<table>
<thead>
<tr>
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<th>Form</th>
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<tbody>
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<td>Registry 110</td>
</tr>
<tr>
<td>Version Number</td>
<td>1.0</td>
</tr>
<tr>
<td>Title</td>
<td>HCT FU D100</td>
</tr>
<tr>
<td>Author</td>
<td>Annelot van Amerongen</td>
</tr>
<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>
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 ≥ 0.5x10⁹ 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 ≥ 20x10⁹ cells/L):
☐ No: Date of the last assessment: _ _ _ / _ _ / _ (YYYY/MM/DD)
☐ Yes: Date of platelet reconstitution: _ _ _ / _ _ / _ (YYYY/MM/DD)  
(first of 3 consecutive values after 7 days without platelet transfusion) ☐ Date unknown
☐ 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:

<table>
<thead>
<tr>
<th>Organ</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin</td>
<td>0 (none)</td>
</tr>
<tr>
<td>Liver</td>
<td>0 (none)</td>
</tr>
<tr>
<td>Lower GI tract</td>
<td>0 (none)</td>
</tr>
<tr>
<td>Upper GI tract</td>
<td>0 (none)</td>
</tr>
<tr>
<td>Other site affected</td>
<td>No</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:

☐ Mild

☐ Moderate

☐ Severe

☐ Unknown

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

Maximum observed organ severity score:

<table>
<thead>
<tr>
<th>Organ</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin</td>
<td>0 (none)</td>
</tr>
<tr>
<td>Oral</td>
<td>0 (none)</td>
</tr>
<tr>
<td>Gastrointestinal</td>
<td>0 (none)</td>
</tr>
<tr>
<td>Eyes</td>
<td>0 (none)</td>
</tr>
<tr>
<td>Liver</td>
<td>0 (none)</td>
</tr>
<tr>
<td>Joints and fascia</td>
<td>0 (none)</td>
</tr>
<tr>
<td>Lungs</td>
<td>0 (none)</td>
</tr>
<tr>
<td>Genitalia</td>
<td>0 (none)</td>
</tr>
<tr>
<td>Other site affected</td>
<td>No</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 □ Yes</td>
<td>□ 3 □ 4 □ 5 (fatal) □ Unknown</td>
<td>_ _ _ / _ _ / _ _</td>
</tr>
<tr>
<td>Cardiovascular event</td>
<td>□ No □ Yes</td>
<td>□ 3 □ 4 □ 5 (fatal) □ Unknown</td>
<td>_ _ _ / _ _ / _ _</td>
</tr>
<tr>
<td>Aseptic bone necrosis</td>
<td>□ No □ Yes</td>
<td>□ 3 □ 4 □ 5 (fatal) □ Unknown</td>
<td>_ _ _ / _ _ / _ _</td>
</tr>
<tr>
<td>Pure red cell aplasia</td>
<td>□ No □ Yes</td>
<td></td>
<td>Not applicable</td>
</tr>
<tr>
<td>Gastrointestinal (GI) toxicity</td>
<td>□ No □ Yes</td>
<td>□ 3 □ 4 □ 5 (fatal) □ Unknown</td>
<td>_ _ _ / _ _ / _ _</td>
</tr>
<tr>
<td>Skin toxicity</td>
<td>□ No □ Yes</td>
<td>□ 3 □ 4 □ 5 (fatal) □ Unknown</td>
<td>_ _ _ / _ _ / _ _</td>
</tr>
<tr>
<td>Renal failure (chronic kidney disease, acute kidney injury)</td>
<td>□ No □ Yes</td>
<td>□ 3 □ 4 □ 5 (fatal) □ Unknown</td>
<td>_ _ _ / _ _ / _ _</td>
</tr>
<tr>
<td>Haemorrhage</td>
<td>□ No □ Yes</td>
<td>□ 3 □ 4 □ 5 (fatal) □ Unknown</td>
<td>_ _ _ / _ _ / _ _</td>
</tr>
<tr>
<td>Transplant-associated microangiopathy</td>
<td>□ No □ Yes</td>
<td>□ Non-severe □ Severe □ Unknown</td>
<td>_ _ _ / _ _ / _ _</td>
</tr>
<tr>
<td>Veno-occlusive disease (VOD)</td>
<td>□ No □ Yes</td>
<td>□ Mild □ Moderate □ Severe □ Very severe □ Unknown</td>
<td>_ _ _ / _ _ / _ _</td>
</tr>
<tr>
<td>Liver disorder</td>
<td>□ No □ Yes</td>
<td>□ 3 □ 4 □ 5 (fatal) □ Unknown</td>
<td>_ _ _ / _ _ / _ _</td>
</tr>
<tr>
<td>Hemophagocytic lymphohistiocytosis (HLH)</td>
<td>□ No □ Yes</td>
<td>□ 3 □ 4 □ 5 (fatal) □ Unknown</td>
<td>_ _ _ / _ _ / _ _</td>
</tr>
<tr>
<td>Cytokine release syndrome (CRS)</td>
<td>□ No □ Yes</td>
<td>□ 3 □ 4 □ 5 (fatal) □ Unknown</td>
<td>_ _ _ / _ _ / _ _</td>
</tr>
<tr>
<td>Central nervous system (CNS) toxicity</td>
<td>□ No □ Yes</td>
<td>□ 3 □ 4 □ 5 (fatal) □ Unknown</td>
<td>_ _ _ / _ _ / _ _</td>
</tr>
<tr>
<td>Stroke</td>
<td>□ No □ Yes</td>
<td>□ 3 □ 4 □ 5 (fatal) □ Unknown</td>
<td>_ _ _ / _ _ / _ _</td>
</tr>
<tr>
<td>Posterior reversible encephalopathy syndrome (PRES)</td>
<td>□ No □ Yes</td>
<td>□ 3 □ 4 □ 5 (fatal) □ Unknown</td>
<td>_ _ _ / _ _ / _ _</td>
</tr>
<tr>
<td>Other; specify:</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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Index: Registry 110 | Title: HCT FU D100 | Version: 1.0 | Effective Date: 2023-08-22 | THIS IS AN UNCONTROLLED COPY
**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 19
COMPLICATIONS SINCE THE LAST REPORT
-- Infectious complications -- continued

