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

Treatment Type ☐ HCT

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

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

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

☐ Relapse or progression/persistent disease

☐ Secondary malignancy

☐ CT-related

☐ HCT-related

☐ GT-related

☐ IST-related

Select treatment related cause: *(select all that apply)*

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

☐ Other treatment related cause of death; specify: _____

☐ Unknown

☐ Other cause of death; specify: _____

BEST RESPONSE
Not applicable for Inborn Errors

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

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

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

RECOVERY

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

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

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

☐ Never below

☐ Unknown

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

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

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

☐ Never below

☐ Unknown

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

Primary graft failure?

☐ No

☐ Yes

☐ Unknown

GRAFT FUNCTION

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

☐ No

☐ Yes; **Date of poor graft function**: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* ☐ Unknown

☐ Unknown

Complete for every chimaerism test performed:
(complete only if patient received an allogeneic HCT. This section is optional for malignant disorders)

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; **Immunosuppresion stopped:**

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

☐ Unknown

Letermovir used as primary CMV prophylaxis:

☐ No

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

Letermovir prophylaxis stopped?

- ☐ 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:	☐ 0 *(none)*	☐ 1	☐ 2	☐ 3	☐ 4	☐ Not evaluated	☐ Unknown
Liver:	☐ 0 *(none)*	☐ 1	☐ 2	☐ 3	☐ 4	☐ Not evaluated	☐ Unknown
Lower GI tract:	☐ 0 *(none)*	☐ 1	☐ 2	☐ 3	☐ 4	☐ Not evaluated	☐ Unknown
Upper GI tract:	☐ 0 *(none)*	☐ 1	☐ Not evaluated	☐ Unknown			
Other site affected:	☐ No	☐ 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

☐ 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:	☐ 0 *(none)*	☐ 1	☐ 2	☐ 3	☐ Not evaluated	☐ Unknown
Oral:	☐ 0 *(none)*	☐ 1	☐ 2	☐ 3	☐ Not evaluated	☐ Unknown
Gastrointestinal:	☐ 0 *(none)*	☐ 1	☐ 2	☐ 3	☐ Not evaluated	☐ Unknown
Eyes:	☐ 0 *(none)*	☐ 1	☐ 2	☐ 3	☐ Not evaluated	☐ Unknown
Liver:	☐ 0 *(none)*	☐ 1	☐ 2	☐ 3	☐ Not evaluated	☐ Unknown
Joints and fascia:	☐ 0 *(none)*	☐ 1	☐ 2	☐ 3	☐ Not evaluated	☐ Unknown
Lungs:	☐ 0 *(none)*	☐ 1	☐ 2	☐ 3	☐ Not evaluated	☐ Unknown
Genitalia:	☐ 0 *(none)*	☐ 1	☐ 2	☐ 3	☐ Not evaluated	☐ Unknown
Other site affected:	☐ No	☐ Yes; specify: _____				

Steroid-refractory chronic GvHD: ☐ No
☐ Yes: **Date of onset:** _ _ _ _ / _ _ / _ _ *(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*)

☐ Unknown

Secondary graft failure

Complication observed? ☐ No ☐ Yes ☐ Unknown

Maximum grade observed during <u>this period</u>: ☐ Non-fatal ☐ Fatal

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

Cardiac event

Complication observed? ☐ No* ☐ Yes: ☐ Unknown

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

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

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

* Grade 0-2

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

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

Respiratory disorders

Complication observed? ☐ No*
☐ Yes:
☐ Unknown

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

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

* Grade 0-2

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

Avascular necrosis (AVN)

Complication observed? ☐ No*
☐ Yes:
☐ Unknown

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

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

Cerebral haemorrhage

Complication observed? ☐ No*
☐ Yes:
☐ Unknown

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

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

* Grade 0-2

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

Cytokine release syndrome (CRS)

Complication observed? ☐ No*
☐ Yes:
☐ Unknown

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

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

Haemophagocytic lymphohistiocytosis (HLH)

