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)

☐ Relapse or progression/persistent disease	
☐ Secondary malignancy	
☐ CT-related	**Select treatment related cause:** *(select all that apply)* ☐ 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
☐ HCT-related	
☐ GT-related	
☐ IST-related	
☐ Unknown	
☐ Other; specify: _____	

Was an autopsy performed?

☐ No
☐ Yes
☐ Unknown

BEST RESPONSE

Complete only once at one of the assessment periods: 100 days, 6 months or first annual follow-up
Not applicable for Inborn Errors

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

Date best response first observed: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* ☐ Unknown

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

BEST RESPONSE continued

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

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

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 ≥ 0.5x10^9 /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 ≥ 20x10^9 /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 <u>first</u> 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	☐ Not evaluated	☐ Unknown
Platelets	_____ 10^9 /L	☐ Not evaluated	☐ Unknown
Were platelets transfused within 7 days before assessment?		☐ No ☐ Yes	☐ Unknown
White blood cells	_____ 10^9 /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 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:	☐ 0 *(none)*	☐ 1	☐ 2	☐ 3	☐ 4	☐ Not evaluated	☐ Unknown
Liver:	☐ 0 *(none)*	☐ 1	☐ 2	☐ 3	☐ 4	☐ Not evaluated	☐ Unknown
Lower GI tract:	☐ 0 *(none)*	☐ 1	☐ 2	☐ 3	☐ 4	☐ Not evaluated	☐ Unknown
Upper GI tract:	☐ 0 *(none)*	☐ 1	☐ 2	☐ 3	☐ 4	☐ Not evaluated	☐ Unknown
Other site affected:	☐ No	☐ 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:	☐ 0 *(none)*	☐ 1	☐ 2	☐ 3	☐ 4	☐ Not evaluated	☐ Unknown
Oral:	☐ 0 *(none)*	☐ 1	☐ 2	☐ 3	☐ 4	☐ Not evaluated	☐ Unknown
Gastrointestinal:	☐ 0 *(none)*	☐ 1	☐ 2	☐ 3	☐ 4	☐ Not evaluated	☐ Unknown
Eyes:	☐ 0 *(none)*	☐ 1	☐ 2	☐ 3	☐ 4	☐ Not evaluated	☐ Unknown
Liver:	☐ 0 *(none)*	☐ 1	☐ 2	☐ 3	☐ 4	☐ Not evaluated	☐ Unknown
Joints and fascia:	☐ 0 *(none)*	☐ 1	☐ 2	☐ 3	☐ 4	☐ Not evaluated	☐ Unknown
Lungs:	☐ 0 *(none)*	☐ 1	☐ 2	☐ 3	☐ 4	☐ Not evaluated	☐ Unknown
Genitalia:	☐ 0 *(none)*	☐ 1	☐ 2	☐ 3	☐ 4	☐ Not evaluated	☐ Unknown
Other site affected:	☐ No	☐ Yes; specify: _____					

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

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

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

☐ Unknown

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

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

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

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

Cytokine release syndrome (CRS)

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

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

Grading system:
☐ ASTCT consensus (Lee 2019)
☐ Penn
☐ CTCAE
☐ Lee 2014
☐ MDACC
☐ Other; specify: _____

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

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

IEC-associated neurotoxicity syndrome (ICANS)

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

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

Grading system:
☐ ASTCT consensus (Lee 2019)
☐ CTCAE
☐ Lee 2014
☐ MDACC
☐ Other; specify: _____

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

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

* Grade 0-2

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

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

Specify:_____

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

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

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

Macrophage activation syndrome (MAS)

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

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

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

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

Secondary haemophagocytic lymphohistiocytosis

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

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

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

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

Organ toxicity: skin

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

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

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

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

*Grade 0-2

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

Organ toxicity: liver

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

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

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

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

Organ toxicity: lung

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

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

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

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

Organ toxicity: heart

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

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

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

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

Organ toxicity: kidney

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

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

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

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

* Grade 0-2

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

Organ toxicity: gastrointestinal

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

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

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

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

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

Organ specify:_____

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

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

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

Tumour lysis syndrome

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

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

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

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

B-cell aplasia

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

% B-cells: ____ ☐ Not evaluated

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

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

* Grade 0-2

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

Bone marrow aplasia

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

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

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

Hypogammaglobulinemia

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

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

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

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

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

Specify:_____
(Indicate CTCAE term)

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

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

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

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

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

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

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

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

*Grade 0-2

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

COMPLICATIONS SINCE THE LAST REPORT
-- Infectious complications --

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

Did infectious complications occur during the follow-up period?

