

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☐ HCT-related☐ GT-related☐ IST-related☐ Unknown☐ Other; specify: _____**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

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 $\geq 0.5 \times 10^9/L$*):

- ☐ 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 $\geq 20 \times 10^9/L$*):

- ☐ No: **Date of the last assessment:** ____/____/____ (YYYY/MM/DD) ☐ Unknown
- ☐ Yes: **Date of platelet reconstitution:** ____/____/____ (YYYY/MM/DD) ☐ Unknown
(first of 3 consecutive values after 7 days without platelet transfusion)
- ☐ Never below
- ☐ 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 absence 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:

- ☐ No
☐ Yes; **Immunosuppression stopped:**
☐ No
☐ Yes; **End date:** ____/____/____ (YYYY/MM/DD) ☐ Unknown
☐ Unknown
☐ Unknown

Letermovir used as CMV prophylaxis:

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

COMPLICATIONS POST HCT TREATMENT

-- GvHD --

Allogeneic HCT only

Did graft versus host disease (GvHD) occur?

☐ 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:	<input type="checkbox"/> 0 (none)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> Unknown
Liver:	<input type="checkbox"/> 0 (none)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> Unknown
Lower GI tract:	<input type="checkbox"/> 0 (none)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> Unknown
Upper GI tract:	<input type="checkbox"/> 0 (none)		<input type="checkbox"/> 1	<input type="checkbox"/> Not evaluated		<input type="checkbox"/> Unknown	
Other site affected:	<input type="checkbox"/> No		<input type="checkbox"/> Yes; specify: _____				

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

Steroid-refractory acute GvHD: ☐ No

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

☐ 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:**

- ☐ Mild
☐ Moderate
☐ Severe
☐ Unknown
☐ Not evaluated

Date of maximum NIH score: ____/____/____ (YYYY/MM/DD) ☐ Unknown**Maximum observed organ severity score:**

Skin:	<input type="checkbox"/> 0 (none)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> Unknown
Oral:	<input type="checkbox"/> 0 (none)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> Unknown
Gastrointestinal:	<input type="checkbox"/> 0 (none)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> Unknown
Eyes:	<input type="checkbox"/> 0 (none)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> Unknown
Liver:	<input type="checkbox"/> 0 (none)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> Unknown
Joints and fascia:	<input type="checkbox"/> 0 (none)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> Unknown
Lungs:	<input type="checkbox"/> 0 (none)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> Unknown
Genitalia:	<input type="checkbox"/> 0 (none)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> Unknown
Other site affected:	<input type="checkbox"/> No	<input type="checkbox"/> Yes; specify: _____				

Steroid-refractory chronic GvHD: ☐ No☐ Yes: **Date of onset:** ____/____/____ (YYYY/MM/DD) ☐ Unknown☐ 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?

☐ No

☐ Yes

☐ Unknown

Maximum grade observed during this period: ☐ Non-fatal ☐ Fatal

Onset date (YYYY/MM/DD): ____/____/____ ☐ Unknown

Resolved: ☐ No

☐ Yes; **Stop date (YYYY/MM/DD):** ____/____/____ ☐ Unknown

☐ Unknown

Cardiac event

Complication observed? ☐ 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? ☐ 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? ☐ 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

COMPLICATIONS SINCE THE LAST REPORT

-- Non-infectious complications --
 continued

Liver disorder

Complication observed?

☐ 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?

☐ 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?

☐ 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?

☐ 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

COMPLICATIONS SINCE THE LAST REPORT

-- Non-infectious complications --
 continued

Vascular event

Complication observed? ☐ 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? ☐ 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? ☐ 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? ☐ 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

COMPLICATIONS SINCE THE LAST REPORT

-- Non-infectious complications --
 continued

Cerebral thrombosis

Complication observed? ☐ 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? ☐ 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? ☐ 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? ☐ 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



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

Treatment Type ☐ HCT
Treatment Date ____/____/____ (YYYY/MM/DD)

COMPLICATIONS SINCE THE LAST REPORT

-- Non-infectious complications --
continued

Posterior reversible encephalopathy syndrome (PRES)

Complication observed? ☐ 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? ☐ No*