Complication observed? ☐ No*
☐ Yes:
☐ Unknown

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

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

Pure red cell aplasia (PRCA)

Complication observed? ☐ No
☐ Yes:
☐ Unknown

Maximum grade observed: ☐ Non-fatal ☐ Fatal

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

* Grade 0-2

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

Transplant-associated microangiopathy (TMA)

Complication observed? ☐ No*
☐ Yes:
☐ Unknown

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

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

Sinusoidal obstruction syndrome/Veno-occulive disease (SOS/VOD)

Complication observed? ☐ No* ☐ Yes ☐ Unknown

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

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

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

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*)
☐ Unknown

Bacterial infection: ☐ No ☐ Yes ☐ Unknown

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

☐ Gram-positive ☐ Gram-negative ☐ Other
Pathogen*: _____

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

Indicate at least 1 location involved during this period:
Localisation 1 (CTCAE term)**: _____
Localisation 2 (CTCAE term)**: _____
Localisation 3 (CTCAE term)**: _____

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

If more than 1 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

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

Viral infection: ☐ No ☐ Yes ☐ Unknown

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

Pathogen*: _____

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

☐ Unknown

Indicate at least 1 location involved during this period:

Localisation 1 (CTCAE term):** _____

Localisation 2 (CTCAE term):** _____

Localisation 3 (CTCAE term):** _____

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

If more than 1 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
****Also answer 'Yes' in case of pre-emptive therapy*

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

Invasive fungal infection: ☐ No ☐ Yes ☐ Unknown

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)**: _____

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

If more than 1 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

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

Parasitic infection: ☐ No ☐ Yes ☐ Unknown

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):** _____

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

If more than 1 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

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

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

1) **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)*: _____

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

If more than 1 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

SECONDARY MALIGNANCIES AND AUTOIMMUNE DISORDERS

Did a secondary malignancy or autoimmune disorder occur after HCT?

☐ No

☐ Yes: **Was it a secondary malignancy or autoimmune disorder?**

- ☐ Secondary malignancy
- ☐ Autoimmune disorder

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

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?

☐ No

☐ Yes: **complete the "Treatment — non-HCT/CT/GT/IST form and /or the Cell infusion sheet"**

☐ 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)*

☐ Unknown

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

Did the patient receive subsequent HCT/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)

MRD detectable (with any method): (only for Acute leukaemia)

☐ No

☐ Yes: **Date of first detectable MRD:** _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* ☐ Unknown

☐ Not evaluated

☐ Unknown

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.

☐ Unknown

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

Appendix 1
Best Response and Disease Status (Disease Specific)

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

Appendix 1
Best Response and Disease Status (Disease Specific)

Acute leukaemias (AML, PLN, Other)

- ☐ Complete remission (CR)
- ☐ Not in complete remission
- ☐ 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:

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

Proceed to next page for Diseases Status section

Plasma cell neoplasms (PCN)

☐ Complete remission (CR)	**Number:** ☐ 1st ☐ 2nd ☐ 3rd or higher ☐ Unknown
☐ Stringent complete remission (sCR)	
☐ Very good partial remission (VGPR)	
☐ Partial remission (PR)	
☐ Relapse	
☐ Progression	
☐ Stable disease (no change, no response/loss of response)	
☐ Not evaluated	
☐ Unknown	

Proceed to next page for Diseases Status section

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

Complete only for PCN Disease Status

Was the patient on dialysis 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
☐ Not evaluated
☐ Unknown

Method used:
(select the most sensitive method used)

☐ PCR
☐ Flow cytometry
☐ NGS
☐ Other; specify: _____
☐ Unknown

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

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

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

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

Lymphomas

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

Technique used for disease assessment:

- ☐ CT scan
- ☐ PET-CT
- ☐ MRI
- ☐ Clinical assessment (for continuous CR)
- ☐ Other; specify: _____
- ☐ Unknown

Solid tumours

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

Bone marrow failures (incl. AA)

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

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

Did transfusions stop during the follow-up period?

