<table>
<thead>
<tr>
<th>Document Type</th>
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<tbody>
<tr>
<td>Index Number</td>
<td>Registry 114</td>
</tr>
<tr>
<td>Version Number</td>
<td>1.0</td>
</tr>
<tr>
<td>Title</td>
<td>Cellular Therapy FU</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>
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</table>

Index: Registry 114 | Title: Cellular Therapy FU | Version: 1.0 | Effective Date: 2023-08-22 | THIS IS AN UNCONTROLLED COPY
CELLULAR THERAPIES
--- Day 100, 6 Months, 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

Assessment period covered by this report:
☐ Day 100
☐ 6 Months
☐ Annual or unscheduled follow-up

BEST RESPONSE
Complete only for Day 100 and 6 Months Follow-Up.

Best clinical/biological response after this CT (observed before any subsequent treatment):

If the indication was the treatment of a primary disease:
☐ Continued complete remission (CCR)
☐ Complete remission (CR)
☐ Partial remission
☐ No response / Stable disease / No change
☐ Disease progression
☐ Not evaluated
☐ Unknown

If the indication was the treatment of complications derived from a previous transplant/cellular therapy:

<table>
<thead>
<tr>
<th></th>
<th>Resolved</th>
<th>Improved</th>
<th>No response</th>
<th>Progressed</th>
<th>Not evaluated</th>
</tr>
</thead>
<tbody>
<tr>
<td>GvHD</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Graft failure</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Immune reconstitution</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Infection</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Date response evaluated: _ _ _ / _ _ / _ _ (YYYY/MM/DD)
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

Was B-cell count monitored after CT?

☐ No

☐ Yes: Was there a B-cell recovery?

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

☐ Yes: Date of the first B-cell recovery: __ __ / __ / __ (YYYY/MM/DD)

☐ Unknown

CURRENT HAEMATOLOGICAL FINDINGS

<table>
<thead>
<tr>
<th>Component</th>
<th>Value</th>
<th>Not evaluated</th>
<th>Unknown</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hb</td>
<td>__ __ g/dL</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Platelets</td>
<td>__ __ 10⁹ cells/L</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>White blood cells</td>
<td>__ __ 10⁹ cells/L</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Lymphocytes</td>
<td>__ __ %</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Neutrophils</td>
<td>__ __ %</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

Index: Registry 114 | Title: Cellular Therapy FU | Version: 1.0 | Effective Date: 2023-08-22 | THIS IS AN UNCONTROLLED COPY
COMPLICATIONS SINCE THE LAST REPORT
-- GvHD --

Do not report complications that were resolved before this cellular therapy.
Do not report complications that were previously reported as resolved, unless they recurred.

Did graft versus host disease (GvHD) occur?
☐ No (proceed to 'Complications since the last report - Non-infectious complications' on page 4)
☐ 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></th>
<th>Skin:</th>
<th>0 (none)</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Liver:</td>
<td>0 (none)</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Lower GI tract:</td>
<td>0 (none)</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Upper GI tract:</td>
<td>0 (none)</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other site affected:</td>
<td>☐ No</td>
<td>☐ Yes; specify: __________________</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></th>
<th>Skin:</th>
<th>0 (none)</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral:</td>
<td>0 (none)</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Gastrointestinal:</td>
<td>0 (none)</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Eyes:</td>
<td>0 (none)</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Liver:</td>
<td>0 (none)</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Joints and fascia:</td>
<td>0 (none)</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Lungs:</td>
<td>0 (none)</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Genitalia:</td>
<td>0 (none)</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Other site affected:</td>
<td>☐ No</td>
<td>☐ Yes; specify: __________________</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 --

Do not report complications that were resolved before this cellular therapy.
Do not report complications that were previously reported as resolved, unless they recurred.

Did non-infectious complications occur during the follow-up period?
☐ No (proceed to 'Complications since the last report - Infectious complications' on page 7)
☐ Yes (report in the table below)

<table>
<thead>
<tr>
<th>Adverse event (check all that apply)</th>
<th>Maximum grade observed*</th>
<th>Onset date (YYYY/MM/DD)</th>
<th>Treated</th>
<th>Resolved</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cytokine release syndrome (CRS)</td>
<td>1 2 3 4 5 (fatal) Unknown</td>
<td>_ _ _ / _ / _ _</td>
<td>☐ No Yes Unknown</td>
<td>☐ No Yes Unknown</td>
</tr>
<tr>
<td>Grading system:</td>
<td>ASTCT consensus (Lee 2019)</td>
<td>☐ Penn ☐ CTCAE ☐ Lee 2014 ☐ MDACC ☐ Other: specify: __________</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| IEC-associated neurotoxicity syndrome (ICANS) | 1 2 3 4 5 (fatal) Unknown | _ _ _ / _ / _ _ | ☐ No Yes Unknown | ☐ No Yes Unknown |
| Grading system: | ASTCT consensus (Lee 2019) | ☐ CTCAE ☐ Lee 2014 ☐ MDACC ☐ Other: specify: __________ |

