<table>
<thead>
<tr>
<th>Document Type</th>
<th>Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>Index Number</td>
<td>Registry 128</td>
</tr>
<tr>
<td>Version Number</td>
<td>1.0</td>
</tr>
<tr>
<td>Title</td>
<td>HCT Annual FU</td>
</tr>
<tr>
<td>Author</td>
<td>Annelot van Amerongen</td>
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<tr>
<td>Authorised By</td>
<td>Annelot van Amerongen</td>
</tr>
<tr>
<td>Authorised On</td>
<td>22-Aug-2023</td>
</tr>
<tr>
<td>Release Date</td>
<td>22-Aug-2023</td>
</tr>
</tbody>
</table>

Index: Registry 128 | Title: HCT Annual FU | Version: 1.0 | Effective Date: 2023-08-22 | THIS IS AN UNCONTROLLED COPY
# 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

## BEST RESPONSE  
*Complete only for the first annual follow-up*

**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
**COMPLICATIONS SINCE THE LAST REPORT**

--- GyHD ---

*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:**

<table>
<thead>
<tr>
<th>Organ</th>
<th>0 (none)</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Liver</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lower GI tract</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Upper GI tract</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other site</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**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 this period:**

<table>
<thead>
<tr>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
<th>Unknown</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

**Maximum observed organ severity score:**

<table>
<thead>
<tr>
<th>Organ</th>
<th>0 (none)</th>
<th>1</th>
<th>2</th>
<th>3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gastrointestinal</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Eyes</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Liver</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Joints and fascia</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lungs</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Genitalia</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other site</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**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)

<table>
<thead>
<tr>
<th>Adverse event (check all that apply)</th>
<th>Observed?</th>
<th>maximum CTCAE grade observed</th>
<th>Onset date (YYYY/MM/DD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Respiratory, thoracic and mediastinal disorders</td>
<td>[ ] No</td>
<td>[ ] 3  [ ] 4  [ ] 5 (fatal)  [ ] Unknown</td>
<td><em><strong>/</strong></em>/___</td>
</tr>
<tr>
<td>Cardiovascular event</td>
<td>[ ] No</td>
<td>[ ] 3  [ ] 4  [ ] 5 (fatal)  [ ] Unknown</td>
<td><em><strong>/</strong></em>/___</td>
</tr>
<tr>
<td>Aseptic bone necrosis</td>
<td>[ ] No</td>
<td>[ ] 3  [ ] 4  [ ] 5 (fatal)  [ ] Unknown</td>
<td><em><strong>/</strong></em>/___</td>
</tr>
<tr>
<td>Pure red cell aplasia</td>
<td>[ ] No</td>
<td>Not applicable</td>
<td><em><strong>/</strong></em>/___</td>
</tr>
<tr>
<td>Gastrointestinal (GI) toxicity</td>
<td>[ ] No</td>
<td>[ ] 3  [ ] 4  [ ] 5 (fatal)  [ ] Unknown</td>
<td><em><strong>/</strong></em>/___</td>
</tr>
<tr>
<td>Skin toxicity</td>
<td>[ ] No</td>
<td>[ ] 3  [ ] 4  [ ] 5 (fatal)  [ ] Unknown</td>
<td><em><strong>/</strong></em>/___</td>
</tr>
<tr>
<td>Renal failure (chronic kidney disease, acute kidney injury)</td>
<td>[ ] No</td>
<td>[ ] 3  [ ] 4  [ ] 5 (fatal)  [ ] Unknown</td>
<td><em><strong>/</strong></em>/___</td>
</tr>
<tr>
<td>Haemorrhage</td>
<td>[ ] No</td>
<td>[ ] 3  [ ] 4  [ ] 5 (fatal)  [ ] Unknown</td>
<td><em><strong>/</strong></em>/___</td>
</tr>
<tr>
<td>Transplant-associated microangiopathy</td>
<td>[ ] No</td>
<td>[ ] Non-severe  [ ] Severe  [ ] Unknown</td>
<td><em><strong>/</strong></em>/___</td>
</tr>
<tr>
<td>Veno-oclusive disease (VOD)</td>
<td>[ ] No</td>
<td>[ ] Mild  [ ] Severe  [ ] Very severe  [ ] Unknown</td>
<td><em><strong>/</strong></em>/___</td>
</tr>
<tr>
<td>Liver disorder</td>
<td>[ ] No</td>
<td>[ ] 3  [ ] 4  [ ] 5 (fatal)  [ ] Unknown</td>
<td><em><strong>/</strong></em>/___</td>
</tr>
<tr>
<td>Hemophagocytic lymphohistiocytosis (HLH)</td>
<td>[ ] No</td>
<td>[ ] 3  [ ] 4  [ ] 5 (fatal)  [ ] Unknown</td>
<td><em><strong>/</strong></em>/___</td>
</tr>
<tr>
<td>Cytokine release syndrome (CRS)</td>
<td>[ ] No</td>
<td>[ ] 3  [ ] 4  [ ] 5 (fatal)  [ ] Unknown</td>
<td><em><strong>/</strong></em>/___</td>
</tr>
<tr>
<td>Central nervous system (CNS) toxicity</td>
<td>[ ] No</td>
<td>[ ] 3  [ ] 4  [ ] 5 (fatal)  [ ] Unknown</td>
<td><em><strong>/</strong></em>/___</td>
</tr>
<tr>
<td>Stroke</td>
<td>[ ] No</td>
<td>[ ] 3  [ ] 4  [ ] 5 (fatal)  [ ] Unknown</td>
<td><em><strong>/</strong></em>/___</td>
</tr>
<tr>
<td>Posterior reversible encephalopathy syndrome (PRES)</td>
<td>[ ] No</td>
<td>[ ] 3  [ ] 4  [ ] 5 (fatal)  [ ] Unknown</td>
<td><em><strong>/</strong></em>/___</td>
</tr>
<tr>
<td>Other; specify:</td>
<td>[ ] No</td>
<td>[ ] 3  [ ] 4  [ ] 5 (fatal)  [ ] Unknown</td>
<td><em><strong>/</strong></em>/___</td>
</tr>
</tbody>
</table>
## 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:** 
   