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

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

Autoimmune disorders

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

Haemoglobinopathies

Thalassaemia:

Complete only for Thalassemia Best Response

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

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

Complete only for Sickle cell disease Disease Status

Sickling episodes occur during follow-up period:

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

Other diagnosis

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

Appendix 1
Disease Status
Inborn errors only

Patient height at this follow-up: _____ cm ☐ Not evaluated ☐ Unknown

Patient weight at this follow-up: _____ kg ☐ Not evaluated ☐ Unknown

Patient is attending:
☐ Regular school/work
☐ Alternative school/adapted work
☐ Patient is not able to attend work/school
☐ Unknown

(Only for Inborn errors of Immunity)

Immune profiling done during this follow-up period: ☐ No ☐ Yes ☐ Unknown

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

Cell type and test results			**Units** *(for CD4 and CD8, select unit)*
CD3 T-cells: _____	☐ Not evaluated	☐ Unknown	Cells/µl
CD4 T-cells: _____	☐ Not evaluated	☐ Unknown	Cells/µl
CD8 T-cells: _____	☐ Not evaluated	☐ Unknown	Cells/µl
B-cells (i.e. CD19): _____	☐ Not evaluated	☐ Unknown	Cells/µl
NK-cells (CD16/CD56): _____	☐ Not evaluated	☐ Unknown	Cells/µl
Naive CD4 T-cells (CD4/CD45RA): _____	☐ Not evaluated	☐ Unknown	☐ % of CD4 ☐ Cells/µl
Naive CD8 T-cells (CD8/CD45RA): _____	☐ Not evaluated	☐ Unknown	☐ % of CD8 ☐ Cells/µl
IgG: _____	☐ Not evaluated	☐ Unknown	Gram/l
IgA: _____	☐ Not evaluated	☐ Unknown	Gram/l
IgM: _____	☐ Not evaluated	☐ Unkown	Gram/l

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:
. Bacillus (in blood: report only if ≥2 positive separately taken cultures)
. Clostridioides difficile (c difficile/CDT/CDI)
. Clostridium other (NOT difficile)
. Corynebacterium jeikeium
. Corynebacterium other (NOT jeikeium) (in blood: report only if ≥2 positive separately taken cultures)
· Enterococcus faecalis (vancomycin-susceptible)
· Enterococcus faecalis (vancomycin-resistant)
· Enterococcus faecium (vancomycin-susceptible)
· Enterococcus faecium (vancomycin-resistant)
· Listeria monocytogenes
· Nocardia (specify)
. Propionibacterium (in blood: report only if ≥2 positive separately taken cultures)
. Rothia
· Staphylococcus aureus (s aureus/staph aureus) MSSA (methicillin-susceptible)
· Staphylococcus aureus (s aureus/staph aureus) MRSA (methicillin-resistant) vancomycin-susceptible
· Staphylococcus coagulase-negative (in blood: report only if ≥2 positive separately taken cultures)
. Staphylococcus lugdunensis
· Streptococcus pneumoniae (pneumococcus)
· Streptococcus viridans
· Streptococcus other (specify)
· Gram-positive bacteria other (specify)

