant non-indication diagnosis form*)

☐ Yes (*complete the relevant indication diagnosis form*)

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)*

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

Technique used for testing:
- ☐ Molecular (PCR)
- ☐ Flow cytometry
- ☐ Chimerism
- ☐ 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)*

POST-THERAPY TREATMENT

Include only systemic treatments designed to consolidate the anti-tumour activity of CT cells, prevent relapse (i.e. administration of immune checkpoint inhibitors) or treat complications. Do not include supportive care, including anti-infectious agents. Indicate only treatments that have not been reported at previous follow-up(s).

Did the patient undergo additional treatment during or immediately after this cellular therapy or since the last follow-up?

☐ No

☐ Yes; Date started: _ _ _ _ / _ _ / _ _ (*YYYY/MM/DD)*

☐ Unknown

Did the patient receive additional cell infusions *(excluding a new HCT and CT)***?**

☐ No

☐ Yes; **Is this cell infusion an allogeneic boost* ?** ☐ No ☐ Yes; Date of the boost: _ _ _ _ / _ _ / _ _ (*YYYY/MM/DD)*

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

Is this cell infusion an autologous boost? ☐ No ☐ Yes; Date of the boost: _ _ _ _ / _ _ / _ _ (*YYYY/MM/DD)*

If the cell infusion is not a boost, attach the Cell Infusion (CI) sheet available in Appendix 4 at page 30, completing as many CI sheets as episodes of cell infusion that took place during this period; then continue with questions below.

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

☐ No

☐ Yes

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

Radiotherapy:

☐ No

☐ Yes

☐ Unknown

Drugs/chemotherapy:

☐ No (*continue at page 16)*

☐ Yes (*complete the table on the next page)*

POST-THERAPY TREATMENT continued

List all chemotherapy/drugs given during one line of treatment:

Line of treatment	Drug/regimen used*	Start date *(YYYY/MM/DD)*	Reason	Response to this line of treatment	Response assessment date *(YYYY/MM/DD)*
1		_ _ _ _/ _ _ / _ _	☐ Prophylaxis/preventive ☐ Relapse ☐ Maintenance ☐ Consolidation ☐ Non-inf. complications ☐ Infectious complications ☐ Other; specify_____	☐ Continued complete remission (CCR) ☐ Complete remission (CR) ☐ Partial remission ☐ No response/Stable disease/No change ☐ Disease progression ☐ Not evaluated ☐ Unknown	_ _ _ _/ _ _ / _ _
2		_ _ _ _/ _ _ / _ _	☐ Prophylaxis/preventive ☐ Relapse ☐ Maintenance ☐ Consolidation ☐ Non-inf. complications ☐ Infectious complications ☐ Other; specify_____	☐ Continued complete remission (CCR) ☐ Complete remission (CR) ☐ Partial remission ☐ No response/Stable disease/No change ☐ Disease progression ☐ Not evaluated ☐ Unknown	_ _ _ _/ _ _ / _ _
3		_ _ _ _/ _ _ / _ _	☐ Prophylaxis/preventive ☐ Relapse ☐ Maintenance ☐ Consolidation ☐ Non-inf. complications ☐ Infectious complications ☐ Other; specify_____	☐ Continued complete remission (CCR) ☐ Complete remission (CR) ☐ Partial remission ☐ No response/Stable disease/No change ☐ Disease progression ☐ Not evaluated ☐ Unknown	_ _ _ _/ _ _ / _ _
4		_ _ _ _/ _ _ / _ _	☐ Prophylaxis/preventive ☐ Relapse ☐ Maintenance ☐ Consolidation ☐ Non-inf. complications ☐ Infectious complications ☐ Other; specify_____	☐ Continued complete remission (CCR) ☐ Complete remission (CR) ☐ Partial remission ☐ No response/Stable disease/No change ☐ Disease progression ☐ Not evaluated ☐ Unknown	_ _ _ _/ _ _ / _ _

Copy and fill-in this section as many times as necessary.

*Please consult the **LIST OF CHEMOTHERAPY DRUGS/AGENTS AND REGIMENS** on the EBMT website for drugs/regimens names.

POST-THERAPY TREATMENT continued

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 cellular therapy (which was not part of this cellular therapy), please, make sure that this subsequent treatment is registered using a new CT treatment form before proceeding.

Is the patient receiving any medication not related to cell therapy or its indications?

☐ No

☐ Yes

☐ Unknown

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 OR SIGNIFICANT WORSENING

Was there a relapse/progression or significant worsening of organ function related to the primary disease after CT? *(detected by any method)*

☐ No

☐ Continuous progression since CT

☐ Yes: Number of relapses/progressions since CT: ____

Date of first relapse/progression: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*

Date of subsequent relapse/progression: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*

If more than 2 relapses/progressions occurred, copy and fill-in this section as many times as necessary.