<table>
<thead>
<tr>
<th>Viral infection:</th>
<th>□ No</th>
<th>□ Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1) Start date:</td>
<td>_ _ _ / _ _ / _ _ (YYYY/MM/DD)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>□ No</td>
<td>□ Yes</td>
</tr>
<tr>
<td>Pathogen*:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>If the pathogen was CMV/EBV:</td>
<td>□ No</td>
<td>□ Yes</td>
</tr>
<tr>
<td>Infection with clinical implications:</td>
<td>□ No</td>
<td>□ Yes</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>□ Symptoms/signs of disease</td>
<td></td>
</tr>
<tr>
<td></td>
<td>□ Administration of pathogen-directed therapy</td>
<td></td>
</tr>
<tr>
<td></td>
<td>□ Isolation precautions or surveillance</td>
<td></td>
</tr>
<tr>
<td></td>
<td>□ Unknown</td>
<td></td>
</tr>
<tr>
<td>Localisation (CTCAE term)**:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Resolved:</td>
<td>□ No</td>
<td>□ Yes</td>
</tr>
</tbody>
</table>

| 2) Start date: | _ _ _ / _ _ / _ _ (YYYY/MM/DD) |
| Pathogen*: | | |
| If the pathogen was CMV/EBV: | □ 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
## 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

**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
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

* 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

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

<table>
<thead>
<tr>
<th>Option</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ No</td>
<td></td>
</tr>
</tbody>
</table>
| ☐ 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):*

<table>
<thead>
<tr>
<th>Option</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ No</td>
<td></td>
</tr>
<tr>
<td>☐ Yes:</td>
<td></td>
</tr>
</tbody>
</table>
 **Date:** __/__/__ (YYYY/MM/DD)  
  
 **Unknown** |

**Percentage of donor cells (chimerism):** _________ %  
*(only if patient received an allogeneic transplant)*

<table>
<thead>
<tr>
<th>Option</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Not evaluated</td>
<td></td>
</tr>
<tr>
<td>☐</td>
<td><strong>Chimerism test date:</strong> <strong>/</strong>/__ (YYYY/MM/DD)</td>
</tr>
</tbody>
</table>

**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 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:

<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>
<tbody>
<tr>
<td>1</td>
<td></td>
<td><strong>/</strong>/__</td>
<td></td>
<td>□ Continued complete remission (CCR)</td>
<td><strong>/</strong>/__</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>□ Complete remission (CR)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>□ Partial remission</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>□ No response / Stable disease / No change</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>□ Disease progression</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>□ Not evaluated</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>□ Unknown</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
<td><strong>/</strong>/__</td>
<td></td>
<td>□ Continued complete remission (CCR)</td>
<td><strong>/</strong>/__</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>□ Complete remission (CR)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>□ Partial remission</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>□ No response / Stable disease / No change</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>□ Disease progression</td>
<td></td>
</tr>
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*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 --


**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)

**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
  - Merkel cell
  - Other polyomavirus (specify)
- Respiratory viruses:
  - Enterovirus
  - Human coronavirus
  - Influenza A
  - Influenza B
  - Metapneumovirus
  - Parainfluenza
  - Rhinovirus
  - RSV
  - SARS-CoV-2
  - Respiratory virus other (specify)
- Viruses other (specify)

**Other bacteria:**
- Chlamydia species
- Chlamydophila
- 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)
- Mould other species (specify)
- Mould infection diagnosed based on positive galactomannan only, without microbiological confirmation
- Blastomycosis
- Histoplasmosis (specify)
- Coccioidiomycosis
- 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

**Nervous system infection**
- Cranial nerve infection
- Encephalitis infection
- Encephalomyelitis infection
- Meningitis
- Myelitis
- Peripheral nerve infection

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

**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

**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

Index: Registry 110 | Title: HCT FU D100 | Version: 1.0 | Effective Date: 2023-08-22 | THIS IS AN UNCONTROLLED COPY
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-specific 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