| Other neurotoxicity, specify: __________ | 2 3 4 5 (fatal) Unknown | _ _ _ / _ / _ _ | ☐ No Yes Unknown | ☐ No Yes Unknown |

| Macrophage activation syndrome (MAS) | 2 3 4 5 (fatal) Unknown | _ _ _ / _ / _ _ | ☐ No Yes Unknown | ☐ No Yes Unknown |

| Secondary haemophagocytic lymphohistiocytosis (HLH) | 2 3 4 5 (fatal) Unknown | _ _ _ / _ / _ _ | ☐ No Yes Unknown | ☐ No Yes Unknown |

*If not otherwise specified, CTCAE grading system is to be used.
### COMPLICATIONS SINCE THE LAST REPORT
-- Non-infectious complications -- continued

<table>
<thead>
<tr>
<th>Adverse event (check all that apply)</th>
<th>Maximum grade observed*</th>
<th>Onset date (YYYY/MM/DD)</th>
<th>Treated</th>
<th>Resolved</th>
</tr>
</thead>
<tbody>
<tr>
<td>Organ toxicity: skin</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Absent</td>
<td></td>
<td></td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>□ Present</td>
<td></td>
<td></td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>□ Unknown</td>
<td></td>
<td></td>
<td>Unknown</td>
<td>Unknown</td>
</tr>
<tr>
<td>Organ toxicity: liver</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Absent</td>
<td></td>
<td></td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>□ Present</td>
<td></td>
<td></td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>□ Unknown</td>
<td></td>
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<td>Unknown</td>
<td>Unknown</td>
</tr>
<tr>
<td>Organ toxicity: lung</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Absent</td>
<td></td>
<td></td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>□ Present</td>
<td></td>
<td></td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>□ Unknown</td>
<td></td>
<td></td>
<td>Unknown</td>
<td>Unknown</td>
</tr>
<tr>
<td>Organ toxicity: heart</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>□ Absent</td>
<td></td>
<td></td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>□ Present</td>
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<td>Yes</td>
</tr>
<tr>
<td>□ Unknown</td>
<td></td>
<td></td>
<td>Unknown</td>
<td>Unknown</td>
</tr>
<tr>
<td>Organ toxicity: kidney</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Absent</td>
<td></td>
<td></td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>□ Present</td>
<td></td>
<td></td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>□ Unknown</td>
<td></td>
<td></td>
<td>Unknown</td>
<td>Unknown</td>
</tr>
<tr>
<td>Organ toxicity: gastrointestinal</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Absent</td>
<td></td>
<td></td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>□ Present</td>
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<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>□ Unknown</td>
<td></td>
<td></td>
<td>Unknown</td>
<td>Unknown</td>
</tr>
<tr>
<td>Organ toxicity: other; specify: ________</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>□ Absent</td>
<td></td>
<td></td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>□ Present</td>
<td></td>
<td></td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>□ Unknown</td>
<td></td>
<td></td>
<td>Unknown</td>
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</tr>
</tbody>
</table>

*If not otherwise specified, CTCAE grading system is to be used.
### COMPLICATIONS SINCE THE LAST REPORT

---

**Non-infectious complications -- continued**

<table>
<thead>
<tr>
<th>Adverse event (check all that apply)</th>
<th>Maximum grade observed*</th>
<th>Onset date (YYYY/MM/DD)</th>
<th>Treated</th>
<th>Resolved</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tumour lysis syndrome (TLS)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Absent</td>
<td>□ 2 □ 3 □ 4 □ 5 (fatal)</td>
<td>---/---/---</td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Present</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Unknown</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>B-cell aplasia</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Absent</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Present</td>
<td>% B-cells: _____</td>
<td>---/---/---</td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Unknown</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bone marrow aplasia</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Absent</td>
<td></td>
<td>---/---/---</td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Present</td>
<td></td>
<td>---/---/---</td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Unknown</td>
<td></td>
<td>---/---/---</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hypogammaglobulinemia</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Absent</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Present</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Was it also present at time of the cellular therapy?</td>
<td></td>
<td>---/---/---</td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ No, occurred after the cellular therapy</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Yes</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Was it worsened by the cellular therapy?</td>
<td></td>
<td>---/---/---</td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ No</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Yes</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exacerbation of existing neurological disorder, specify:</td>
<td></td>
<td>---/---/---</td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Absent</td>
<td>□ 2 □ 3 □ 4 □ 5 (fatal)</td>
<td>---/---/---</td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Present</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Unknown</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other complication, specify:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Absent</td>
<td>□ 2 □ 3 □ 4 □ 5 (fatal)</td>
<td>---/---/---</td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Present</td>
<td></td>
<td>---/---/---</td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Unknown</td>
<td></td>
<td>---/---/---</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*If not otherwise specified, CTCASE grading system is to be used.
Do not report complications that were resolved before this cellular therapy.
Do not report complications that were previously reported as resolved, unless they recurred.

