Document Type	|	Form
Index Number	|	Registry 110
Version Number	|	1.0
Title	|	HCT FU D100
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Authorised By	|	Annelot van Amerongen
Authorised On	|	22-Aug-2023
Release Date:		22-Aug-2023

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

BEST RESPONSE

Best clinical/biological response after HCT *(observed before any subsequent treatment):*
(this field is not mandatory for Inherited Disorders)

☐ Continued complete remission (CCR)
☐ Complete remission (CR)
☐ Partial remission
☐ No response / Stable disease / No change
☐ Disease progression
☐ Not evaluated
☐ Unknown

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

RECOVERY

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

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

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

☐ Never below

☐ Unknown

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

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

☐ Yes: **Date of platelet reconstitution:** _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* ☐ Date 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)* ☐ Date unknown

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

Did graft versus host disease (GvHD) occur?

☐ No *(proceed to 'Complications since the last report - Non-infectious complications' on page 3)*

☐ Yes: **Did the patient receive a systemic immunosuppressive treatment for GvHD?**

☐ No

☐ Yes; **Date treatment started:** _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*

Immunosuppression ongoing: ☐ No ☐ Yes ☐ Unknown

Acute GvHD: ☐ No

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

Maximum observed organ severity score:

Skin:	☐ 0 *(none)*	☐ 1	☐ 2	☐ 3	☐ 4
Liver:	☐ 0 *(none)*	☐ 1	☐ 2	☐ 3	☐ 4
Lower GI tract:	☐ 0 *(none)*	☐ 1	☐ 2	☐ 3	☐ 4
Upper GI tract:	☐ 0 *(none)*	☐ 1			
Other site affected:	☐ No	☐ Yes; specify: _____			

Overall maximum grade observed: ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ Unknown

Steroid-refractory acute GvHD: ☐ No ☐ Yes

Date of aGvHD resolution: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* ☐ Ongoing

Chronic GvHD: ☐ No

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

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

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

Maximum observed organ severity score:

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

Steroid-refractory chronic GvHD: ☐ No ☐ Yes

Date of cGvHD resolution: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* ☐ Ongoing

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

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

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

☐ No (*proceed to 'Complications since the last report - Infectious complications' on page 4)*
☐ Yes (*report in the table below*)

Adverse event *(check all that apply)*	**Observed?**	**maximum CTCAE grade observed**	**Onset date** *(YYYY/MM/DD)*
Respiratory, thoracic and mediastinal disorders	☐ No ☐ Yes	☐ 3 ☐ 4 ☐ 5 (fatal) ☐ Unknown	_ _ _ _/ _ _/ _ _
Cardiovascular event	☐ No ☐ Yes	☐ 3 ☐ 4 ☐ 5 (fatal) ☐ Unknown	_ _ _ _/ _ _/ _ _
Aseptic bone necrosis	☐ No ☐ Yes	☐ 3 ☐ 4 ☐ 5 (fatal) ☐ Unknown	_ _ _ _/ _ _/ _ _
Pure red cell aplasia	☐ No ☐ Yes	Not applicable	_ _ _ _/ _ _/ _ _
Gastrointestinal (GI) toxicity	☐ No ☐ Yes	☐ 3 ☐ 4 ☐ 5 (fatal) ☐ Unknown	_ _ _ _/ _ _/ _ _
Skin toxicity	☐ No ☐ Yes	☐ 3 ☐ 4 ☐ 5 (fatal) ☐ Unknown	_ _ _ _/ _ _/ _ _
Renal failure (chronic kidney disease, acute kidney injury)	☐ No ☐ Yes	☐ 3 ☐ 4 ☐ 5 (fatal) ☐ Unknown	_ _ _ _/ _ _/ _ _
Haemorhage	☐ No ☐ Yes	☐ 3 ☐ 4 ☐ 5 (fatal) ☐ Unknown	_ _ _ _/ _ _/ _ _
Transplant-associated microangiopathy	☐ No ☐ Yes	☐ Non-severe ☐ Severe ☐ Unknown	_ _ _ _/ _ _/ _ _
Veno-occlusive disease (VOD)	☐ No ☐ Yes	☐ Mild ☐ Severe ☐ Unknown ☐ Moderate ☐ Very severe	_ _ _ _/ _ _/ _ _
Liver disorder	☐ No ☐ Yes	☐ 3 ☐ 4 ☐ 5 (fatal) ☐ Unknown	_ _ _ _/ _ _/ _ _
Hemophagocytic lymphohistiocytosis (HLH)	☐ No ☐ Yes	☐ 3 ☐ 4 ☐ 5 (fatal) ☐ Unknown	_ _ _ _/ _ _/ _ _
Cytokine release syndrome (CRS)	☐ No ☐ Yes	☐ 3 ☐ 4 ☐ 5 (fatal) ☐ Unknown	_ _ _ _/ _ _/ _ _
Central nervous system (CNS) toxicity	☐ No ☐ Yes	☐ 3 ☐ 4 ☐ 5 (fatal) ☐ Unknown	_ _ _ _/ _ _/ _ _
Stroke	☐ No ☐ Yes	☐ 3 ☐ 4 ☐ 5 (fatal) ☐ Unknown	_ _ _ _/ _ _/ _ _
Posterior reversible encephalopathy syndrome (PRES)	☐ No ☐ Yes	☐ 3 ☐ 4 ☐ 5 (fatal) ☐ Unknown	_ _ _ _/ _ _/ _ _
Other; specify: _____		☐ 3 ☐ 4 ☐ 5 (fatal) ☐ Unknown	_ _ _ _/ _ _/ _ _