Gram-negative:
· Acinetobacter baumannii
. Acinetobacter lwoffi (in blood: report only if ≥2 positive separately taken cultures)
. Acinetobacter other (NOT baumannii, NOT lwoffi)
. Bacteroides fragilis
. Bordetella pertussis
. Borrelia
. Brucella
· Campylobacter jejuni
· Citrobacter freundii
. Coxiella burnetti (Q fever)
· Enterobacter cloacae
· Enterobacter other
· Escherichia coli (e coli)
. Fusobacterium
· Haemophilus influenzae (haemophilus influenzae type B/Hib/hemophilus influenzae)
. Haemophilus other (hemophilus)
· Helicobacter pylori
· Klebsiella pneumoniae (carbapenem-susceptible)
. Klebsiella other (NOT pneumoniae) (carbapenem-susceptible)
· Klebsiella (any species) (carbapenem-resistant)
. Klebsiella (any species) (carbapenem-susceptibility not checked)
· Legionella pneumophila
· Morganella morganii
. Micrococcus (in blood: report only if ≥2 positive separately taken cultures)
. Moraxella catarrhalis
· Neisseria gonorrhoeae (gonococcus)
· Neisseria meningitidis (meningococcus)
· Proteus vulgaris
· Providencia
· Pseudomonas aeruginosa (PSA) (carbapenem-susceptible)
· Pseudomonas aeruginosa (PSA) (carbapenem-resistant)
. Pseudomonas aeruginosa (PSA) (carbapenem-susceptibility not checked)
. Pseudomonas other (NOT aeruginosa)
. Raoultella
· Salmonella (specify)
· Serratia marcescens
· Shigella
· Stenotrophomonas maltophilia
· Treponema pallidum (syphilis/lues)
. Yersinia
· Gram-negative bacteria other (specify)

Other bacteria:
· Chlamydia
· Chlamydophila
· Mycobacterium other (specify)
· Mycobacterium tuberculosis (TB)
· Mycoplasma pneumoniae
· Rickettsia
. Ureoplasma
· Bacteria other (specify)

Viral infections:
· Adenovirus (ADV)
. Chikungunya virus
. Crimean-Congo haemorrhagic fever virus (CCHV)
. Dengue virus
· Gastrointestinal viruses:
  o Norovirus
  o Rotavirus
  o Sapovirus
  o Astrovirus
· Hepatotropic viruses:
  o Hepatitis A virus (HAV)
  o Hepatitis B virus (HBV)
  o Hepatitis C virus (HCV)
  o Hepatitis D virus (HDV)
  o Hepatitis E virus (HEV)
· Herpes group:
  o Cytomegalovirus (CMV)
  o Epstein-Barr virus (EBV)
  o Herpes simplex virus (HS/HSV)
  o Herpesvirus 6 (HHV6)
  o Herpesvirus 7 (HHV7)
  o Herpesvirus 8 (HHV8/Kaposi's sarcoma-associated herpesvirus/KSHV/Kaposi)
  o Varicella zoster virus (VZ/VZV/HZV/shingles/zoster/chickenpox)
· Human immunodeficiency virus (HIV)
· Human papilloma viruses (HPV)
. Human T-lymphotropic virus 1 (HTLV-1)
. Human T-lymphotropic virus 2 (HTLV-2)
. Measles virus
. Mumps virus
. Parechovirus
· Parvovirus (parvovirus B-19/B-19)
. Poliovirus
· Polyomaviruses:
  o BK polyomavirus (BKV)
  o JC virus (JCV)
  o Merkel cell virus
· Respiratory viruses:
  o Bocavirus
  o Enterovirus
  o Human coronavirus (excluding SARS-CoV-2 or COVID-19)
  o Influenza A virus (including birdflu)
  o Influenza B virus
  o Human metapneumovirus (hMPV)
  o Parainfluenza
  o Rhinovirus
  o Respiratory syncytial virus (RSV)
  o SARS-CoV-2 virus (COVID-19)
· Rubella virus
. Sandfly viruses (Naples virus/Sicilian virus/Toscana virus/Cyprus virus/Turkey virus/Tehran virus/phlebovirus)
. Tick-borne encephalitis virus (TBE)
. West Nile virus (WNV)
. Yellow fever virus
. Zika virus (ZIKV)
. 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
. Geotrichum
. Magnusiomyces
· Pneumocystis jirovecii
. Saccharomyces
. Saprochaete
· Trichosporon
· Yeasts other (specify)

Moulds:
· Aspergillus flavus
· Aspergillus fumigatus
· Aspergillus other (NOT flavus, NOT fumigatus, NOT terreus)
· Aspergillus terreus
· Blastomyces
· Coccidioides
· Dematiaceous fungi / phaeohyphomycosis (specify)
· Fusarium solani
· Fusarium other (NOT solani)
· Galactomannan positive in blood or BAL, without microbiological confirmation of fungal infection
· Histoplasma
· Lomentospora prolificans / scedosporium prolificans
· Mucorales (mucor/rhizomucor/rhizopus/lichteinia) (specify)
· Paracoccidioides
· Scedosporium other (NOT prolificans) (specify)
. Moulds other (specify)