   - [ ] 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)**:  

2. **Start date:**

   - [ ] 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***:

   **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 15-16

** Indicate CTCAE term by choosing from the list provided in Appendix 2 at page 17

*** If intravascular catheter-related infection, specify it by choosing from the list provided in Appendix 3 at page 17

---

2023-08-22
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)**: __________________________

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

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)**: __________________________

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

Resolved:  ☐ No  ☐ Yes  ☐ Unknown

* Indicate the pathogen and sub-type (if applicable) from the list of pathogens provided in Appendix 1 at pages 15-16
** Indicate CTCAE term by choosing from the list provided in Appendix 2 at page 17
*** If intravascular catheter-related infection, specify it by choosing from the list provided in Appendix 3 at page 17

If more than 2 episodes, copy and fill-in this table as many times as necessary.
### COMPLICATIONS SINCE THE LAST REPORT
--- Infectious complications --- continued

<table>
<thead>
<tr>
<th>Fungal infection:</th>
<th>No</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1) Start date:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- 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

<table>
<thead>
<tr>
<th>2) Start date:</th>
<th></th>
<th></th>
</tr>
</thead>
</table>

- 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 15-16

** Indicate CTCAE term by choosing from the list provided in Appendix 2 at page 17

*** If intravascular catheter-related infection, specify it by choosing from the list provided in Appendix 3 at page 17

---

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### Complications since the last report

#### Infectious complications -- continued

<table>
<thead>
<tr>
<th>Parasitic infection:</th>
<th>☐ No</th>
<th>☐ Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1) Start date:</strong></td>
<td>_ _ _ / _ _ / _ _ (_YYYY/MM/DD)</td>
<td></td>
</tr>
<tr>
<td>☐ Protozoa</td>
<td>☐ Helminths</td>
<td></td>
</tr>
<tr>
<td><strong>Pathogen</strong>:</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Infection with clinical implications:</strong></td>
<td>☐ No</td>
<td>☐ Yes:</td>
</tr>
<tr>
<td>☐ Symptoms/signs or disease</td>
<td>☐ Administration of pathogen-directed therapy</td>
<td>☐ Isolation precautions or surveillance</td>
</tr>
<tr>
<td>☐ Unknown</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Localisation (CTCAE term)</strong>:</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Intravascular catheter-related infection</strong>:</td>
<td>☐ No</td>
<td>☐ Yes; specify***:</td>
</tr>
<tr>
<td>☐ Unknown</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Resolved</strong>:</td>
<td>☐ No</td>
<td>☐ Yes</td>
</tr>
</tbody>
</table>

| **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)**: | | |
| **Intravascular catheter-related infection**: | ☐ No | ☐ Yes; specify***: | |
| ☐ Unknown | | |
| **Resolved**: | ☐ No | ☐ Yes | ☐ Unknown |