COMPLICATIONS SINCE THE LAST REPORT
-- Infectious complications --

Did infectious complications occur during the follow-up period?

☐ No (*proceed to 'SARS-CoV2 related questions' on page 9*)

☐ Yes (*report all infection-related complications below*)

Bacterial infection: ☐ No ☐ Yes

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

☐ Gram-positive ☐ Gram-negative ☐ Other

Pathogen*: _____

Infection with clinical implications: ☐ No
☐ Yes:
- ☐ Symptoms/signs of disease
- ☐ Administration of pathogen-directed therapy
- ☐ Isolation precautions or surveillance

☐ Unknown

Localisation (CTCAE term)**: _____

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

Resolved: ☐ No ☐ Yes ☐ Unknown

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

☐ Gram-positive ☐ Gram-negative ☐ Other

Pathogen*: _____

Infection with clinical implications: ☐ No
☐ Yes:
- ☐ Symptoms/signs of disease
- ☐ Administration of pathogen-directed therapy
- ☐ Isolation precautions or surveillance

☐ Unknown

Localisation (CTCAE term)**: _____

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

Resolved: ☐ No ☐ Yes ☐ Unknown

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

* Indicate the pathogen and sub-type (if applicable) from the list of pathogens provided in Appendix 1 at pages 16-17
** Indicate CTCAE term by choosing from the list provided in Appendix 2 at page 18
*** If intravascular catheter-related infection, specify it by choosing from the list provided in Appendix 3 at page 18

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 a primary infection in a previously seronegative patient?** ☐ No ☐ Yes

Infection with clinical implications: ☐ No ☐ Yes:
- ☐ Symptoms/signs of disease
- ☐ Administration of pathogen-directed therapy
- ☐ Isolation precautions or surveillance

☐ Unknown

Localisation (CTCAE term)****: _____

Resolved: ☐ No ☐ Yes ☐ Unknown

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

Pathogen*: _____

If the pathogen was CMV/EBV: **Was this a primary infection in a previously seronegative patient?** ☐ No ☐ Yes

Infection with clinical implications: ☐ No ☐ Yes:
- ☐ Symptoms/signs of disease
- ☐ Administration of pathogen-directed therapy
- ☐ Isolation precautions or surveillance