Did infectious complications occur during the follow-up period?
- No (proceed to ‘SARS-CoV2 related questions’ on page 12)
- Yes (report all infectious complications below)

### Bacterial Infection: No / Yes

1. **Start date:** ____/__/__ (YYYY/MM/DD)
   - Gram-positive [ ]
   - Gram-negative [ ]
   - Other [ ]
   - Pathogen*: __________________________
   - Infection with clinical implications: [ ]
     - Symptoms/signs of disease [ ]
     - Administration of pathogen-directed therapy [ ]
     - Isolation precautions or surveillance [ ]
     - Unknown [ ]
   - Localization (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: [ ]
     - Symptoms/signs of disease [ ]
     - Administration of pathogen-directed therapy [ ]
     - Isolation precautions or surveillance [ ]
     - Unknown [ ]
   - Localization (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 27-28
*** Indicate CTCAE term by choosing from the list provided in Appendix 2 at page 29

---

If intravascular catheter related infection, specify if by choosing from the list provided in Appendix 3 at page 29
### COMPLICATIONS SINCE THE LAST REPORT
-- Infectious complications -- continued

#### Viral infection:
- [ ] No
- [ ] Yes

1) Start date: _ _ _ / _ _ / _ _ (YYYY/MM/DD)
   **Pathogen***:
   - [ ] 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 infection a reactivation?**
   - [ ] 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

*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 27-28
** Indicate CTCAE term by choosing from the list provided in Appendix 2 at page 29
*** If intravascular catheter-related infection, specify it by choosing from the list provided in Appendix 3 at page 29
### COMPLICATIONS SINCE THE LAST REPORT
-- Infectious complications --

<table>
<thead>
<tr>
<th>Fungal infection:</th>
<th></th>
<th>Yes</th>
</tr>
</thead>
</table>

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 27-28

** Indicate CTCAE term by choosing from the list provided in Appendix 2 at page 29

*** If intravascular catheter-related infection, specify it by choosing from the list provided in Appendix 3 at page 29
### 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> _ _ _ _ / _ _ / _ _ (YYYY/MM/DD)</td>
<td></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></td>
<td></td>
</tr>
<tr>
<td>□ Administration of pathogen-directed therapy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Isolation precautions or surveillance</td>
<td></td>
<td></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>□ No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Yes; specify***:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Unknown</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Resolved:</strong></td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>□ No</td>
<td>□ Yes</td>
<td>□ Unknown</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 |
| □ No | | | | |
| □ Yes; specify***: | | | | |
| □ Unknown | | | | |
| **Resolved:** | No | Yes | Unknown |
| □ 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 27-28

** Indicate CTCAE term by choosing from the list provided in Appendix 2 at page 29

*** If intravascular catheter-related infection, specify it by choosing from the list provided in Appendix 3 at page 29
### 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 27-28

** Indicate CTCAE term by choosing from the list provided in Appendix 2 at page 29

*** If intravascular catheter-related infection, specify it by choosing from the list provided in Appendix 3 at page 29
**SARS-CoV-2 RELATED QUESTIONS**

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

- [ ] No
- [ ] Yes: Number of doses: ____________
  - Date of the last dose: _ _ _ / _ _ / _ _ (YYYY/MM/DD)

**Did the patient have a SARS-CoV-2 infection after CT (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: Iatrogenic disease in relation with treatments administered prior to cellular therapy cells indication and administration (i.e. cytotoxic agents, targeted therapies, immunotherapies, radiation therapy, etc. Please provide more details below)

  - Transformation of engineered immune effector cells through insertional mutagenesis or other mechanisms (please provide more details below)

  Further details on secondary malignancy or autoimmune disorder: ____________________________

  - Date of diagnosis: _ _ _ _ / _ _ / _ _ (YYYY/MM/DD)
  - Histologic type *(if applicable)*: ____________________________
  - Location *(if applicable)*: ____________________________

**Secondary malignancy material preserved:**

<table>
<thead>
<tr>
<th></th>
<th>Concomitant PBMCs preserved:</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Unknown</td>
<td>Unknown</td>
</tr>
</tbody>
</table>

**Was this disease an indication for a subsequent HCT/ICT/IST?**

- [ ] No *(complete the relevant non-indication diagnosis form)*
- [ ] Yes *(complete the relevant indication diagnosis form)*
PERSISTENCE OF THE INFUSED CELLS

Was persistence of the infused cellular products assessed since the last follow-up?

