HAEMATOPOIETIC CELL TRANSPLANTATION (HCT)
--- Day 100 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

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: _____	

Autopsy performed:

☐ No
☐ Yes
☐ Unknown

BEST RESPONSE
Not applicable for Inborn Errors

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

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

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

RECOVERY

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

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

☐ Yes: **Date of ANC recovery:** _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* ☐ Unknown
(first of 3 consecutive values after 7 days without transfusion containing neutrophils)

☐ Never below

☐ 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

☐ Unknown

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

GRAFT FUNCTION

Poor graft function *(defined as: frequent dependence on blood and/or platelet transfusions and/or growth factor support in the absense of other explanations, such as disease relapse, drugs, or infection)*:

☐ No
☐ Yes; **Date of poor graft function**: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* ☐ Unknown
☐ Unknown

Complete for every chimaerism test performed:
(complete only if patient received an allogeneic HCT)

Chimaerism test date: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* ☐ Unknown

Source of cells tested: ☐ Peripheral blood
☐ Bone marrow

Select cell type and complete relevant test results:

☐ Global: _____ % donor ☐ Unknown
☐ Myeloid cells (i.e. CD33, CD15 or CD14):_____% donor ☐ Unknown
☐ T-cells (CD3): _____% donor ☐ Unknown
☐ B-cells (CD19 or CD20): _____% donor ☐ Unknown
☐ CD34+ cells: _____% donor ☐ Unknown
☐ Other cell type; specify cells; _____ _____% donor ☐ Unknown

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

PREVENTIVE THERAPIES
(Complete only if the patient received an alloHCT)

Immunosuppression during this follow-up period:

☐ No
☐ Yes; **Immunosuppresion stopped:**
  ☐ No
  ☐ Yes; **End date:** _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* ☐ Unknown
  ☐ Unknown
☐ Unknown

Letermovir used as CMV prophylaxis during this follow-up period:

☐ No
☐ Yes; **Start date:** _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* ☐ Unknown
  Letermovir treatment stop? ☐ No
  ☐ Yes; **End date:** _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* ☐ Unknown
  ☐ Unknown
☐ Unknown

COMPLICATIONS SINCE THE LAST REPORT
-- GvHD --
Allogeneic HCT only

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?**

- ☐ No
- ☐ Yes: **Date treatment started:** _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* ☐ Unknown

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

Maximum observed organ severity score:

Skin:	☐ 0 *(none)*	☐ 1	☐ 2	☐ 3	☐ 4	☐ Unknown ☐ Not evaluated
Liver:	☐ 0 *(none)*	☐ 1	☐ 2	☐ 3	☐ 4	☐ Unknown ☐ Not evaluated
Lower GI tract:	☐ 0 *(none)*	☐ 1	☐ 2	☐ 3	☐ 4	☐ Unknown ☐ Not evaluated
Upper GI tract:	☐ 0 *(none)*	☐ 1			☐ Unknown	☐ Not evaluated
Other site affected:	☐ No	☐ Yes; specify: _____				

Overall maximum grade observed: ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ Unknown ☐ Not evaluated

Steroid-refractory acute GvHD: ☐ No ☐ Yes ☐ Unknown

if steroid-refractory acute GvHD observed:

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

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

☐ Unknown

COMPLICATIONS SINCE THE LAST REPORT

-- GvHD --

Allogeneic HCT only

Did chronic GvHD occur during this follow-up period?

☐ No

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

Maximum NIH score during <u>this period</u>: ☐ Mild ☐ Moderate ☐ Severe ☐ Unknown

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

Maximum observed organ severity score:

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

Steroid-refractory chronic GvHD: ☐ No ☐ Yes ☐ Unknown

if steroid-refractory chronic GvHD observed:

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

Did non-infectious complications occur during the follow-up period?
(Please only report toxic events here that are above Grade 2 and not linked to GvHD and/or infections)