☐ Unknown

Localisation (CTCAE term)****: _____

Resolved: ☐ No ☐ Yes ☐ Unknown

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

* Indicate the pathogen and sub-type (if applicable) from the list of pathogens provided in Appendix 1 at pages 16-17
** Indicate CTCAE term by choosing from the list provided in Appendix 2 at page 18
*** If intravascular catheter-related infection, specify it by choosing from the list provided in Appendix 3 at page 18

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:
- ☐ Symptoms/signs of disease
- ☐ Administration of pathogen-directed therapy
- ☐ Isolation precautions or surveillance

☐ Unknown

Localisation (CTCAE term)**: _____

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

Resolved: ☐ No ☐ Yes ☐ Unknown

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

☐ Yeasts ☐ Moulds

Pathogen*: _____

Infection with clinical implications: ☐ No
☐ Yes:
- ☐ Symptoms/signs or disease
- ☐ Administration of pathogen-directed therapy
- ☐ Isolation precautions or surveillance

☐ Unknown

Localisation (CTCAE term)**: _____

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

Resolved: ☐ No ☐ Yes ☐ Unknown

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

* Indicate the pathogen and sub-type (if applicable) from the list of pathogens provided in Appendix 1 at pages 16-17
** Indicate CTCAE term by choosing from the list provided in Appendix 2 at page 18
*** If intravascular catheter-related infection, specify it by choosing from the list provided in Appendix 3 at page 18

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:
- ☐ Symptoms/signs or disease
- ☐ Administration of pathogen-directed therapy
- ☐ Isolation precautions or surveillance

☐ Unknown

Localisation (CTCAE term)**: _____

Resolved: ☐ No ☐ Yes ☐ Unknown

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

☐ Protozoa ☐ Helminths

Pathogen*: _____

Infection with clinical implications: ☐ No
☐ Yes:
- ☐ Symptoms/signs or disease
- ☐ Administration of pathogen-directed therapy
- ☐ Isolation precautions or surveillance

☐ Unknown

Localisation (CTCAE term)**: _____

Resolved: ☐ No ☐ Yes ☐ Unknown

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

* Indicate the pathogen and sub-type (if applicable) from the list of pathogens provided in Appendix 1 at pages 16-17
** Indicate CTCAE term by choosing from the list provided in Appendix 2 at page 18
*** If intravascular catheter-related infection, specify it by choosing from the list provided in Appendix 3 at page 18

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:
- ☐ Symptoms/signs or disease
- ☐ Administration of pathogen-directed therapy
- ☐ Isolation precautions or surveillance

☐ Unknown

Localisation (CTCAE term)**: _____

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

Resolved: ☐ No ☐ Yes ☐ Unknown

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

☐ Unknown

Localisation (CTCAE term)**: _____

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

Resolved: ☐ No ☐ Yes ☐ Unknown

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

* Indicate the pathogen and sub-type (if applicable) from the list of pathogens provided in Appendix 1 at pages 16-17
** Indicate CTCAE term by choosing from the list provided in Appendix 2 at page 18
*** If intravascular catheter-related infection, specify it by choosing from the list provided in Appendix 3 at page 18

SARS-CoV-2 RELATED QUESTIONS

Did the patient receive a vaccination against SARS-CoV-2 after HCT?

☐ No

☐ Yes: Number of doses: _____

Date of the last dose: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*

Did the patient have a SARS-CoV-2 infection after HCT *(positive PCR or antigen test)***:**

☐ No

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

If more than one episode *(new confirmed infection at least ≥ 90 days after the clearance of the previous one or at any time if evidence of a different variant):*

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

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

SECONDARY MALIGNANCIES AND AUTOIMMUNE DISORDERS

Did a secondary malignancy or autoimmune disorder occur?

☐ No

☐ Yes: was this disease an indication for a subsequent HCT/CT/IST?

