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:

<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:
☐ Mild
☐ Moderate
☐ Severe
☐ Unknown

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

---

**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)</td>
<td>Unknown</td>
</tr>
<tr>
<td>Cardiovascular event</td>
<td>[ ] No</td>
<td>[ ] 3 [ ] 4 [ ] 5 (fatal)</td>
<td>Unknown</td>
</tr>
<tr>
<td>Aseptic bone necrosis</td>
<td>[ ] No</td>
<td>[ ] 3 [ ] 4 [ ] 5 (fatal)</td>
<td>Unknown</td>
</tr>
<tr>
<td>Pure red cell aplasia</td>
<td>[ ] No</td>
<td>[ ] 3 [ ] 4 [ ] 5 (fatal)</td>
<td>Unknown</td>
</tr>
<tr>
<td>Gastrointestinal (GI) toxicity</td>
<td>[ ] No</td>
<td>[ ] 3 [ ] 4 [ ] 5 (fatal)</td>
<td>Unknown</td>
</tr>
<tr>
<td>Skin toxicity</td>
<td>[ ] No</td>
<td>[ ] 3 [ ] 4 [ ] 5 (fatal)</td>
<td>Unknown</td>
</tr>
<tr>
<td>Renal failure (chronic kidney disease, acute kidney injury)</td>
<td>[ ] No</td>
<td>[ ] 3 [ ] 4 [ ] 5 (fatal)</td>
<td>Unknown</td>
</tr>
<tr>
<td>Haemorrhage</td>
<td>[ ] No</td>
<td>[ ] 3 [ ] 4 [ ] 5 (fatal)</td>
<td>Unknown</td>
</tr>
<tr>
<td>Transplant-associated microangiopathy</td>
<td>[ ] No</td>
<td>[ ] Non-severe</td>
<td></td>
</tr>
<tr>
<td>Veno-occlusive disease (VOD)</td>
<td>[ ] No</td>
<td>[ ] Mild</td>
<td>Severe</td>
</tr>
<tr>
<td>Liver disorder</td>
<td>[ ] No</td>
<td>[ ] 3 [ ] 4 [ ] 5 (fatal)</td>
<td>Unknown</td>
</tr>
<tr>
<td>Hemophagocytic lymphohistiocytosis (HLH)</td>
<td>[ ] No</td>
<td>[ ] 3 [ ] 4 [ ] 5 (fatal)</td>
<td>Unknown</td>
</tr>
<tr>
<td>Cytokine release syndrome (CRS)</td>
<td>[ ] No</td>
<td>[ ] 3 [ ] 4 [ ] 5 (fatal)</td>
<td>Unknown</td>
</tr>
<tr>
<td>Central nervous system (CNS) toxicity</td>
<td>[ ] No</td>
<td>[ ] 3 [ ] 4 [ ] 5 (fatal)</td>
<td>Unknown</td>
</tr>
<tr>
<td>Stroke</td>
<td>[ ] No</td>
<td>[ ] 3 [ ] 4 [ ] 5 (fatal)</td>
<td>Unknown</td>
</tr>
<tr>
<td>Posterior reversible encephalopathy syndrome (PRES)</td>
<td>[ ] No</td>
<td>[ ] 3 [ ] 4 [ ] 5 (fatal)</td>
<td>Unknown</td>
</tr>
<tr>
<td>Other; specify: __________________________</td>
<td>[ ] No</td>
<td>[ ] 3 [ ] 4 [ ] 5 (fatal)</td>
<td>Unknown</td>
</tr>
</tbody>
</table>

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**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 6 at page 19
**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

*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.*

---

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## 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><strong>1) Start date:</strong></td>
<td>__ __ / __ / __ (YYYY/MM/DD)</td>
<td></td>
</tr>
<tr>
<td>☐ Yeasts</td>
<td>☐ Moulds</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 of disease</td>
<td>☐ Administration of pathogen-directed therapy</td>
<td></td>
</tr>
<tr>
<td>☐ Isolation precautions or surveillance</td>
<td>☐ Unknown</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) |
| ☐ 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 |

*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
**Infection with unknown pathogen:**
- [ ] No
- [ ] Yes

(for clinical infections without microbiological documentation, like pneumonia, cellulitis, etc.)

1) **Start date:** __ __ / __ / __ (YYYY/MM/DD)
- [ ] 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)
- [ ] 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):** ________ %

*(only if patient received an allogeneic transplant)*

- [ ] Not evaluated

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

**Source of cells tested:**

- [ ] Peripheral blood
- [ ] Bone marrow
- [ ] Other
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:
  ☐ 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>_ _ / _ / _</td>
<td></td>
<td>□ Prophylaxis / preventive</td>
<td>Continued complete remission (CCR)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>□ Relapse</td>
<td>Complete remission (CR)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>□ Maintenance</td>
<td>Partial remission</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>□ Consolidation</td>
<td>No response / Stable disease / No change</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>□ Other; specify:</td>
<td>Disease progression</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>□</td>
<td>Not evaluated</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>□</td>
<td>Unknown</td>
</tr>
<tr>
<td>2</td>
<td></td>
<td>_ _ / _ / _</td>
<td></td>
<td>□ Prophylaxis / preventive</td>
<td>Continued complete remission (CCR)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>□ Relapse</td>
<td>Complete remission (CR)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>□ Maintenance</td>
<td>Partial remission</td>
</tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>□ Consolidation</td>
<td>No response / Stable disease / No change</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>□ Other; specify:</td>
<td>Disease progression</td>
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<tr>
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<td></td>
<td></td>
<td></td>
<td>□</td>
<td>Not evaluated</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>□</td>
<td>Unknown</td>
</tr>
<tr>
<td>3</td>
<td></td>
<td>_ _ / _ / _</td>
<td></td>
<td>□ Prophylaxis / preventive</td>
<td>Continued complete remission (CCR)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>□ Relapse</td>
<td>Complete remission (CR)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>□ Maintenance</td>
<td>Partial remission</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>□ Consolidation</td>
<td>No response / Stable disease / No change</td>
</tr>
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<td></td>
<td>□ Other; specify:</td>
<td>Disease progression</td>
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<td>4</td>
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<td>_ _ / _ / _</td>
<td></td>
<td>□ Prophylaxis / preventive</td>
<td>Continued complete remission (CCR)</td>
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<td></td>
<td>□ Relapse</td>
<td>Complete remission (CR)</td>
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<td>□ Maintenance</td>
<td>Partial remission</td>
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<td></td>
<td>□ Consolidation</td>
<td>No response / Stable disease / No change</td>
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<td></td>
<td>□ Other; specify:</td>
<td>Disease progression</td>
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<td>Not evaluated</td>
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<td>Unknown</td>
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</tbody>
</table>

*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
- Chlamydomphila
- 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)
- Coccioidymycosis
- Paracoccidioidomycosis

Parasitic infections:

Protozoa:
- Babesiosis (specify)
- Cryptosporidium
- Giardiasis
- Leishmaniasis 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
- Enterocolitis 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: DRAFT HCT FU D100 v0.0 | Version: 0.0 | Effective Date: | 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

**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