☐ Yes:

☐ Unknown

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

Onset date (YYYY/MM/DD): ____/____/____ ☐ Unknown

Resolved: ☐ No

☐ Yes; Stop date (YYYY/MM/DD): ____/____/____ ☐ Unknown

☐ Unknown

* Grade 0-2



EBMT Centre Identification Code (CIC): ____

Hospital Unique Patient Number (UPN): _____

Patient Number in EBMT Registry: _____

Treatment Type ☐ HCT

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

COMPLICATIONS SINCE THE LAST REPORT

-- Non-infectious complications --

Veno-occlusive disease (VOD)

Complication observed? ☐ 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

COMPLICATIONS SINCE THE LAST REPORT

-- Non-infectious complications --

Other complication observed? ☐ 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 ☐ Yes1) **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☐ 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 ☐ Unknown2) **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☐ 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
☐ 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
☐ 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

☐ 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

☐ 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

☐ 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

☐ 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

☐ 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

☐ 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



EBMT Centre Identification Code (CIC): _____

Hospital Unique Patient Number (UPN): _____

Patient Number in EBMT Registry: _____

Treatment Type ☐ HCT

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

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



EBMT Centre Identification Code (CIC): ____

Hospital Unique Patient Number (UPN): _____

Patient Number in EBMT Registry: _____

Treatment Type ☐ HCT

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

ADDITIONAL TREATMENTS

Did the patient receive any additional disease treatment?

☐ No

☐ Yes:

complete the "Treatment — non-HCT/CT/GT/IST" form

☐ Unknown

ADDITIONAL CELL INFUSIONS

Did the patient receive additional cell infusions during this 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.



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

Treatment Type ☐ HCT
Treatment Date ____/____/____ (YYYY/MM/DD)

DISEASE STATUS

Disease status after HCT 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



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

Treatment Type ☐ HCT
Treatment Date ____/____/____ (YYYY/MM/DD)

Appendix 1

Best Response and Disease Status (Disease Specific)

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

ACUTE LEUKAEMIAS	<i>Go to page 39</i>
CHRONIC LEUKAEMIAS	<i>Go to page 39</i>
PLASMA CELL NEOPLASMS (PCN)	<i>Go to page 40</i>
MPN, MDS, MDS / MPN OVERLAP SYNDROMES	<i>Go to page 42</i>
LYMPHOMAS	<i>Go to page 43</i>
SOLID TUMOURS	<i>Go to page 43</i>
BONE MARROW FAILURE SYNDROMES (BMF) including APLASTIC ANAEMIA (AA)	<i>Go to page 43</i>
AUTOIMMUNE DISORDERS	<i>Go to page 44</i>
HAEMOGLOBINOPATHIES	<i>Go to page 44</i>
OTHER DIAGNOSIS	<i>Go to page 45</i>
Inborn Errors	<i>Go to page 46</i>

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

Appendix 1

Best Response and Disease Status (Disease Specific)

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

<input type="checkbox"/> Complete remission (CR)
<input type="checkbox"/> Partial remission (PR)
<input type="checkbox"/> Progression: <input type="checkbox"/> Resistant to last regimen <input type="checkbox"/> Sensitive to last regimen <input type="checkbox"/> Unknown
<input type="checkbox"/> Stable disease (no change, no response/loss of response)
<input type="checkbox"/> Relapse
<input type="checkbox"/> Not evaluated
<input type="checkbox"/> Unknown

Proceed to next page for Diseases Status section

Plasma cell neoplasms (PCN)

<input type="checkbox"/> Complete remission (CR)	<u>Number:</u> <input type="checkbox"/> 1st <input type="checkbox"/> 2nd <input type="checkbox"/> 3rd or higher <input type="checkbox"/> Unknown
<input type="checkbox"/> Stringent complete remission (sCR)	
<input type="checkbox"/> Very good partial remission (VGPR)	
<input type="checkbox"/> Partial remission (PR)	
<input type="checkbox"/> Relapse	
<input type="checkbox"/> Progression	
<input type="checkbox"/> Stable disease (no change, no response/loss of response)	
<input type="checkbox"/> Not evaluated	
<input type="checkbox"/> Unknown	

Proceed to next page for Diseases Status section

Appendix 1

Best Response and Disease Status (Disease Specific)

continued

Complete only for PCN Disease Status

Was the patient on dialysis after HCT?