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

GRAFT FUNCTION

Early graft loss/failure (*engraftment followed by loss of graft within the first 100 days or no engraftment at all)*:

☐ No

☐ Yes: **Type of graft loss:** ☐ Primary *(no engraftment at all)*
☐ Secondary *(after initial engraftment)*

Date of graft loss: _ _ _ _ / _ _ / _ _ (*YYYY/MM/DD)*

☐ Unknown

Severe poor graft function (defined as: platelets <20, WBC <1.0, Neu <0.5 with full donor chimerism beyond day+30)**:**

☐ No

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

☐ Unknown

Percentage of donor cells (chimerism): _____ **%** ☐ Not evaluated
(only if patient received an allogeneic transplant)

Chimerism test date: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*

Source of cells tested: ☐ Peripheral blood
☐ Bone marrow
☐ Other

ADDITIONAL TREATMENT incl. CELL THERAPY

Did the patient receive any additional disease treatment <u>since the last follow-up</u>?

☐ No

☐ Yes; **Date started**: _ _ _ _/ _ _/ _ _ *(YYYY/MM/DD)*

Did the patient receive additional <u>cell infusions</u> *(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.*

Is this cell infusion an autologous boost? ☐ No ☐ Yes

Date boost took place: _ _ _ _/ _ _/ _ _ *(YYYY/MM/DD)*

If this cell infusion is not a boost, attach the Cell Infusion (CI) sheet available in Appendix 4, 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.

Radiotherapy:

☐ No

☐ Yes

☐ Unknown

Drugs/chemotherapy?

☐ No (*proceed to 'Relapse/progression or significant worsening' at page 13*)

☐ Yes (*complete the table on the next page*)

ADDITIONAL TREATMENT incl. CELL THERAPY continued

List all chemotherapy/drugs given during one line of treatment:

Line of treatment	Drug/regimen used*	Start date *(YYYY/MM/DD)*	Reason	Response to this line of treatment	Response assessment date *(YYYY/MM/DD)*
1		_ _ _ _/ _ _ / _ _	☐ Prophylaxis / preventive ☐ Relapse ☐ Maintenance ☐ Consolidation ☐ Other; specify: _____	☐ Continued complete remission (CCR) ☐ Complete remission (CR) ☐ Partial remission ☐ No response / Stable disease / No change ☐ Disease progression ☐ Not evaluated ☐ Unknown	_ _ _ _/ _ _ / _ _
2		_ _ _ _/ _ _ / _ _	☐ Prophylaxis / preventive ☐ Relapse ☐ Maintenance ☐ Consolidation ☐ Other; specify: _____	☐ Continued complete remission (CCR) ☐ Complete remission (CR) ☐ Partial remission ☐ No response / Stable disease / No change ☐ Disease progression ☐ Not evaluated ☐ Unknown	_ _ _ _/ _ _ / _ _
3		_ _ _ _/ _ _ / _ _	☐ Prophylaxis / preventive ☐ Relapse ☐ Maintenance ☐ Consolidation ☐ Other; specify: _____	☐ Continued complete remission (CCR) ☐ Complete remission (CR) ☐ Partial remission ☐ No response / Stable disease / No change ☐ Disease progression ☐ Not evaluated ☐ Unknown	_ _ _ _/ _ _ / _ _
4		_ _ _ _/ _ _ / _ _	☐ Prophylaxis / preventive ☐ Relapse ☐ Maintenance ☐ Consolidation ☐ Other; specify: _____	☐ Continued complete remission (CCR) ☐ Complete remission (CR) ☐ Partial remission ☐ No response / Stable disease / No change ☐ Disease progression ☐ Not evaluated ☐ Unknown	_ _ _ _/ _ _ / _ _

Copy and fill-in this section as many times as necessary

*Please consult the **LIST OF CHEMOTHERAPY DRUGS/AGENTS AND REGIMENS** on the EBMT website for drugs/regimens names

RELAPSE/PROGRESSION OR SIGNIFICANT WORSENING

Was there a relapse/progression or significant worsening of organ function related to the primary disease after HCT? *(detected by any method)*

☐ No
☐ Continuous progression since HCT
☐ Yes: Date of first relapse/progression: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*