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

Bacterial infection: ☐ No ☐ Yes ☐ Unknown

1) **New or ongoing:** ☐ Newly developed ☐ Ongoing since previous assessment
Start date: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* *only if newly developed*
☐ Gram-positive ☐ Gram-negative ☐ Other
Pathogen*: _____
Infection with clinical implications: ☐ No ☐ Yes: *(select all that apply during this period)*
☐ Symptoms/signs of disease
☐ Administration of pathogen-directed therapy
☐ Unknown
Indicate at least 1 location involved during this period:
Localisation 1 (CTCAE term)**: _____
Localisation 2 (CTCAE term)**: _____
Localisation 3 (CTCAE term)**: _____
Intravascular catheter-related infection: ☐ No ☐ Yes; specify***: _____ ☐ Unknown
Resolved: ☐ No ☐ Yes ☐ Unknown
(if patient died)
Contributory cause of death: ☐ No ☐ Yes ☐ Unknown

2) **New or ongoing:** ☐ Newly developed ☐ Ongoing since previous assessment
Start date: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* *only if newly developed*
☐ Gram-positive ☐ Gram-negative ☐ Other
Pathogen*: _____
Infection with clinical implications: ☐ No ☐ Yes: *(select all that apply during this period)*
☐ Symptoms/signs of disease
☐ Administration of pathogen-directed therapy
☐ Unknown
Indicate at least 1 location involved during this period:
Localisation 1 (CTCAE term)**: _____
Localisation 2 (CTCAE term)**: _____
Localisation 3 (CTCAE term)**: _____
Intravascular catheter-related infection: ☐ No ☐ Yes; specify***: _____ ☐ Unknown
Resolved: ☐ No ☐ Yes ☐ Unknown
(if patient died)
Contributory cause of death: ☐ No ☐ Yes ☐ Unknown

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

* Indicate the pathogen and sub-type (if applicable) by choosing from the list of pathogens provided in Appendix 2
** Indicate CTCAE term by choosing from the list provided in Appendix 3
*** If intravascular catheter-related infection, specify it by choosing from the list provided in Appendix 5

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

Viral infection: ☐ No ☐ Yes ☐ Unknown

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

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

Pathogen*: _____

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

Infection with clinical implications: ☐ No ☐ Yes: *(select all that apply during this period)*
- ☐ Symptoms/signs of disease
- ☐ Administration of pathogen-directed therapy

☐ Unknown

Indicate at least 1 location involved during this period:

Localisation 1 (CTCAE term)**: _____

Localisation 2 (CTCAE term)**: _____

Localisation 3 (CTCAE term)**: _____

Resolved: ☐ No ☐ Yes ☐ Unknown

(if patient died)
Contributory cause of death: ☐ No ☐ Yes ☐ Unknown

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

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

Pathogen*: _____

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

Infection with clinical implications: ☐ No ☐ Yes: *(select all that apply during this period)*
- ☐ Symptoms/signs of disease
- ☐ Administration of pathogen-directed therapy

☐ Unknown

Indicate at least 1 location involved during this period:

Localisation 1 (CTCAE term)**: _____

Localisation 2 (CTCAE term)**: _____

Localisation 3 (CTCAE term)**: _____

Resolved: ☐ No ☐ Yes ☐ Unknown

(if patient died)
Contributory cause of death: ☐ No ☐ Yes ☐ Unknown

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

* Indicate the pathogen and sub-type (if applicable) by choosing from the list of pathogens provided in Appendix 2
** Indicate CTCAE term by choosing from the list provided in Appendix 3
*** If intravascular catheter-related infection, specify it by choosing from the list provided in Appendix 5