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

- ☐ Negative
- ☐ Positive;
- ☐ Increasing (>1log10 change) ☐ Stable (<1log10 change) ☐ Decreasing (>1log10 change) ☐ Unknown
- ☐ 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



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

Treatment Type ☐ HCT
Treatment Date ____/____/____ (YYYY/MM/DD)

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

Myeloproliferative neoplasms (MPN), Myelodysplastic neoplasms (MDS), MDS/MPN overlap syndromes

<input type="checkbox"/> Complete remission (CR)	<u>Number:</u> <input type="checkbox"/> 1st <input type="checkbox"/> 2nd <input type="checkbox"/> 3rd or higher <input type="checkbox"/> Unknown
<input type="checkbox"/> Improvement but no CR	
<input type="checkbox"/> Primary refractory phase (no change)	
<input type="checkbox"/> Relapse	<u>Number:</u> <input type="checkbox"/> 1st <input type="checkbox"/> 2nd <input type="checkbox"/> 3rd or higher <input type="checkbox"/> Unknown
<input type="checkbox"/> Progression/Worsening	
<input type="checkbox"/> Not evaluated	
<input type="checkbox"/> Unknown	

Appendix 1

Best Response and Disease Status (Disease Specific)

continued

Lymphomas

<input type="checkbox"/> Chemorefractory relapse or progression, including primary refractory disease
<input type="checkbox"/> Complete remission (CR): <input type="checkbox"/> Confirmed <input type="checkbox"/> Unconfirmed (CRU*) <input type="checkbox"/> Unknown
<input type="checkbox"/> Partial remission (PR)
<input type="checkbox"/> Stable disease (no change, no response/loss of response)
<input type="checkbox"/> Untreated relapse (from a previous CR) or progression (from a previous PR)
<input type="checkbox"/> Not evaluated
<input type="checkbox"/> Unknown

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

Solid tumours

<input type="checkbox"/> Complete remission (CR): <input type="checkbox"/> Confirmed <input type="checkbox"/> Unconfirmed <input type="checkbox"/> Unknown
<input type="checkbox"/> First partial remission
<input type="checkbox"/> Partial remission (PR)
<input type="checkbox"/> Progressive disease
<input type="checkbox"/> Relapse: <input type="checkbox"/> Resistant <input type="checkbox"/> Sensitive <input type="checkbox"/> Unknown
<input type="checkbox"/> Stable disease (no change, no response/loss of response)
<input type="checkbox"/> Not evaluated
<input type="checkbox"/> Unknown

Bone marrow failures (incl. AA)

<input type="checkbox"/> Complete remission (CR)
<input type="checkbox"/> Partial remission (PR)
<input type="checkbox"/> Haematological improvement (HI); <i>NIH partial response</i>
<input type="checkbox"/> Stable disease (no change, no response/loss of response)
<input type="checkbox"/> Relapse / Progression
<input type="checkbox"/> Not evaluated
<input type="checkbox"/> Unknown

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

Did transfusions stop during the follow-up period?	<input type="checkbox"/> Patient was never transfusion dependent
	<input type="checkbox"/> No
	<input type="checkbox"/> Yes; Did the patient return to transfusion dependency afterwards?
	<input type="checkbox"/> No
	<input type="checkbox"/> Yes; First transfusion date: ____/____/____ (YYYY/MM/DD) <input type="checkbox"/> Unknown (after transfusion free period)
	<input type="checkbox"/> Unknown
	<input type="checkbox"/> Unknown

Appendix 1

Best Response and Disease Status (Disease Specific)

continued

Autoimmune disorders

<input type="checkbox"/> No evidence of disease
<input type="checkbox"/> Improved
<input type="checkbox"/> Unchanged
<input type="checkbox"/> Worse
<input type="checkbox"/> Not evaluated
<input type="checkbox"/> Unknown

Haemoglobinopathies

Thalassaemia:

Complete only for Thalassemia Best Response

<input type="checkbox"/> Transfusion independent;	Date of last transfusion: ____/____/____ (YYYY/MM/DD) <input type="checkbox"/> Unknown (after HCT)
<input type="checkbox"/> Transfusions required;	Date of first transfusion: ____/____/____ (YYYY/MM/DD) <input type="checkbox"/> Unknown (after HCT)
<input type="checkbox"/> Not evaluated	
<input type="checkbox"/> Unknown	

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**

<input type="checkbox"/> No return of sickling episodes
<input type="checkbox"/> Return of sickling episodes; Date of first episode: ____/____/____ (YYYY/MM/DD) <input type="checkbox"/> Unknown (after HCT)
<input type="checkbox"/> Not evaluated
<input type="checkbox"/> Unknown

Complete only for Sickle cell disease Disease Status**Sickling episodes occur during follow-up period:**

<input type="checkbox"/> No
<input type="checkbox"/> Yes; <input type="checkbox"/> First return of sickling episodes after HCT Date of first episode : ____/____/____ (YYYY/MM/DD) <input type="checkbox"/> Unknown (after HCT) <input type="checkbox"/> Ongoing presence of sickling episodes Number of SCD episodes: ____ <input type="checkbox"/> Unknown (after HCT)
<input type="checkbox"/> Unknown

Other diagnosis

<input type="checkbox"/> No evidence of disease
<input type="checkbox"/> Improved
<input type="checkbox"/> No response
<input type="checkbox"/> Worse
<input type="checkbox"/> Not evaluated
<input type="checkbox"/> Unknown

Appendix 2

-- Pathogens as per EBMT Registry database --

**As defined by the IDSA (Mermel LA, Allon M, Bouza E, Craven DE, Flynn P, O'Grady NP, et al. Clinical practice guidelines for the diagnosis and management of intravascular catheter-related infection: 2009 Update by the Infectious Diseases Society of America. Clin Infect Dis. 2009;49(1):1-45)*

Bacterial infections

Gram-positive:

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

Gram-negative:

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

Other bacteria:

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

Viral infections:

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

Appendix 2

-- Pathogens as per EBMT Registry database -- continued

**As defined by the IDSA (Mermel LA, Allon M, Bouza E, Craven DE, Flynn P, O'Grady NP, et al. Clinical practice guidelines for the diagnosis and management of intravascular catheter-related infection: 2009 Update by the Infectious Diseases Society of America. Clin Infect Dis. 2009;49(1):1-45)*

Fungal infections:

Yeasts:

- Candida albicans
- Candida auris
- Candida other (specify)
- Cryptococcus neoformans
- Trichosporon (specify)
- Pneumocystis 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



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

Treatment Type ☐ HCT
Treatment Date ____/____/____ (YYYY/MM/DD)

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 Complications CTCAE term -- **No Reporting Required**

Non-infectious complications

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

Infectious complications

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

Appendix 5
 -- Intravascular catheter-related infections --

CVC infections:

- Catheter colonization
- Tunnel infection
- Phlebitis
- Pocket infection
- Exit site infection
- Bloodstream infection

Appendix 6

Cell Infusion Sheet

Chronological number of CI episode for this patient: _____

Date of the first infusion (after HCT): ____/____/____ (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-specific T-cells; specify virus: _____
☐ Other; specify: _____

Not applicable for Inborn Errors

Disease status at time of this cell infusion*: _____

* Indicate the disease status corresponding to indication diagnosis by selecting from the list provided in Appendix 1

Indication:

(check all that apply)

- | | |
|--|--|
| <input type="checkbox"/> Planned/protocol
<input type="checkbox"/> Prophylactic
<input type="checkbox"/> Treatment of acute GvHD
<input type="checkbox"/> Treatment of chronic GvHD
<input type="checkbox"/> Treatment PTLD, EBV lymphoma
<input type="checkbox"/> Treatment for primary disease
<input type="checkbox"/> Mixed chimaerism
<input type="checkbox"/> Loss/decreased donor chimaerism
<input type="checkbox"/> Treatment of viral infection other than EBV | <input type="checkbox"/> Poor graft function
<input type="checkbox"/> Infection prophylaxis
<input type="checkbox"/> 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