Malignant disorders only:

Type of relapse:

☐ Medullary only
☐ Extra-medullary only
☐ Both, medullary and extra-medullary
☐ Unknown

If the relapse was extra-medullary or both medullary and extra-medullary:

Involvement at time of relapse:

Skin:	☐ No	☐ Yes	☐ Not evaluated
CNS:	☐ No	☐ Yes	☐ Not evaluated
Testes/Ovary:	☐ No	☐ Yes	☐ Not evaluated
Other:	☐ No	☐ Yes; specify: _____	

DISEASE STATUS

Disease status at the last assessment before this follow-up or date of death:
(record the most recent status)

- ☐ Continued complete remission (CCR)
- ☐ Complete remission (CR)
- ☐ Partial remission
- ☐ No response / Stable disease / No change
- ☐ Disease progression
- ☐ Not evaluated
- ☐ Unknown

Was the disease detected by any method?

- ☐ No
- ☐ Yes: Date last assessed: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*

  Method; specify:
  - ☐ Haematological
  - ☐ Radiological
  - ☐ Molecular
  - ☐ Other; specify _____

Immunosuppression post transplant? *(Allogeneic HCT only)*

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

Did transfusions stop after HCT? *(Haemoglobinopathies and bone marrow failures only)*

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

DISEASE STATUS
Leukaemias only

Minimal residual disease (MRD):

- ☐ Positive;
  - ☐ Increasing (>1log10 change) ☐ Stable (<1log10 change) ☐ Decreasing (>1log10 change)
- ☐ Negative
- ☐ Not evaluated

Date MRD status evaluated: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*

Sensitivity of MRD assay:

- ☐ $<10^{-5}$
- ☐ $<10^{-4}$
- ☐ $<10^{-3}$
- ☐ Other, specify: _____

DISEASE STATUS continued
Leukaemias only

Method used:
(select all that apply)

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

CAUSE OF DEATH
(if patient died)

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

☐ Relapse or progression/persistent disease	
☐ Secondary malignancy	
☐ Cellular therapy-related	**Select treatment related cause:** ☐ Graft versus Host Disease ☐ Non-infectious complication ☐ Infectious complication: *(select all that apply)* ☐ Bacterial infection ☐ Viral infection ☐ Fungal infection ☐ Parasitic infection ☐ Infection with unknown pathogen
☐ HCT-related	
☐ Unknown	
☐ Other; specify: _____	

Appendix 1
-- 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:
- Clostridium difficile
- Enterococcus faecalis Vancomycin susceptible
- Enterococcus faecalis Vancomycin-resistant
- Enterococcus faecium Vancomycin susceptible
- Enterococcus faecium Vancomycin-resistant
- Listeria monocytogenes
- Nocardia spp (specify)
- Staphylococcus aureus MRSA (methicillin-resistant)
- Staphylococcus aureus MSSA (methicillin-susceptible)
- Staphylococcus aureus VISA (intermediate vancomycin resistant , MIC 4-8 µg/ml)
- Staphylococcus aureus VRSA (Vancomycin-resistant, MIC ≥ 16µg/ml)
- Staphylococcus coagulase-negative spp (at least two positive blood cultures)
- Streptococcus pneumoniae
- Streptococcus viridans
- Streptococcus other species (specify)
- Gram-positive bacteria other species (specify)

Gram-negative:
- Acinetobacter baumannii
- Campylobacter jejuni
- Citrobacter freundii
- Enterobacter cloacae
- Enterobacter other species (specify)
- Escherichia coli
- Haemophilus influenzae
- Helicobacter pylori
- Klebsiella aerogenes (carbapenem susceptible)
- Klebsiella pneumoniae (carbapenem susceptible)
- Klebsiella 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 species (specify)