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

Fungal infection: ☐ No ☐ Yes ☐ Unknown

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 ☐ Unknown

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

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

☐ Protozoa ☐ Helminths

Pathogen*: _____

Infection with clinical implications: ☐ No
☐ Yes: *(select all that apply during this period)*
☐ Symptoms/signs or disease
☐ Administration of pathogen-directed therapy
☐ Unknown

Indicate at least 1 location involved during this period:

Localisation 1 (CTCAE term)**: _____

Localisation 2 (CTCAE term)**: _____

Localisation 3 (CTCAE term)**: _____

Resolved: ☐ No ☐ Yes ☐ Unknown

(if patient died)

Contributory cause of death: ☐ No ☐ Yes ☐ Unknown

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

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

☐ Protozoa ☐ Helminths

Pathogen*: _____

Infection with clinical implications: ☐ No
☐ Yes: *(select all that apply during this period)*
☐ Symptoms/signs or disease
☐ Administration of pathogen-directed therapy
☐ Unknown

Indicate at least 1 location involved during this period:

Localisation 1 (CTCAE term)**: _____

Localisation 2 (CTCAE term)**: _____

Localisation 3 (CTCAE term)**: _____

Resolved: ☐ No ☐ Yes ☐ Unknown

(if patient died)

Contributory cause of death: ☐ No ☐ Yes ☐ Unknown

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

* Indicate the pathogen and sub-type (if applicable) by choosing from the list of pathogens provided in Appendix 2
** Indicate CTCAE term by choosing from the list provided in Appendix 3
*** If intravascular catheter-related infection, specify it by choosing from the list provided in Appendix 5

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

Infection with unknown pathogen: ☐ No ☐ Yes: ☐ Unknown
(for clinical infections without microbiological documentation, like pneumonia, cellulitis, etc.)

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

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

Infection with clinical implications: ☐ No
☐ Yes: *(select all that apply during this period)*
☐ Symptoms/signs or disease
☐ Administration of pathogen-directed therapy
☐ Unknown

Indicate at least 1 location involved during this period:

Localisation 1 (CTCAE term)*: _____

Localisation 2 (CTCAE term)*: _____

Localisation 3 (CTCAE term)*: _____

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

Resolved: ☐ No ☐ Yes ☐ Unknown

(if patient died)
Contributory cause of death: ☐ No ☐ Yes ☐ Unknown

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

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

Infection with clinical implications: ☐ No
☐ Yes: *(select all that apply during this period)*
☐ Symptoms/signs or disease
☐ Administration of pathogen-directed therapy
☐ Unknown

Indicate at least 1 location involved during this period:

Localisation 1 (CTCAE term)*: _____

Localisation 2 (CTCAE term)*: _____

Localisation 3 (CTCAE term)*: _____

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

Resolved: ☐ No ☐ Yes ☐ Unknown

(if patient died)
Contributory cause of death: ☐ No ☐ Yes ☐ Unknown

If more than 2 infections with unknown pathogen, copy and fill-in this table as many times as necessary.

* Indicate CTCAE term by choosing from the list provided in Appendix 3
** If intravascular catheter-related infection, specify it by choosing from the list provided in Appendix 5

SECONDARY MALIGNANCIES AND AUTOIMMUNE DISORDERS

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

☐ No

☐ Yes:

☐ Iatrogenic disease in relation with treatments administered prior to cellular therapy cells indication and administration (i.e. cytotoxic agents, targeted therapies, immunotherapies, radiation therapy, etc. Please provide more details below)

☐ Transformation of engineered immune effector cells through insertional mutagenesis or other mechanisms (please provide more details below)

Further details on secondary malignancy or autoimmune disorder: _____

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

Histologic type *(if applicable)*: _____

Location *(if applicable)*: _____

Secondary malignancy material preserved:	Concomitant PBMCs preserved:
☐ No	☐ No
☐ Yes	☐ Yes
☐ Unknown	☐ 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)*