*Indicate the pathogen and sub-type (if applicable) from the list of pathogens provided in Appendix 1 at pages 15-16

**Indicate CTCAE term by choosing from the list provided in Appendix 2 at page 17

***If intravascular catheter-related infection, specify it by choosing from the list provided in Appendix 3 at page 17

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

---

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### 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 15-16

** Indicate CTCAE term by choosing from the list provided in Appendix 2 at page 17

*** If intravascular catheter-related infection, specify it by choosing from the list provided in Appendix 3 at page 17
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

Late graft loss:

☐ No
☐ Yes: Date of graft loss: __ __ / __ / __ (YYYY/MM/DD)

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 *since the last follow-up*?
- [ ] No
- [ ] Yes; Date started: _ _ _ _ / _ _ _ _ (YYYY/MM/DD)

Did the patient receive additional *cell infusions* *(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 12)*
- [ ] Yes *(complete the table on the next page)*
## ADDITIONAL TREATMENT incl. CELL THERAPY

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

<table>
<thead>
<tr>
<th>Line of treatment</th>
<th>Drug/regimen used*</th>
<th>Start date (YYYY/MM/DD)</th>
<th>Reason</th>
<th>Response to this line of treatment</th>
<th>Response assessment date (YYYY/MM/DD)</th>
</tr>
</thead>
</table>
| 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: Number of relapses/progressions since HCT: ___
  Date of first relapse/progression: ___/___/___ (YYYY/MM/DD)
  Date of subsequent relapse/progression: ___/___/___ (YYYY/MM/DD)
  If more than 2 relapses/progressions occurred, copy and fill this section as many times as necessary.

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 only)
☐ Patient was never transfusion dependent
☐ No
☐ Yes: Did the patient go back to regular transfusion dependency?
  ☐ 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: _______

Method used:
☐ PCR
☐ Flow cytometry
☐ NGS
☐ Other; specify: ____________
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
   ☐ Yes
   ☐ Still pregnant at time of follow-up
   ☐ Unknown
☐ Unknown

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 --


### 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 (carbenem susceptible)
- Klebsiella pneumoniae (carbenem susceptible)
- Klebsiella species Carbenem-resistant (specify)
- Legionella pneumophila
- Morganella morgani
- Neisseria gonorrhoeae
- Neisseria meningitidis
- Proteus vulgaris
- Providencia spp
- Pseudomonas aeruginosa (carbenem susceptible)
- Pseudomonas aeruginosa (carbenem-resistant)
- Salmonella spp (specify)
- Serratia marcescens
- Shigella spp
- Stenotrophomonas maltophilia
- Treponema pallidum
- Gram-negative bacteria other species (specify)

### Viral infections:

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

### Other bacteria:
- Chlamydia species
- Chlamydia phila
- Mycobacterium other spp (specify)
- Mycobacterium tuberculosis
- Mycoplasma pneumoniae
- Rickettsia species
- Bacteria other (specify)
Appendix 1
-- Pathogens as per EBMT Registry database -- continued


**Fungal infections:**

**Yeast:**
- Candida albicans
- Candida auris
- Candida other (specify)
- Cryptococcus neoformans
- Trichosporon (specify)
- Pneumocystis jiroveci
- Yeasts other (specify)

**Moulds:**
- Aspergillus flavus
- Aspergillus fumigatus
- Aspergillus other spp (specify)
- Aspergillus terreus
- Fusarium other spp (specify)
- Fusarium solani
- Lomentospora prolificans (formerly Scedosporium prolificans)
- 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
- Leishmania 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

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

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

Blood
- Bacteremia
- Fungemia
- Viremia

Appendix 3
-- Intravascular catheter-related infections --

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

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### 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
- 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
- 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