☐ No
☐ Yes: Date of the last assessment: __ __ / __ / __ (YYYY/MM/DD)

Source of cells used for testing:
☐ Bone marrow
☐ Peripheral blood
☐ Tumour
☐ Other; specify: ____________

Technique used for testing:
☐ Molecular (PCR)
☐ Flow cytometry
☐ Chimerism
☐ Imaging
☐ Immunohistochemistry
☐ Other; specify: ____________

Were immune effector cells (IEC) detected: ☐ No ☐ Yes
☐ Unknown

LAST DISEASE STATUS
Additional Assessments

Disease burden:

LDH level:
☐ Normal
☐ Elevated
☐ Not evaluated
☐ Unknown

Inflammatory state (C-reactive protein [CRP] concentration):

☐ Normal
☐ Elevated: Maximum CRP concentration: ____________ Unit (check only one): ☐ mg/dL ☐ mg/L
☐ Not evaluated
☐ Unknown

Date of C-reactive protein level assessment: __ __ / __ / __ (YYYY/MM/DD)
POST-THERAPY TREATMENT

Include only systemic treatments designed to consolidate the anti-tumour activity of CT cells, prevent relapse (i.e. administration of immune checkpoint inhibitors) or treat complications. Do not include supportive care, including anti-infectious agents. Indicate only treatments that have not been reported at previous follow-up(s).

Did the patient undergo additional treatment during or immediately after this cellular therapy or since the last follow-up?

- No
- Yes; Date started: __ __ / __ / __ (YYYY/MM/DD)
- Unknown

Did the patient receive additional cell infusions (excluding a new HCT and CT)?

- No
- Yes; Is this cell infusion an allogeneic boost?  
  - No
  - Yes; Date of the boost: __ __ / __ / __ (YYYY/MM/DD)

  * 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 of the boost: __ __ / __ / __ (YYYY/MM/DD)

If the cell infusion is not a boost, attach the Cell Infusion (CI) sheet available in Appendix 4 at page 30, completing as many CI sheets as episodes of cell infusion that took place during this period; then continue with questions below.

Did the patient receive subsequent HCT (either at your or another centre)?

- No
- Yes

If the patient had a subsequent HCT, please, make sure that this subsequent treatment is registered using a new HCT treatment form before proceeding.

Radiotherapy:

- No
- Yes
- Unknown

Drugs/chemotherapy:

- No (continue at page 16)
- Yes (complete the table on the next page)
## POST-THERAPY TREATMENT 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>☐ Prophylaxis/preventive</td>
<td>☐ Continued complete remission (CCR)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>☐ Relapse</td>
<td>☐ Complete remission (CR)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>☐ Maintenance</td>
<td>☐ Partial remission</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>☐ Consolidation</td>
<td>☐ No response/Stable disease/No change</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>☐ Non-inf. complications</td>
<td>☐ Disease progression</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>☐ Infectious complications</td>
<td>☐ Not evaluated</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>☐ Other; specify________</td>
<td>☐ Unknown</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
<td>_ _ _ / _ _ _</td>
<td>☐ Prophylaxis/preventive</td>
<td>☐ Continued complete remission (CCR)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>☐ Relapse</td>
<td>☐ Complete remission (CR)</td>
<td></td>
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<tr>
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<td></td>
<td></td>
<td>☐ Maintenance</td>
<td>☐ Partial remission</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>☐ Consolidation</td>
<td>☐ No response/Stable disease/No change</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>☐ Non-inf. complications</td>
<td>☐ Disease progression</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>☐ Infectious complications</td>
<td>☐ Not evaluated</td>
<td></td>
</tr>
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</tr>
<tr>
<td>3</td>
<td></td>
<td>_ _ _ / _ _ _</td>
<td>☐ Prophylaxis/preventive</td>
<td>☐ Continued complete remission (CCR)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<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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<tr>
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<td></td>
<td>☐ Consolidation</td>
<td>☐ No response/Stable disease/No change</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>☐ Non-inf. complications</td>
<td>☐ Disease progression</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>☐ Infectious complications</td>
<td>☐ Not evaluated</td>
<td></td>
</tr>
<tr>
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<td>☐ Unknown</td>
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</tr>
<tr>
<td>4</td>
<td></td>
<td>_ _ _ / _ _ _</td>
<td>☐ Prophylaxis/preventive</td>
<td>☐ Continued complete remission (CCR)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>☐ Relapse</td>
<td>☐ Complete remission (CR)</td>
<td></td>
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<td></td>
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<td>☐ Non-inf. complications</td>
<td>☐ Disease progression</td>
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</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>☐ Infectious complications</td>
<td>☐ Not evaluated</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>☐ Other; specify________</td>
<td>☐ Unknown</td>
<td></td>
</tr>
</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.*
POST-THERAPY TREATMENT continued