Type of relapse:

☐ Medullary only

☐ Extra-medullary only

☐ Both, medullary and extra-medullary

☐ Unknown

If the relapse was extra-medullary or both medullary and extra-medullary:

Involvement at time of relapse:

Medullary:	☐ No	☐ Yes	☐ Not evaluated
Skin:	☐ No	☐ Yes	☐ Not evaluated
CNS:	☐ No	☐ Yes	☐ Not evaluated
Testes/Ovary:	☐ No	☐ Yes	☐ Not evaluated
Other:	☐ No	☐ Yes; specify: _____	

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:									
☐ Karnofsky ☐ Lansky	☐ 10	☐ 20	☐ 30	☐ 40	☐ 50	☐ 60	☐ 70	☐ 80	☐ 90	☐ 100
☐ ECOG	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4					

PREGNANCY AFTER CELLULAR THERAPY

Complete only for 6 Months and Annual/Unscheduled Follow-Up.

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

- ☐ No
- ☐ Yes: Did the pregnancy result in a live birth?
  - ☐ No
  - ☐ Yes
  - ☐ Still pregnant at time of follow-up
  - ☐ Unknown
- ☐ Unknown

CAUSE OF DEATH

Main cause of death:
(check only one main cause)

- ☐ Relapse or progression/persistent disease
- ☐ Secondary malignancy
- ☐ Cellular therapy-related
- ☐ HCT-related

Select treatment related cause:

- ☐ Graft versus Host Disease
- ☐ Non-infectious complication
- ☐ Infectious complication: *(select all that apply)*
  - ☐ Bacterial infection
  - ☐ Viral infection
  - ☐ Fungal infection
  - ☐ Parasitic infection
  - ☐ Infection with unknown pathogen

- ☐ Unknown
- ☐ Other; specify: _____

END OF GENERAL SECTION

TO COMPLETE FOLLOW-UP REPORT, PLEASE FILL IN THE APPLICABLE DIAGNOSE-SPECIFIC QUESTIONS ATTACHED

LAST DISEASE STATUS

Complete only if the indication was the treatment of a primary disease including infections; complete only one section with the main indication diagnosis for which cellular therapy was given.

ACUTE LEUKAEMIAS
Other Acute Leukaemias - Last Disease Status

Status:

☐ Primary induction failure

☐ Complete haematological remission (CR)

Number:	Cytogenetic remission:	Molecular remission:
☐ 1st	☐ No	☐ No
☐ 2nd	☐ Yes	☐ Yes
☐ 3rd or higher	☐ Not evaluated	☐ Not evaluated
	☐ Not applicable *	☐ Not applicable *
	☐ Unknown	☐ Unknown

** No abnormalities detected prior to this time point*

☐ Relapse

Number:

☐ 1st
☐ 2nd
☐ 3rd or higher

CHRONIC LEUKAEMIAS
Chronic Myeloid Leukaemias (CML) - Last Disease Status

Status:

☐ Chronic phase (CP)

Number:	Haematological remission:	Cytogenetic remission:	Molecular remission:
☐ 1st	☐ No	☐ No	☐ No
☐ 2nd	☐ Yes	☐ Yes	☐ Yes
☐ 3rd or higher	☐ Not evaluated	☐ Not evaluated	☐ Not evaluated
	☐ Unknown	☐ Not applicable *	☐ Not applicable *
		☐ Unknown	☐ Unknown

** No abnormalities detected prior to this time point*

☐ Accelerated phase

Number:
- ☐ 1st
- ☐ 2nd
- ☐ 3rd or higher

☐ Blast crisis

Number:
- ☐ 1st
- ☐ 2nd
- ☐ 3rd or higher

CHRONIC LEUKAEMIAS
Chronic Lymphoid Leukaemias (CLL) - Last Disease Status

Status:

☐ Complete remission (CR)

☐ Partial remission (PR)

Minimal residual disease (MRD) *(by FACS or PCR)*

☐ Negative ☐ Positive ☐ Not evaluated

☐ Stable disease (SD)

☐ Relapse (untreated)

☐ Progressive disease (PD)

☐ Never treated

CHRONIC LEUKAEMIAS
Prolymphocytic and Other Chronic Leukaemias (PLL & Other) - Last Disease Status

Status:

- ☐ Complete remission (CR)
- ☐ Partial remission (PR)
- ☐ Stable disease (SD)
- ☐ Relapse (untreated)
- ☐ Progressive disease (PD)
- ☐ Never treated

LYMPHOMAS
All Lymphomas - Last Disease Status

Technique used for disease assessment:

CT Scan done:	PET:
☐ No	☐ Negative
☐ Yes	☐ Positive
	☐ Not evaluated

Status:

- ☐ Never treated
- ☐ Complete remission (CR)
  - ☐ Unconfirmed (CRU *) ☐ Confirmed
  - ** CRU: Complete response with persistent scan abnormalities of unknown significance*
- ☐ Partial response (PR) with or without a prior CR
- ☐ Stable disease
- ☐ Untreated relapse from a previous CR / untreated progression from a previous PR
  - Histopathological verification of relapse: ☐ No ☐ Yes
- ☐ Chemorefractory relapse or progression, including primary refractory disease
  - Histopathological verification of relapse: ☐ No ☐ Yes
- ☐ Disease status unknown or Not evaluated/Not evaluable

MYELODYSPLASTIC SYNDROMES (MDS) - Last Disease Status

Status:

Treated with chemotherapy:

☐ Primary refractory phase (no change)

☐ Complete remission (CR) — Number:
- ☐ 1st
- ☐ 2nd
- ☐ 3rd or higher

☐ Improvement but no CR

☐ Relapse after CR — Number:
- ☐ 1st
- ☐ 2nd
- ☐ 3rd or higher

☐ Progression/Worsening

☐ Never treated (supportive care or treatment without chemotherapy)

COMBINED MYELODYSPLASTIC SYNDROMES/MYELOPROLIFERATIVE NEOPLASMS (MDS/MPN) - Last Disease Status

Status:

Treated with chemotherapy:

☐ Primary refractory phase (no change)

☐ Complete remission (CR) — Number:
- ☐ 1st
- ☐ 2nd
- ☐ 3rd or higher

☐ Improvement but no CR

☐ Relapse after CR — Number:
- ☐ 1st
- ☐ 2nd
- ☐ 3rd or higher

☐ Progression/Worsening

☐ Never treated (supportive care or treatment without chemotherapy)

MYELOPROLIFERATIVE NEOPLASMS (MPN) - Last Disease Status

Status:

Treated with chemotherapy: ☐ Primary refractory phase (no change)	
☐ Complete remission (CR)	Number: ☐ 1st ☐ 2nd ☐ 3rd or higher
☐ Improvement but no CR	
☐ Relapse after CR	Number: ☐ 1st ☐ 2nd ☐ 3rd or higher
☐ Progression/Worsening	
☐ Never treated (supportive care or treatment without chemotherapy)	

PLASMA CELL DISORDERS (PCD) incl. MULTIPLE MYELOMA (MM) - Last Disease Status

Status:

☐ Never treated	
☐ Stringent complete remission (SCR) ☐ Complete remission (CR) ☐ Very good partial remission (VGPR) ☐ Partial remission (PR) ☐ Relapse from CR (untreated)	Number: ☐ 1st ☐ 2nd ☐ 3rd or higher
☐ Progression	
☐ Stable disease / No change	

SOLID TUMOURS - Last Disease Status

Status:

- ☐ Adjuvant
- ☐ Never treated *(upfront)*
- ☐ Stable disease/No response
- ☐ Complete remission (CR)
  - ☐ Unconfirmed (CRU*)
  - ☐ Confirmed

  * *CRU: complete response with persistent scan abnormalities of unknown significance*

  Number:
  - ☐ 1st
  - ☐ 2nd
  - ☐ 3rd or higher
- ☐ 1st partial response (PR1)
- ☐ Relapse

  Number:
  - ☐ 1st
  - ☐ 2nd
  - ☐ 3rd or higher

  Sensitivity to chemotherapy:
  - ☐ Sensitive
  - ☐ Resistant
  - ☐ Untreated
- ☐ Progressive disease (PD)

BONE MARROW FAILURE SYNDROMES (BMF) incl. APLASTIC ANAEMIA (AA) - Last Disease Status

Status:

- ☐ Stable disease/No response
- ☐ Complete remission (CR)
- ☐ Partial remission
- ☐ Relapse/Progression

HAEMOGLOBINOPATHIES - Last Disease Status

Transfusion status:

- ☐ No transfusion required
- ☐ Transfusion required: Date of the 1st transfusion: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*

OTHER DIAGNOSES - Last Disease Status

Status:

☐ Cured
☐ Improved
☐ Unchanged
☐ Worse

Appendix 1
-- 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:
- Clostridium difficile
- Enterococcus faecalis Vancomycin susceptible
- Enterococcus faecalis Vancomycin-resistant
- Enterococcus faecium Vancomycin susceptible
- Enterococcus faecium Vancomycin-resistant
- Listeria monocytogenes
- Nocardia spp (specify)
- Staphylococcus aureus MRSA (methicillin-resistant)
- Staphylococcus aureus MSSA (methicillin-susceptible)
- Staphylococcus aureus VISA (intermediate vancomycin resistant , MIC 4-8 µg/ml)
- Staphylococcus aureus VRSA (Vancomycin-resistant, MIC ≥ 16µg/ml)
- Staphylococcus coagulase-negative spp (at least two positive blood cultures)
- Streptococcus pneumoniae
- Streptococcus viridans
- Streptococcus other species (specify)
- Gram-positive bacteria other species (specify)

