

HAEMATOPOIETIC CELL TRANSPLANTATION (HCT)

--- 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

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

<input type="checkbox"/> Relapse or progression/persistent disease	
<input type="checkbox"/> Secondary malignancy	
<input type="checkbox"/> CT-related <input type="checkbox"/> HCT-related <input type="checkbox"/> GT-related <input type="checkbox"/> IST-related	Select treatment related cause: <i>(select all that apply)</i> <input type="checkbox"/> Graft versus Host Disease <input type="checkbox"/> Non-infectious complication <input type="checkbox"/> Infectious complication: <i>(select all that apply)</i> <input type="checkbox"/> Bacterial infection <input type="checkbox"/> Viral infection <input type="checkbox"/> Fungal infection <input type="checkbox"/> Parasitic infection <input type="checkbox"/> Infection with unknown pathogen
<input type="checkbox"/> Unknown	
<input type="checkbox"/> Other; specify: _____	

Was an autopsy performed?

- No
- Yes
- Unknown

BEST RESPONSE

Complete only for the first annual follow-up

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

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 since last follow-up:
(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 allogeneic HCT)

Immunosuppression during this follow-up period:

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

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

- No
 Yes; Started in this follow-up period; **Start date:** ____/____/____ (YYYY/MM/DD) Unknown
 Ongoing since previous follow-up

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

Unknown

COMPLICATIONS SINCE THE LAST REPORT

-- GvHD --

(Complete only if the patient received an alloHCT)

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 (proceed to 'Complications since the last report - Non-infectious complications')

Did acute GvHD occur during this follow-up period?

No

Yes: Started in this follow-up period; **Date of onset:** ____/____/____ (YYYY/MM/DD) Unknown

Ongoing since previous follow-up

Maximum observed organ severity score during this period:

Skin:	<input type="checkbox"/> 0 (none)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> Unknown	<input type="checkbox"/> Not evaluated
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"/> Unknown	<input type="checkbox"/> Not evaluated
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"/> Unknown	<input type="checkbox"/> Not evaluated
Upper GI tract:	<input type="checkbox"/> 0 (none)	<input type="checkbox"/> 1	<input type="checkbox"/> Unknown	<input type="checkbox"/> Not evaluated			
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: 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 --

Allogeneic HCT only

Did chronic GvHD occur during this follow-up period?

- No
- Yes: Started in this follow-up period; **Date of onset:** ____/____/____ (YYYY/MM/DD) Unknown
- Ongoing since previous follow-up
- Maximum NIH score during this period:** Mild
 Moderate
 Severe
 Unknown
 Not evaluated
- Date of maximum NIH score:** ____/____/____ (YYYY/MM/DD) Unknown

Maximum observed organ severity score during this period:

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

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

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

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

Unknown



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 --

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: Newly developed Ongoing since previous assessment
 Unknown

Maximum grade observed during this period: Non-fatal Fatal

Onset date (YYYY/MM/DD): ____/____/____ Unknown *only if newly developed*

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

Cardiac event

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

Central nervous system (CNS) toxicity

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

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

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 --

Liver disorder

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

Renal failure (chronic kidney disease, acute kidney injury)

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

Respiratory disorders

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

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

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 --

Vascular event

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

Avascular necrosis (AVN)

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

Cerebral haemorrhage

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

Haemorrhage (other than cerebral haemorrhage)

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 --

Cerebral thrombosis

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

Cytokine release syndrome (CRS)

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

Haemophagocytic lymphohistiocytosis (HLH)

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

Pure red cell aplasia (PRCA)

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

Maximum grade observed during this period: Non-fatal Fatal

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 --

Posterior reversible encephalopathy syndrome (PRES)

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

Maximum grade observed during this period: Non-severe Severe Fatal Unknown

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

Resolved: No
 Yes; Stop date (YYYY/MM/DD): ____/____/____ Unknown
 Unknown

Transplant-associated microangiopathy (TMA)

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

Veno-occlusive disease (VOD)

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

Maximum grade observed during this period: Mild Moderate Severe Very severe 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 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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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 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 secondary malignancy or autoimmune disorder occur since the last follow-up?

- 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 follow-up?

- No
- Yes: **complete the "Treatment — non-HCT/CT/GT/IST" form**
- Unknown

ADDITIONAL CELL INFUSIONS

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

- 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 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.

DISEASE STATUS
Only for malignancies

Disease detected during this follow-up period?