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

Secondary graft failure

Complication observed during this follow-up period? ☐ No ☐ Yes ☐ Unknown

Maximum grade observed: ☐ Non-fatal ☐ Fatal

Onset date (*YYYY/MM/DD***):** _ _ _ _ / _ _ / _ _ ☐ Unknown

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

Cardiac event

Complication observed during this follow-up period? ☐ No* ☐ Yes ☐ Unknown

Maximum CTCAE grade observed ☐ 3 ☐ 4 ☐ 5 (fatal) ☐ Unknown

Onset date (*YYYY/MM/DD***):** _ _ _ _ / _ _ / _ _ ☐ Unknown

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

Central nervous system (CNS) toxicity

Complication observed during this follow-up period? ☐ No* ☐ Yes ☐ Unknown

Maximum CTCAE grade observed ☐ 3 ☐ 4 ☐ 5 (fatal) ☐ Unknown

Onset date (*YYYY/MM/DD***):** _ _ _ _ / _ _ / _ _ ☐ Unknown

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

Gastrointestinal (GI) Toxicity (non-GvHD and non-infectious related)

Complication observed during this follow-up period? ☐ No* ☐ Yes ☐ Unknown

Maximum CTCAE grade observed ☐ 3 ☐ 4 ☐ 5 (fatal) ☐ Unknown

Onset date (*YYYY/MM/DD***):** _ _ _ _ / _ _ / _ _ ☐ Unknown

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

* Grade 0-2

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

Liver disorder

Complication observed during this follow-up period? ☐ No* ☐ Yes ☐ Unknown

Maximum CTCAE grade observed ☐ 3 ☐ 4 ☐ 5 (fatal) ☐ Unknown

Onset date (*YYYY/MM/DD***):** _ _ _ _ / _ _ / _ _ ☐ Unknown

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

Renal failure (chronic kidney disease, acute kidney injury)

Complication observed during this follow-up period? ☐ No* ☐ Yes ☐ Unknown

Maximum CTCAE grade observed ☐ 3 ☐ 4 ☐ 5 (fatal) ☐ Unknown

Onset date (*YYYY/MM/DD***):** _ _ _ _ / _ _ / _ _ ☐ Unknown

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

Respiratory disorders

Complication observed during this follow-up period? ☐ No* ☐ Yes ☐ Unknown

Maximum CTCAE grade observed ☐ 3 ☐ 4 ☐ 5 (fatal) ☐ Unknown

Onset date (*YYYY/MM/DD***):** _ _ _ _ / _ _ / _ _ ☐ Unknown

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

Skin Toxicity (non-GvHD and non-infectious related)

Complication observed during this follow-up period? ☐ No* ☐ Yes ☐ Unknown

Maximum CTCAE grade observed ☐ 3 ☐ 4 ☐ 5 (fatal) ☐ Unknown

Onset date (*YYYY/MM/DD***):** _ _ _ _ / _ _ / _ _ ☐ Unknown

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

* Grade 0-2

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

Vascular event

Complication observed during this follow-up period? ☐ No* ☐ Yes ☐ Unknown

Maximum CTCAE grade observed ☐ 3 ☐ 4 ☐ 5 (fatal) ☐ Unknown

Onset date (*YYYY/MM/DD***):** _ _ _ _ / _ _ / _ _ ☐ Unknown

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

Avascular necrosis (AVN)

Complication observed during this follow-up period? ☐ No* ☐ Yes ☐ Unknown

Maximum CTCAE grade observed ☐ 3 ☐ 4 ☐ 5 (fatal) ☐ Unknown

Onset date (*YYYY/MM/DD***):** _ _ _ _ / _ _ / _ _ ☐ Unknown

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

Cerebral haemorrhage

Complication observed during this follow-up period? ☐ No* ☐ Yes ☐ Unknown

Maximum CTCAE grade observed ☐ 3 ☐ 4 ☐ 5 (fatal) ☐ Unknown

Onset date (*YYYY/MM/DD***):** _ _ _ _ / _ _ / _ _ ☐ Unknown

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

Haemorrhage (other than cerebral haemorrhage)