Did the patient receive subsequent cellular therapy (either at your or another centre)?

☐ No
☐ Yes; Reason for subsequent CT:
  ☐ Primary failure
  ☐ Consolidation
  ☐ Mitigation of side effects

If the patient had a subsequent cellular therapy (which was not part of this cellular therapy), please, make sure that this subsequent treatment is registered using a new CT treatment form before proceeding.

Is the patient receiving any medication not related to cell therapy or its indications?

☐ No
☐ Yes
☐ Unknown

HOSPITAL ADMISSION
Complete only for Day 100 and 6 Months Follow-Up.

Was inpatient admission and care needed since the last follow-up?

☐ No
☐ Yes; Number of days in hospital: _____________
☐ Unknown

Was the patient transferred to the intensive care unit (ICU) since the last follow-up?

☐ No
☐ Yes; Number of days in ICU: _____________
☐ Unknown
RELAPSE/PROGRESSION OR SIGNIFICANT WORSENING

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

☐ No
☐ Continuous progression since CT
☐ Yes: Number of relapses/progressions since CT: ____
  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-in 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:

- Medullary:
  ☐ No  ☐ Yes  ☐ Not evaluated
- Skin:
  ☐ No  ☐ Yes  ☐ Not evaluated
- CNS:
  ☐ No  ☐ Yes  ☐ Not evaluated
- Testes/Ovary:
  ☐ No  ☐ Yes  ☐ Not evaluated
- Other:
  ☐ No  ☐ Yes; specify: ________

CD19 expression at relapse after CT (only for Precursor lymphoid neoplasms):

☐ Absent
☐ Present
☐ Unknown

PATIENT STATUS

Performance status at the last assessment (check only one):

Type of scale used:  Score:

☐ Karnofsky  ☐ 10  ☐ 20  ☐ 30  ☐ 40  ☐ 50  ☐ 60  ☐ 70  ☐ 80  ☐ 90  ☐ 100
☐ Lansky  
☐ ECOG  ☐ 0  ☐ 1  ☐ 2  ☐ 3  ☐ 4
PREGNANCY AFTER CELLULAR THERAPY
Complete only for 6 Months and Annual/Unscheduled Follow-Up.

Has patient become pregnant or impregnated another person since the 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

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: ____________

END OF GENERAL SECTION

TO COMPLETE FOLLOW-UP REPORT, PLEASE FILL IN THE APPLICABLE
DIAGNOSE-SPECIFIC QUESTIONS ATTACHED

Index: Registry 114 | Title: Cellular Therapy FU | Version: 1.0 | Effective Date: 2023-08-22 | THIS IS AN UNCONTROLLED COPY
# LAST DISEASE STATUS

Complete only if the indication was the treatment of a primary disease including infections; complete only one section with the main indication diagnosis for which cellular therapy was given.

<table>
<thead>
<tr>
<th>Disease Category</th>
<th>Go to page</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACUTE LEUKAEMIAS</td>
<td>20</td>
</tr>
<tr>
<td>CHRONIC LEUKAEMIAS - Chronic Myelogenous Leukaemias (CML)</td>
<td>21</td>
</tr>
<tr>
<td>CHRONIC LEUKAEMIAS - Chronic Lymphocytic Leukaemias (CLL)</td>
<td>21</td>
</tr>
<tr>
<td>CHRONIC LEUKAEMIAS - Prolymphocytic (PLL) and Other Chronic Leukaemias</td>
<td>22</td>
</tr>
<tr>
<td>LYMPHOMAS</td>
<td>22</td>
</tr>
<tr>
<td>MYELODYSPLASTIC SYNDROMES (MDS)</td>
<td>23</td>
</tr>
<tr>
<td>COMBINED MYELODYSPLASTIC SYNDROMES/MYELOPROLIFERATIVE NEOPLASMS (MDS/MPN)</td>
<td>23</td>
</tr>
<tr>
<td>MYELOPROLIFERATIVE NEOPLASMS (MPN)</td>
<td>24</td>
</tr>
<tr>
<td>PLASMA CELL DISORDERS (PCD) including MULTIPLE MYELOMA (MM)</td>
<td>24</td>
</tr>
<tr>
<td>SOLID TUMOURS</td>
<td>25</td>
</tr>
<tr>
<td>BONE MARROW FAILURE SYNDROMES (BMF) including APLASTIC ANAEMIA (AA)</td>
<td>25</td>
</tr>
<tr>
<td>HAEMOGLOBINOPATHIES</td>
<td>25</td>
</tr>
<tr>
<td>OTHER DIAGNOSIS</td>
<td>26</td>
</tr>
</tbody>
</table>
**Status:**