☐ Unknown

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

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

☐ No

☐ Yes

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

☐ No

☐ Yes; **Reason for subsequent CT:** ☐ Primary failure

☐ Consolidation

☐ Mitigation of side effects

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

HOSPITAL ADMISSION

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

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

☐ No

☐ Yes; **Number of days in hospital**: _____

☐ Unknown

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

☐ No

☐ Yes; **Number of days in ICU**: _____

☐ Unknown

RELAPSE/PROGRESSION, RECURRENCE OF DISEASE OR SIGNIFICANT WORSENING

(not relevant for Inborn Errors)

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

☐ No

☐ Yes; *for every relapse, progression, recurrence, significant worsening complete the questions below*

Type: ☐ Relapse / Recurrence of disease

☐ (Continuous) progression / Significant worsening

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

Malignant disorders only:

Type of relapse/progression:

Medullary: ☐ No ☐ Yes ☐ Unknown

Extramedullary: ☐ No ☐ Yes ☐ Unknown

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

Involvement at time of relapse/progression:

Skin: ☐ No ☐ Yes ☐ Not evaluated

CNS: ☐ No ☐ Yes ☐ Not evaluated

Testes/Ovaries: ☐ No ☐ Yes ☐ Not evaluated

Other: ☐ No ☐ Yes; specify: _____

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

☐ Unknown

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

☐ Absent

☐ Present

☐ Unknown

PATIENT STATUS

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

Type of scale used:	Score:
☐ Karnofsky ☐ Lansky	☐ 10 ☐ 20 ☐ 30 ☐ 40 ☐ 50 ☐ 60 ☐ 70 ☐ 80 ☐ 90 ☐ 100
☐ ECOG	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4
☐ Not evaluated	
☐ Unknown	

PREGNANCY AFTER CELLULAR THERAPY

Complete only after 6 Months

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

☐ No

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

- ☐ No; **Date of spontaneous or induced termination**: _ _ _ _ / _ _ / _ _ (YYYY/MM/DD) ☐ Unknown
- ☐ Yes; **Year of birth:** _ _ _ _ (YYYY) **Month of birth:** _ _ (MM) ☐ Unknown
- ☐ Still pregnant at time of follow-up
- ☐ Unknown

☐ Unknown

DISEASE STATUS

Disease specific

Not applicable for Inborn Errors

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

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

Appendix 1
Best Response and Disease Status (Disease Specific)

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

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

Appendix 1
Best Response and Disease Status (Disease Specific)

Acute leukaemias (AML, PLN, Other)

- ☐ Complete remission (CR)
- ☐ Not in complete remission
- ☐ Not evaluated
- ☐ Unknown

Proceed to next page for Diseases Status section

Chronic leukaemias (CML, CLL, PLL, Other)

Chronic Myeloid Leukaemia (CML):

- ☐ Chronic phase (CP); **Number**: ☐ 1st ☐ 2nd ☐ 3rd or higher ☐ Unknown
  - **Haematological remission:** ☐ No ☐ Yes ☐ Not evaluated ☐ Unknown
  - **Cytogenetic remission:** ☐ No ☐ Yes ☐ Not evaluated ☐ Unknown
  - **Molecular remission:** ☐ No ☐ Yes ☐ Not evaluated ☐ Unknown
- ☐ Accelerated phase; **Number**: ☐ 1st ☐ 2nd ☐ 3rd or higher ☐ Unknown
- ☐ Blast crisis; **Number**: ☐ 1st ☐ 2nd ☐ 3rd or higher ☐ Unknown
- ☐ Not evaluated
- ☐ Unknown

Proceed to next page for Diseases Status section

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

- ☐ Complete remission (CR)
- ☐ Partial remission (PR)
- ☐ Progression: ☐ Resistant to last regimen ☐ Sensitive to last regimen ☐ Unknown
- ☐ Stable disease (no change, no response/loss of response)
- ☐ Relapse
- ☐ Not evaluated
- ☐ Unknown

Proceed to next page for Diseases Status section

Plasma cell neoplasms (PCN)

- ☐ Complete remission (CR)
- ☐ Stringent complete remission (sCR)
- ☐ Very good partial remission (VGPR)
- ☐ Partial remission (PR)
- ☐ Relapse

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

- ☐ Progression
- ☐ Stable disease (no change, no response/loss of response)
- ☐ Not evaluated
- ☐ 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