Complication observed during this follow-up period? ☐ No* ☐ Yes ☐ Unknown

Maximum CTCAE grade observed ☐ 3 ☐ 4 ☐ 5 (fatal) ☐ Unknown

Onset date (*YYYY/MM/DD***):** _ _ _ _ / _ _ / _ _ ☐ Unknown

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

* Grade 0-2

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

Cerebral thrombosis

Complication observed during this follow-up period? ☐ No* ☐ Yes ☐ Unknown

Maximum CTCAE grade observed ☐ 3 ☐ 4 ☐ 5 (fatal) ☐ Unknown

Onset date (*YYYY/MM/DD***):** _ _ _ _ / _ _ / _ _ ☐ Unknown

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

Cytokine release syndrome (CRS)

Complication observed during this follow-up period? ☐ No* ☐ Yes ☐ Unknown

Maximum CTCAE grade observed ☐ 3 ☐ 4 ☐ 5 (fatal) ☐ Unknown

Onset date (*YYYY/MM/DD***):** _ _ _ _ / _ _ / _ _ ☐ Unknown

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

Haemophagocytic lymphohistiocytosis (HLH)

Complication observed during this follow-up period? ☐ No* ☐ Yes ☐ Unknown

Maximum CTCAE grade observed ☐ 3 ☐ 4 ☐ 5 (fatal) ☐ Unknown

Onset date (*YYYY/MM/DD***):** _ _ _ _ / _ _ / _ _ ☐ Unknown

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

Pure red cell aplasia (PRCA)

Complication observed during this follow-up period? ☐ No ☐ Yes ☐ Unknown

Maximum grade observed ☐ Non-fatal ☐ Fatal

Onset date (*YYYY/MM/DD***):** _ _ _ _ / _ _ / _ _ ☐ Unknown

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

* Grade 0-2

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

Posterior reversible encephalopathy syndrome (PRES)

Complication observed during this follow-up period? ☐ No ☐ Yes ☐ Unknown

Maximum grade observed ☐ Non-severe ☐ Severe ☐ Fatal ☐ Unknown

Onset date (*YYYY/MM/DD*): _ _ _ _ / _ _ / _ _ ☐ Unknown

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

Transplant-associated microangiopathy (TMA)

Complication observed during this follow-up period? ☐ No* ☐ Yes ☐ Unknown

Maximum CTCAE grade observed ☐ 3 ☐ 4 ☐ 5 (fatal) ☐ Unknown

Onset date (*YYYY/MM/DD*): _ _ _ _ / _ _ / _ _ ☐ Unknown

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

Veno-occlusive disease (VOD)

Complication observed during this follow-up period? ☐ No* ☐ Yes ☐ Unknown

Maximum CTCAE grade observed ☐ Mild ☐ Moderate ☐ Severe ☐ Very severe ☐ Fatal ☐ Unknown

Onset date (*YYYY/MM/DD*): _ _ _ _ / _ _ / _ _ ☐ Unknown

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

Other complication observed during this follow-up period? ☐ No* ☐ Yes ☐ Unknown

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

Maximum CTCAE grade observed ☐ 3 ☐ 4 ☐ 5 (fatal) ☐ Unknown

Onset date (*YYYY/MM/DD*): _ _ _ _ / _ _ / _ _ ☐ Unknown

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

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

* Grade 0-2

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

☐ 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
- ☐ Isolation precautions or surveillance

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

☐ 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
- ☐ Isolation precautions or surveillance

☐ 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) **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: *(select all that apply during this period)*
- ☐ Symptoms/signs of disease
- ☐ Administration of pathogen-directed therapy
- ☐ Isolation precautions or surveillance

☐ 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) **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: *(select all that apply during this period)*
- ☐ Symptoms/signs of disease
- ☐ Administration of pathogen-directed therapy
- ☐ Isolation precautions or surveillance

☐ 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) **Start date**: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*
☐ 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
☐ Isolation precautions or surveillance
☐ 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) **Start date**: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*
☐ 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
☐ Isolation precautions or surveillance
☐ 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) **Start date**: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*

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

Indicate at least 1 location:
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) **Start date**: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*
Infection with clinical implications: ☐ No ☐ Yes: (select all that apply)
☐ Symptoms/signs or disease
☐ Administration of pathogen-directed therapy
☐ Isolation precautions or surveillance
☐ Unknown

Indicate at least 1 location:
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 at page 25
** If intravascular catheter-related infection, specify it by choosing from the list provided in Appendix 5 at page 25

SECONDARY MALIGNANCIES AND AUTOIMMUNE DISORDERS

Did a secondary malignancy or autoimmune disorder occur after HCT?