- **Primary induction failure**
- **Complete haematological remission (CR)**
  - **Number:**
    - 1<sup>st</sup>
    - 2<sup>nd</sup>
    - 3<sup>rd</sup> or higher
  - **Cytogenetic remission:**
    - No
    - Yes
    - Not evaluated
    - Not applicable *
    - Unknown
  - **Molecular remission:**
    - No
    - Yes
    - Not evaluated
    - Not applicable *
    - Unknown

*No abnormalities detected prior to this time point*

- **Relapse**
  - **Number:**
    - 1<sup>st</sup>
    - 2<sup>nd</sup>
    - 3<sup>rd</sup> or higher
CHRONIC LEUKAEMIAS
Chronic Myeloid Leukaemias (CML) - Last Disease Status

Status:

☐ Chronic phase (CP)
  Number:
    ☐ 1st
    ☐ 2nd
    ☐ 3rd or higher
  Haematological remission:
    ☐ No
    ☐ Yes
    ☐ Not evaluated
    ☐ Unknown
  Cytogenetic remission:
    ☐ No
    ☐ Yes
    ☐ Not evaluated
    ☐ Not applicable *
    ☐ Unknown
  Molecular remission:
    ☐ No
    ☐ Yes
    ☐ Not evaluated
    ☐ Not applicable *
    ☐ Unknown

* No abnormalities detected prior to this time point

☐ Accelerated phase
  Number:
    ☐ 1st
    ☐ 2nd
    ☐ 3rd or higher

☐ Blast crisis
  Number:
    ☐ 1st
    ☐ 2nd
    ☐ 3rd or higher

CHRONIC LEUKAEMIAS
Chronic Lymphoid Leukaemias (CLL) - Last Disease Status

Status:

☐ Complete remission (CR)
  Minimal residual disease (MRD) (by FACS or PCR)
    ☐ Negative
    ☐ Positive
    ☐ Not evaluated

☐ Partial remission (PR)

☐ Stable disease (SD)

☐ Relapse (untreated)

☐ Progressive disease (PD)

☐ Never treated

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### CHRONIC LEUKAEMIAS
Prolymphocytic and Other Chronic Leukaemias (PLL & Other) - Last Disease Status

**Status:**
- [ ] Complete remission (CR)
- [ ] Partial remission (PR)
- [ ] Stable disease (SD)
- [ ] Relapse (untreated)
- [ ] Progressive disease (PD)
- [ ] Never treated

### LYMPHOMAS
All Lymphomas - Last Disease Status

**Technique used for disease assessment:**

**CT Scan done:**
- [ ] No
- [ ] Yes

**PET:**
- [ ] Negative
- [ ] Positive
- [ ] Not evaluated

**Status:**
- [ ] Never treated
- [ ] Complete remission (CR)
  - [ ] Unconfirmed (CRU *)
  - [ ] Confirmed
  - * CRU: Complete response with persistent scan abnormalities of unknown significance*
- [ ] Partial response (PR) with or without a prior CR
- [ ] Stable disease
- [ ] Untreated relapse from a previous CR / untreated progression from a previous PR
  - Histopathological verification of relapse:
    - [ ] No
    - [ ] Yes
- [ ] Chemorefractory relapse or progression, including primary refractory disease
  - Histopathological verification of relapse:
    - [ ] No
    - [ ] Yes
- [ ] Disease status unknown or Not evaluated/Not evaluable

---

Index: Registry 114 | Title: Cellular Therapy FU | Version: 1.0 | Effective Date: 2023-08-22 | THIS IS AN UNCONTROLLED COPY
### MYELODYSPLASTIC SYNDROMES (MDS) - Last Disease Status

**Status:**

- Treated with chemotherapy:
  - ☐ Primary refractory phase (no change)

- ☐ Complete remission (CR)
  - ☐ 1st
  - ☐ 2nd
  - ☐ 3rd or higher

- ☐ Improvement but no CR

- ☐ Relapse after CR
  - ☐ 1st
  - ☐ 2nd
  - ☐ 3rd or higher

- ☐ Progression/Worsening

- ☐ Never treated (supportive care or treatment without chemotherapy)