☐ Complete remission (CR)	Number:	☐ 1st ☐ 2nd ☐ 3rd or higher ☐ Unknown
☐ Improvement but no CR		
☐ Primary refractory phase (no change)		
☐ Relapse	Number:	☐ 1st ☐ 2nd ☐ 3rd or higher ☐ Unknown
☐ Progression/Worsening		
☐ Not evaluated		
☐ Unknown		

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

Lymphomas

- ☐ Chemorefractory relapse or progression, including primary refractory disease
- ☐ Complete remission (CR): ☐ Confirmed ☐ Unconfirmed (CRU*) ☐ Unknown
- ☐ Partial remission (PR)
- ☐ Stable disease (no change, no response/loss of response)
- ☐ Untreated relapse (from a previous CR) or progression (from a previous PR)
- ☐ Not evaluated
- ☐ Unknown

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

Solid tumours

- ☐ Complete remission (CR): ☐ Confirmed ☐ Unconfirmed ☐ Unknown
- ☐ First partial remission
- ☐ Partial remission (PR)
- ☐ Progressive disease
- ☐ Relapse: ☐ Resistant ☐ Sensitive ☐ Unknown
- ☐ Stable disease (no change, no response/loss of response)
- ☐ Not evaluated
- ☐ Unknown

Bone marrow failures (incl. AA)

- ☐ Complete remission (CR)
- ☐ Partial remission (PR)
- ☐ Haematological improvement (HI); *NIH partial response*
- ☐ Stable disease (no change, no response/loss of response)
- ☐ Relapse / Progression
- ☐ Not evaluated
- ☐ Unknown

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

Did transfusions stop during the follow-up period?

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

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

Autoimmune disorders

- ☐ No evidence of disease
- ☐ Improved
- ☐ Unchanged
- ☐ Worse
- ☐ Not evaluated
- ☐ Unknown

Haemoglobinopathies

Thalassaemia:

Complete only for Thalassemia Best Response

☐ Transfusion independent;	**Date of last transfusion:** _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* ☐ Unknown *(after cellular therapy)*
☐ Transfusions required;	**Date of first transfusion:** _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* ☐ Unknown *(after cellular therapy)*
☐ Not evaluated	
☐ Unknown	

Complete only for Thalassemia Disease Status

Patient requires transfusions during follow-up period:

☐ No

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

☐ No return of sickling episodes
☐ Return of sickling episodes; **Date of first episode:** _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* ☐ Unknown *(after cellular therapy)*
☐ Not evaluated
☐ Unknown

Complete only for Sickle cell disease Disease Status

Sickling episodes occur during follow-up period:

☐ No
☐ Yes; ☐ First return of sickling episodes after cellular therapy **Date of first episode :** _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* ☐ Unknown (after cellular therapy) ☐ Ongoing presence of sickling episodes **Number of SCD episodes**: ____ ☐ Unknown (during follow-up)
☐ Unknown

Other diagnosis

☐ No evidence of disease
☐ Improved
☐ No response
☐ Worse
☐ Not evaluated
☐ 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

Intra-abdominal infections
· Esophagus or gastric infection
· Liver site infection (including biliary tract and gallbladder)
· Lower gastrointestinal infection
· Other intra-abdominal infection

Skin, soft tissue and muscle infections
. Lymph gland infection
. Skin, soft tissue or muscle infection

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
· Urinary tract infection

Nervous system infection
· Central nervous system infection
· Other nervous system infection

Cardiovascular infections
. Endocarditis infective
. Other cardiovascular infection

Head and neck infections (excluding lymph gland)
· Conjunctivitis infective
· Corneal infection
. Ear infection
· Endophthalmitis infective
· Oral cavity infection
· Retinitis infective
· Sinusitis infective

Osteoarticular infections
· Joint infection
· Bone infection

Appendix 4
-- Non-infectious and Infectious Complications CTCAE term -- No Reporting Required

Non-infectious complications

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

Infectious complications

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

Appendix 5
-- Intravascular catheter-related infections --

CVC infections:

- Catheter colonization
- Phlebitis
- Exit site infection
- Tunnel infection
- Pocket 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-specifc 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)

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

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