☐ No

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

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

☐ Unknown

ADDITIONAL TREATMENTS

Did the patient receive any additional disease treatment since the last report?

☐ No

☐ Yes: **complete the "Treatment — non-HCT/CT/GT/IST" form**

☐ Unknown

ADDITIONAL CELL INFUSIONS

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

☐ 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/CT *(either at your or another centre)***?**

☐ No

☐ Yes

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

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 after HCT? *(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.

DISEASE STATUS

Only for malignancies

Disease detected after HCT?

☐ No

☐ Yes; **Date last assessed**: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* ☐ Unknown

Method; specify:
(select all that apply)

☐ Haematological
☐ Radiological
☐ Molecular
☐ Cytogenetic
☐ Other; specify _____

☐ Unknown

DISEASE STATUS

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 HCT was given.

Appendix 1
Best Response and Disease Status (Disease Specific)

Acute leukaemias (AML, PLN, Other)

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

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
- ☐ Unknown
- ☐ Not evaluated

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)
- ☐ Unknown
- ☐ Not evaluated

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)
- ☐ Unknown
- ☐ Not evaluated

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 after HCT?

☐ Yes; **Start date:** _ _ _ _ / _ _ / _ _ (YYYY/MM/DD) ☐ Unknown

Did dialysis stop? ☐ No
☐ Yes; **End date:** _ _ _ _ / _ _ / _ _ (YYYY/MM/DD) ☐ Unknown
☐ Unknown

☐ No
☐ Unknown

Complete only for leukaemias (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:
- ☐ ≤10^{-6}
- ☐ ≤10^{-5}
- ☐ ≤10^{-4}
- ☐ ≤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		
☐ Unknown		
☐ Not evaluated		

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)
- ☐ Unknown
- ☐ Not evaluated

** 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)
- ☐ Unknown
- ☐ Not evaluated

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
- ☐ Unknown
- ☐ Not evaluated

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
- ☐ Unknown

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

Autoimmune disorders

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

Haemoglobinopathies

Thalassaemia:

Complete only for Thalassemia Best Response

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

Complete only for Thalassemia Disease Status

Patient requires transfusions during follow-up period:

☐ No

☐ Yes; **Date of first transfusion:** _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* ☐ Unknown (after HCT)

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 HCT)*
☐ Unknown
☐ Not evaluated

Complete only for Sickle cell disease Disease Status

Sickling episodes occur during follow-up period:

☐ No
☐ Yes; **Date of first episode :** _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* ☐ Unknown (after HCT) **Number of SCD episodes**: ____ ☐ Unknown (during follow-up)
☐ Unknown

Other diagnosis

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

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 other spp (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
- Bronchial infection
- Lung infection
- Laryngitis infective
- Pleural infection
- Tracheitis infective
- Upper respiratory infection

Intra-abdominal infections
- Anorectal infection
- Appendicitis infective
- Appendicitis with perforation infective
- Biliary tract infection
- Cecal infection
- Duodenal infection
- Enterocolitis infective
- Esophageal infection
- Gallbladder infection
- Gastritis infective
- Hepatic infection
- Pancreas infection
- Pelvic infection
- Peritoneal infection
- Splenic infection
- Stoma site infection
- Small intestine infection
- Typhlitis infective

Blood
- Bacteremia
- Fungemia
- Viremia

Uro-genital tract infections
- Cystitis infective
- Cervicitis infective
- 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 infective
- Encephalomyelitis infective
- Meningitis infective
- Myelitis infective
- Peripheral nerve infection

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

Skin, soft tissue and mucosal surfaces
- Breast infection
- Folliculitis infective
- Lymph gland infection
- Nail infection
- Mucosal infection
- Papulo/pustular rash
- Paronychia
- Skin infection
- Soft tissue infection
- Wound infection

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

Others
- Device related infection (other than Intravascular catheter)
- Febrile Neutropenia
- Fever of unknown origin (FUO)
- Sepsis

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
- 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:

- ☐ Allogeneic
- ☐ Autologous

Type of cells:

- ☐ 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