Parasitic infections:

Protozoa:
. Amoeba
· Babesia
· Cryptosporidium
· Giardia
· Leishmania
· Plasmodium (malaria)
· Toxoplasma gondii
· Trypanosoma cruzi
· Protozoa other

Helminths:
. Schistosoma
· Strongyloides stercoralis
· Helminths other

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, please specify:

Intra-abdominal infections
· Esophagus or gastric infection
· Liver site infection (including biliary tract and gallbladder), please specify:

· Lower gastrointestinal infection, please specify:

. Enteritis infective, please specify:

· Other intra-abdominal infection, please specify:

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

Blood infections
· Bacteremia
· Fungemia
· Viremia (including DNAemia)
. DNAemia for parasitic infection

Other infections
. Device-related infection (other than intravascular catheter)
. Post-transplant lymphoproliferative disorder (PTLD)**

Uro-genital tract infections
· Genital infection, please specify:

· Urinary tract infection, please specify:

Nervous system infection
· Central nervous system infection, please specify:

· Other nervous system infection, please specify:

Cardiovascular infections
. Endocarditis infective
. Other cardiovascular infection, please specify:

Head and neck infections (excluding lymph gland)

. Ear infection
· Oral cavity infection, please specify:

· Retinitis infective
· Sinusitis infective
Other eye infection, please specify:

Osteoarticular infections
· Joint infection
· Bone infection

** Only if pathogen 'JC virus' is selected*
*** Only if pathogen 'Epstein-Barr virus' is selected*

Appendix 4

-- Non-infectious and infectious Complications CTCAE term -- No Reporting Required

Non-infectious complications

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

Infectious complications

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

Appendix 6
Cell Infusion Sheet

Chronological number of CI episode for this patient: _____

Date of the first infusion *(within this episode)*: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*

Number of infusions within this episode (10 weeks): _____
(Count only infusions that are part of the same regimen and given for the same indication)

Source of cells:

- ☐ Allogeneic
- ☐ Autologous

Type of cells:

- ☐ Lymphocytes (DLI)
- ☐ Mesenchymal
- ☐ Fibroblasts
- ☐ Dendritic cells
- ☐ NK cells
- ☐ Regulatory T-cells
- ☐ Gamma/delta cells
- ☐ Virus-specific T-cells (VST)
- ☐ Other; specify: _____

(Only if 'Type of cells: = Virus-specific T-cells (VST))'

Specificity of VST product: ☐ Single-virus specific ☐ Multi-virus specific

If single-virus specific, to which virus? *(Please register this virus in the Infectious complications - Viral infection part and fill in the VST in the 'Pre-emptive viral therapy' or 'Treatment of end-organ viral disease' section)*

- ☐ EBV
- ☐ CMV
- ☐ ADV
- ☐ BKV or JCV
- ☐ HHV-6

If multi-virus specific, to which viruses? *(Please register these viruses in the Infectious complications - Viral infection part and fill in the VST in the 'Pre-emptive viral therapy' or 'Treatment of end-organ viral disease' section)*
(Select all that apply)

- ☐ EBV
- ☐ CMV
- ☐ ADV
- ☐ BKV or JCV
- ☐ HHV-6

Appendix 6
Cell Infusion Sheet continued

Not applicable for Inborn Errors

Disease status at time of this cell infusion*: _____

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

Indication:
(check all that apply)

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

Only for Acute leukemia donor lymphocyte infusions:

Response to DLI:

- ☐ Complete remission (CR) **MRD status:** ☐ MRD negative ☐ MRD positive ☐ Not evaluated ☐ Unknown
- ☐ Not in CR
- ☐ Not evaluated
- ☐ Unknown