Gram-negative:
- Acinetobacter baumannii
- Campylobacter jejuni
- Citrobacter freundii
- Enterobacter cloacae
- Enterobacter other species (specify)
- Escherichia coli
- Haemophilus influenzae
- Helicobacter pylori
- Klebsiella aerogenes (carbapenem susceptible)
- Klebsiella pneumoniae (carbapenem susceptible)
- Klebsiella 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 species (specify)

Other bacteria:
- Chlamydia species
- Chlamydophila
- Mycobacterium other spp (specify)
- Mycobacterium tuberculosis
- Mycoplasma pneumoniae
- Rickettsia species
- 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 1
-- 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)
· Mucormycosis (specify)
· Phaeohyphomycosis (specify)
· Scedosporium spp (specify)
· Moulds other species (specify)
· Mould infection diagnosed based on positive galactomannan only, without microbiological confirmation
· Blastomycosis
· Histoplasmosis (specify)
· Coccidiomycosis
· Paracoccidiomycosis

Parasitic infections:

Protozoa:
· Babesiosis (specify)
· Cryptosporidium
· Giardiasis
· Leishmaniasia spp (specify)
· Plasmodium spp (specify)
· Toxoplasma gondii
· Trypanosoma cruzi
· Protozoa other species (specify)

Helminths:
· Strongyloides stercoralis
· Other helminths

Appendix 2
-- 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
· Bronchial infection
· Lung infection
· Laryngitis
· Pleural infection
· Tracheitis
· Upper respiratory infection

Intra-abdominal infections
· Anorectal infection
· Appendicitis
· Appendicitis perforated
· Biliary tract infection
· Cecal infection
· Duodenal infection
· Enterocolitis infectious
· Esophageal infection
· Gallbladder infection
· Gastritis
· Hepatic infection
· Pancreas infection
· Pelvic infection
· Peritoneal infection
· Splenic infection
· Stoma site infection
· Small intestine infection
· Typhilitis

Uro-genital tract infections
· Bladder infection
· Cervicitis infection
· Kidney infection
· Ovarian infection
· Scrotal infection
· Penile infection
· Prostate infection
· Urethral infection
· Urinary tract infection
· Uterine infection
· Vaginal infection
· Vulval infection

Muscles and bones
· Bone infection
· Myositis infective
· Joint infection

Nervous system infection
· Cranial nerve infection
· Encephalitis infection
· Encephalomyelitis infection
· Meningitis
· Myelitis
· Peripheral nerve infection

Cardiovascular infections
· Arteritis infective
· Endocarditis infective
· Mediastinal infection
· Phlebitis infective

Skin, soft tissue and mucosal surfaces
· Breast infection
· Folliculitis
· Lymph gland infection
· Nail infection
· Mucosal infection
· Papulopustular rash
· Paronychia
· Rash pustular
· Skin infection
· Soft tissue infection
· Wound infection

Head and neck
· Conjunctivitis infective
· Corneal infection
· Endophthalmitis
· Eye infection
· Gum infection
· Lip infection
· Oral cavity
· Otitis externa
· Otitis media
· Periorbital infection
· Salivary gland infection
· Sinusitis
· Tooth infection

Blood
· Bacteremia
· Fungemia
· Viremia

Others
· Device related infection (other than Intravascular catheter)
· Sepsis

Appendix 3
-- Intravascular catheter-related infections --

CVC infections:
Catheter colonization
Phlebitis
Exit site infection
Tunnel infection
Pocket infection
Bloodstream infection

Appendix 4
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 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
- ☐ Other; specify: _____

Disease status at time of this cell infusion:
- ☐ Complete remission (CR)
- ☐ Not in CR
- ☐ Not evaluated

Indication:
(check all that apply)
- ☐ Planned/protocol
- ☐ Prophylactic
- ☐ Treatment of acute GvHD
- ☐ Treatment of chronic GvHD
- ☐ Treatment PTLD, EBV lymphoma
- ☐ Treatment for primary disease
- ☐ Mixed chimaerism
- ☐ Loss/decreased chimaerism
- ☐ Treatment viral infection
- ☐ Poor graft function
- ☐ Infection prophylaxis
- ☐ Other; specify: _____

Acute GvHD -- maximum grade *(after this infusion episode but before any further infusion/transplant)*:
- ☐ 0 (none)
- ☐ 1
- ☐ 2
- ☐ 3
- ☐ 4
- ☐ Present but grade unknown