---

### COMBINED MYELODYSPLASTIC SYNDROMES/MYELOPROLIFERATIVE NEOPLASMS (MDS/MPN) - Last Disease Status

**Status:**

- Treated with chemotherapy:
  - ☐ Primary refractory phase (no change)

- ☐ Complete remission (CR)
  - ☐ 1st
  - ☐ 2nd
  - ☐ 3rd or higher

- ☐ Improvement but no CR

- ☐ Relapse after CR
  - ☐ 1st
  - ☐ 2nd
  - ☐ 3rd or higher

- ☐ Progression/Worsening

- ☐ Never treated (supportive care or treatment without chemotherapy)
### MYELOPROLIFERATIVE NEOPLASMS (MPN) - Last Disease Status

**Status:**

- Treated with chemotherapy:
  - [ ] Primary refractory phase (no change)

- [ ] Complete remission (CR)
  - Number:
    - [ ] 1st
    - [ ] 2nd
    - [ ] 3rd or higher

- [ ] Improvement but no CR

- [ ] Relapse after CR
  - Number:
    - [ ] 1st
    - [ ] 2nd
    - [ ] 3rd or higher

- [ ] Progression/Worsening

- [ ] Never treated (supportive care or treatment without chemotherapy)

### PLASMA CELL DISORDERS (PCD) incl. MULTIPLE MYELOMA (MM) - Last Disease Status

**Status:**

- [ ] Never treated

- [ ] Stringent complete remission (SCR)
  - Number:
    - [ ] 1st
    - [ ] 2nd
    - [ ] 3rd or higher

- [ ] Complete remission (CR)

- [ ] Very good partial remission (VGPR)

- [ ] Partial remission (PR)

- [ ] Relapse from CR (untreated)

- [ ] Progression

- [ ] Stable disease / No change
### SOLID TUMOURS - Last Disease Status

**Status:**

- [ ] Adjuvant
- [ ] Never treated (upfront)
- [ ] Stable disease/No response
- [ ] Complete remission (CR)
  - [ ] Unconfirmed (CRU*)
  - [ ] Confirmed
  * CRU: complete response with persistent scan abnormalities of unknown significance
- [ ] 1st partial response (PR1)
- [ ] Relapse

**Number:**

- [ ] 1st
- [ ] 2nd
- [ ] 3rd or higher

**Sensitivity to chemotherapy:**

- [ ] Sensitive
- [ ] Resistant
- [ ] Untreated
- [ ] Progressive disease (PD)

### BONE MARROW FAILURE SYNDROMES (BMF)

**incl. APLASTIC ANAEMIA (AA) - Last Disease Status**

**Status:**

- [ ] Stable disease/No response
- [ ] Complete remission (CR)
- [ ] Partial remission
- [ ] Relapse/Progression

### HAEMOGLOBINOPATHIES - Last Disease Status

**Transfusion status:**

- [ ] No transfusion required
- [ ] Transfusion required: Date of the 1st transfusion: __/__/__ (YYYY/MM/DD)

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## OTHER DIAGNOSES - Last Disease Status

<table>
<thead>
<tr>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Cured</td>
</tr>
<tr>
<td>□ Improved</td>
</tr>
<tr>
<td>□ Unchanged</td>
</tr>
<tr>
<td>□ Worse</td>
</tr>
</tbody>
</table>
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 morgani
- 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)
- Mucomycosis (specify)
- Phaeohyphomycosis (specify)
- Scedosporium spp (specify)
- Moulds other species (specify)
- Mould infection diagnosed based on positive galactomanan 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