- No
- Yes; **Date last assessed:** ____/____/____ (YYYY/MM/DD) Unknown
- Method; specify:** Haematological
(select all that apply) Radiological
 Molecular
 Cytogenetic
 Other; specify _____
- 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

PREGNANCY AFTER HCT

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

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 19</i>
CHRONIC LEUKAEMIAS	<i>Go to page 19</i>
PLASMA CELL NEOPLASMS (PCN)	<i>Go to page 19</i>
MPN, MDS, MDS / MPN OVERLAP SYNDROMES	<i>Go to page 20</i>
LYMPHOMAS	<i>Go to page 21</i>
SOLID TUMOURS	<i>Go to page 21</i>
BONE MARROW FAILURE SYNDROMES (BMF) including APLASTIC ANAEMIA (AA)	<i>Go to page 21</i>
AUTOIMMUNE DISORDERS	<i>Go to page 22</i>
HAEMOGLOBINOPATHIES	<i>Go to page 22</i>
OTHER DIAGNOSIS	<i>Go to page 23</i>

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 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 the most sensitive method used)

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

<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"/> Unknown
<input type="checkbox"/> Not evaluated

* 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"/> Unknown
<input type="checkbox"/> Not evaluated

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"/> Unknown
<input type="checkbox"/> 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) Unknown (after transfusion free period)

Unknown

Ongoing transfusion independence since last follow-up

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"/> Unknown
<input type="checkbox"/> Not evaluated

Haemoglobinopathies

Thalassaemia:

Complete only for Thalassemia Best Response

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

Complete only for Thalassemia Disease Status

Patient requires transfusions during follow-up period:

No

Yes; Return to transfusion dependence after HCT or transfusion free period; **Date of first transfusion:** ____/____/____ (YYYY/MM/DD) Unknown
(after HCT or transfusion free period)

Ongoing transfusion dependence since previous assessment

Number of units: ____ Unknown
(during follow-up period)

Did transfusions stop? No
 Yes; **Date of last transfusion:** ____/____/____ (YYYY/MM/DD) Unknown
 Unknown

Unknown

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

Haemoglobinopathies

Sickle cell disease:

Complete only for Sickle cell disease Best Response

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

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 (during follow-up)	
<input type="checkbox"/> Unknown	

Other diagnosis

<input type="checkbox"/> No evidence of disease
<input type="checkbox"/> Improved
<input type="checkbox"/> No response
<input type="checkbox"/> Worse
<input type="checkbox"/> Unknown
<input type="checkbox"/> 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
- Chlamydomphila
- 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

- | | | |
|--|--|---|
| <p>Respiratory tract</p> <ul style="list-style-type: none"> · Bronchial infection · Lung infection · Laryngitis infective · Pleural infection · Tracheitis infective · Upper respiratory infection <p>Intra-abdominal infections</p> <ul style="list-style-type: none"> · 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 <p>Blood</p> <ul style="list-style-type: none"> · Bacteremia · Fungemia · Viremia | <p>Uro-genital tract infections</p> <ul style="list-style-type: none"> · 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 <p>Muscles and bones</p> <ul style="list-style-type: none"> · Bone infection · Myositis infective · Joint infection <p>Nervous system infection</p> <ul style="list-style-type: none"> · Cranial nerve infection · Encephalitis infective · Encephalomyelitis infective · Meningitis infective · Myelitis infective · Peripheral nerve infection <p>Cardiovascular infections</p> <ul style="list-style-type: none"> · Arteritis infective · Endocarditis infective · Mediastinal infection · Phlebitis infective | <p>Skin, soft tissue and mucosal surfaces</p> <ul style="list-style-type: none"> · Breast infection · Folliculitis infective · Lymph gland infection · Nail infection · Mucosal infection · Papulo/pustular rash · Paronychia · Skin infection · Soft tissue infection · Wound infection <p>Head and neck</p> <ul style="list-style-type: none"> · 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 <p>Others</p> <ul style="list-style-type: none"> · 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**

- | | | |
|--|--|--|
| <p>Non-infectious complications</p> <ul style="list-style-type: none"> · 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 | <p>Infectious complications</p> <ul style="list-style-type: none"> · 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 | <ul style="list-style-type: none"> · 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*): Not applicable for Inborn Errors (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"/> Poor graft function |
| <input type="checkbox"/> Prophylactic | <input type="checkbox"/> Infection prophylaxis |
| <input type="checkbox"/> Treatment of acute GvHD | <input type="checkbox"/> Other; specify: _____ |
| <input type="checkbox"/> Treatment of chronic GvHD | |
| <input type="checkbox"/> Treatment PTLD, EBV lymphoma | |
| <input type="checkbox"/> Treatment for primary disease | |
| <input type="checkbox"/> Mixed chimaerism | |
| <input type="checkbox"/> Loss/decreased donor chimaerism | |
| <input type="checkbox"/> Treatment of viral infection other than EBV | |

Acute GvHD -- maximum grade (*after this infusion episode but before any subsequent cell infusion/HCT/CT*):

- 0 (none)
- 1
- 2
- 3
- 4
- Present but grade unknown

Date Acute GvHD onset after cell infusion: ____/____/____ (YYYY/MM/DD)

Unknown