Other bacteria:
- Chlamydia species
- Chlamydophila
- Mycobacterium other spp (specify)
- Mycobacterium tuberculosis
- Mycoplasma pneumoniae
- Rickettsia species
- 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 1
-- 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)
· Mucormycosis (specify)
· Phaeohyphomycosis (specify)
· Scedosporium spp (specify)
· Moulds other species (specify)
· Mould infection diagnosed based on positive galactomannan only, without microbiological confirmation
· Blastomycosis
· Histoplasmosis (specify)
· Coccidiomycosis
· Paracoccidiomycosis

Parasitic infections:

Protozoa:
· Babesiosis (specify)
· Cryptosporidium
· Giardiasis
· Leishmaniasia spp (specify)
· Plasmodium spp (specify)
· Toxoplasma gondii
· Trypanosoma cruzi
· Protozoa other species (specify)

Helminths:
· Strongyloides stercoralis
· Other helminths

Appendix 2
-- CTCAE term --

CTCAE terms related to infections and infestations (version 5.0.)
https://ctep.cancer.gov/protocoldevelopment/electronic_applications/ctc.htm#ctc_50

Respiratory tract
· Bronchial infection
· Lung infection
· Laryngitis
· Pleural infection
· Tracheitis
· Upper respiratory infection

Intra-abdominal infections
· Anorectal infection
· Appendicitis
· Appendicitis perforated
· Biliary tract infection
· Cecal infection
· Duodenal infection
· Enterocolitis infectious
· Esophageal infection
· Gallbladder infection
· Gastritis
· Hepatic infection
· Pancreas infection
· Pelvic infection
· Peritoneal infection
· Splenic infection
· Stoma site infection
· Small intestine infection
· Typhilitis

Uro-genital tract infections
· Bladder infection
· Cervicitis infection
· Kidney infection
· Ovarian infection
· Scrotal infection
· Penile infection
· Prostate infection
· Urethral infection
· Urinary tract infection
· Uterine infection
· Vaginal infection
· Vulval infection

Muscles and bones
· Bone infection
· Myositis infective
· Joint infection

Nervous system infection
· Cranial nerve infection
· Encephalitis infection
· Encephalomyelitis infection
· Meningitis
· Myelitis
· Peripheral nerve infection

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

Skin, soft tissue and mucosal surfaces
· Breast infection
· Folliculitis
· Lymph gland infection
· Nail infection
· Mucosal infection
· Papulopustular rash
· Paronychia
· Rash pustular
· Skin infection
· Soft tissue infection
· Wound infection

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

Blood
· Bacteremia
· Fungemia
· Viremia

Others
· Device related infection (other than Intravascular catheter)
· Sepsis

Appendix 3
-- Intravascular catheter-related infections --

CVC infections:
Catheter colonization
Phlebitis
Exit site infection
Tunnel infection
Pocket infection
Bloodstream infection

Appendix 4
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 10 weeks: _____
(Count only infusions that are part of the same regimen and given for the same indication.)

Source of cells:
(check all that apply)
- ☐ Allogeneic
- ☐ Autologous

Type of cells:
(check all that apply)
- ☐ Lymphocytes (DLI)
- ☐ Mesenchymal
- ☐ Fibroblasts
- ☐ Dendritic cells
- ☐ NK cells
- ☐ Regulatory T-cells
- ☐ Gamma/delta cells
- ☐ Virus-specifc T-cells; specify virus: _____
- ☐ Other; specify: _____

Disease status at time of this cell infusion:
- ☐ Continued complete remission (CCR)
- ☐ Complete remission (CR)
- ☐ Partial remission
- ☐ No response / Stable disease / No change
- ☐ Disease progression
- ☐ Not evaluated
- ☐ Unknown

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 chimaerism
- ☐ Treatment of viral infection other than EBV
- ☐ Poor graft function
- ☐ Infection prophylaxis
- ☐ Other; specify: _____

Acute GvHD -- maximum grade *(after this infusion episode but before any subsequent cell infusion/HCT/CT)*:
- ☐ 0 (none)
- ☐ 1
- ☐ 2
- ☐ 3
- ☐ 4
- ☐ Present but grade unknown