<table>
<thead>
<tr>
<th>Respiratory tract</th>
<th>Nervous system infection</th>
<th>Others</th>
</tr>
</thead>
<tbody>
<tr>
<td>· Bronchial infection</td>
<td>· Cranial nerve infection</td>
<td>· Device related infection (other than Intravascular catheter)</td>
</tr>
<tr>
<td>· Lung infection</td>
<td>· Encephalitis infection</td>
<td>· Sepsis</td>
</tr>
<tr>
<td>· Laryngitis</td>
<td>· Encephalomyelitis infection</td>
<td></td>
</tr>
<tr>
<td>· Pleural infection</td>
<td>· Meningitis</td>
<td></td>
</tr>
<tr>
<td>· Tracheitis</td>
<td>· Myelitis</td>
<td></td>
</tr>
<tr>
<td>· Upper respiratory infection</td>
<td>· Peripheral nerve infection</td>
<td></td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Intra-abdominal infections</th>
<th>Cardiovascular infections</th>
</tr>
</thead>
<tbody>
<tr>
<td>· Anorectal infection</td>
<td>· Arteritis infective</td>
</tr>
<tr>
<td>· Appendicitis</td>
<td>· Endocarditis infective</td>
</tr>
<tr>
<td>· Appendicitis perforated</td>
<td>· Mediastinal infection</td>
</tr>
<tr>
<td>· Biliary tract infection</td>
<td>· Phlebitis infective</td>
</tr>
<tr>
<td>· Cecal infection</td>
<td></td>
</tr>
<tr>
<td>· Duodenal infection</td>
<td></td>
</tr>
<tr>
<td>· Enterocolitis infectious</td>
<td></td>
</tr>
<tr>
<td>· Esophageal infection</td>
<td></td>
</tr>
<tr>
<td>· Gallbladder infection</td>
<td></td>
</tr>
<tr>
<td>· Gastritis</td>
<td></td>
</tr>
<tr>
<td>· Hepatic infection</td>
<td></td>
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<tr>
<td>· Pancreas infection</td>
<td></td>
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<tr>
<td>· Pelvic infection</td>
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<tr>
<td>· Peritoneal infection</td>
<td></td>
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<tr>
<td>· Splenic infection</td>
<td></td>
</tr>
<tr>
<td>· Stoma site infection</td>
<td></td>
</tr>
<tr>
<td>· Small intestine infection</td>
<td></td>
</tr>
<tr>
<td>· Typhilitis</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Uro-genital tract infections</th>
<th>Skin, soft tissue and mucosal surfaces</th>
</tr>
</thead>
<tbody>
<tr>
<td>· Bladder infection</td>
<td>· Breast infection</td>
</tr>
<tr>
<td>· Cervicitis infection</td>
<td>· Folliculitis</td>
</tr>
<tr>
<td>· Kidney infection</td>
<td>· Lymph gland infection</td>
</tr>
<tr>
<td>· Ovarian infection</td>
<td>· Nail infection</td>
</tr>
<tr>
<td>· Scrotal infection</td>
<td>· Mucosal infection</td>
</tr>
<tr>
<td>· Penile infection</td>
<td>· Papulopustular rash</td>
</tr>
<tr>
<td>· Prostate infection</td>
<td>· Paronychia</td>
</tr>
<tr>
<td>· Urethral infection</td>
<td>· Rash pustular</td>
</tr>
<tr>
<td>· Urinary tract infection</td>
<td>· Skin infection</td>
</tr>
<tr>
<td>· Uterine infection</td>
<td>· Soft tissue infection</td>
</tr>
<tr>
<td>· Vaginal infection</td>
<td>· Wound infection</td>
</tr>
<tr>
<td>· Vulval infection</td>
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</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Muscles and bones</th>
<th>Head and neck</th>
</tr>
</thead>
<tbody>
<tr>
<td>· Bone infection</td>
<td>· Conjunctivitis infective</td>
</tr>
<tr>
<td>· Myositis infective</td>
<td>· Corneal infection</td>
</tr>
<tr>
<td>· Joint infection</td>
<td>· Endophthalmitis</td>
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<tr>
<td></td>
<td>· Eye infection</td>
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<tr>
<td></td>
<td>· Gum infection</td>
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<tr>
<td></td>
<td>· Lip infection</td>
</tr>
<tr>
<td></td>
<td>· Oral cavity</td>
</tr>
<tr>
<td></td>
<td>· Otitis externa</td>
</tr>
<tr>
<td></td>
<td>· Otitis media</td>
</tr>
<tr>
<td></td>
<td>· Periorbital infection</td>
</tr>
<tr>
<td></td>
<td>· Salivary gland infection</td>
</tr>
<tr>
<td></td>
<td>· Sinusitis</td>
</tr>
<tr>
<td></td>
<td>· Tooth infection</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Blood</th>
</tr>
</thead>
<tbody>
<tr>
<td>· Bacteremia</td>
</tr>
<tr>
<td>· Fungemia</td>
</tr>
<tr>
<td>· Viremia</td>
</tr>
</tbody>
</table>

### 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  
- Other; specify: __________________________

**Disease status at time of this cell infusion:**  
- Complete remission (CR)  
- Not in CR  
- Not evaluated

**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 viral infection  
- Poor graft function  
- Infection prophylaxis  
- Other; specify: __________________________

**Acute GvHD -- maximum grade (after this infusion episode but before any further infusion/transplant):**  
- 0 (none)  
- 1  
- 2  
- 3  
- 4  
- Present but grade unknown