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<th>Document Type</th>
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<td>Registry 97</td>
</tr>
<tr>
<td>Version Number</td>
<td>N/A</td>
</tr>
<tr>
<td>Title</td>
<td>DRAFT_AlloHCT_Day0</td>
</tr>
<tr>
<td>Author</td>
<td>Annelot van Amerongen</td>
</tr>
<tr>
<td>Authorised By</td>
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<td>Authorised On</td>
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<tr>
<td>Release Date:</td>
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</tr>
</tbody>
</table>
## ALLOGENEIC HAEMATOPOIETIC CELL TRANSPLANTATION (HCT)
### Day 0

**Date of this HCT:** ___/___/___ (YYYY/MM/DD)  
(or planned date of HCT if patient died before treatment)

**Center where treatment took place (CIC):**  

**Survival status at HCT:**  
- [ ] Alive  
- [ ] Died after conditioning but before HCT

**Indication diagnosis for this HCT:**  
(make sure the indication diagnosis has been registered first, using the relevant diagnosis form)

**Chronological number of this treatment:**  
(all types of treatments for this patient, e.g. HCT, CT, IST)

**Chronological number of this HCT:**  
(all HCTs this patient received in the past)

**Chronological number of this allogeneic HCT:**  
(all allogeneic HCTs this patient received in the past)

---

**Complete this section only if the chronological number of the treatment is >1 for this patient.**

**Reason for this HCT:**  
- [ ] Indication diagnosis  
- [ ] Relapse/progression after previous treatment (HCT/CT)  
- [ ] Complication after previous treatment (HCT/CT)  
- [ ] Primary graft failure  
- [ ] Secondary graft failure  
- [ ] Secondary malignancy  
- [ ] Other; specify: ______________________

**Date of the last treatment before this one:** ___/___/___ (YYYY/MM/DD)

**Type of the last treatment before this one:**  
- [ ] Autologous HCT  
- [ ] Allogeneic HCT  
- [ ] Cellular therapy

**Was the last treatment performed at another institution?**  
- [ ] No  
- [ ] Yes: CIC (if known): __________

Name of institution: ____________________________

City: ____________________________

---

Submit the relevant follow-up form for the previous HCT/CT using the follow up assessment date before this HCT. It is required to capture relapse data and other events between transplants/cellular therapies.
DONOR & GRAFT INFORMATION

Is this HCT part of a multiple (sequential) graft program/protocol?

☐ No
☐ Yes: Chronological number of this HCT as part of multiple (sequential) graft program/protocol for this patient: ______

If this is the first allogeneic HCT for this patient, complete the patient HLA section in the database.

Multiple donors (including multiple CB units):

☐ No
☐ Yes: Number of donors: _____
DONOR & GRAFT INFORMATION
--- Donor ___ (number)---

Copy and fill-in this section as many times as necessary, marking if it refers to Donor 1, 2, etc.

Did the donor consent to having their data in the EBMT registry?
□ No (complete only fields marked with * on pages 3-5)
□ Yes

Date of birth: ___ / ___ / ___ (YYYY/MM/DD)
(year of birth is a mandatory field)

*Age at time of donation: _____ years
(optional)

*Age in months: _____
(optional, if the donor was younger than 1 year)

*Sex (at birth):
□ Male
□ Female

Donor Identification:

Donor ID given by the treating centre (mandatory): ______________________

Global registration identifier for donors (GRID): ______________________

ION code of the Donor Registry or Cord Blood Bank (mandatory): ______________________

EuroCORD code for the Cord Blood Bank (if applicable): ______________________

Name of Donor Registry or Cord Blood Bank: ______________________

Donor ID given by the Donor Registry or Cord Blood Bank: ______________________

Patient ID given by the Donor Registry or Cord Blood Bank: ______________________

*Donor EBV status:
□ Negative
□ Positive
□ Not evaluated
□ Unknown

*Donor CMV status:
□ Negative
□ Positive
□ Not evaluated
□ Unknown

Is donor an HbS trait carrier? (for Sickle Cell Disease only)
□ No
□ Yes

Did this donor provide more than one stem cell product:
□ No
□ Yes: Number of different stem cell products from this donor: __________

(if 2 products e.g. BM and PM, complete 'Donor 1 - Product Number 1 and 2' on page 3)
DONOR & GRAFT INFORMATION
--- Donor ____(number) continued ---

*Donor ____(number) - Product Number 1

If more than one stem cell product, this is the first product collected from this donor.

**Source of stem cells:**
(select only one)
- Bone Marrow
- Peripheral Blood
- Cord Blood
- Other; specify: ____________

**Graft manipulation ex-vivo including T-cell depletion:**
(other than for RBC removal or volume reduction)

<table>
<thead>
<tr>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes:</td>
</tr>
<tr>
<td>T-cell receptor αβ depletion</td>
</tr>
<tr>
<td>B-cell depletion (CD19+) by MoAB</td>
</tr>
<tr>
<td>NK cell depletion by MoAB</td>
</tr>
<tr>
<td>CD34+ enrichment</td>
</tr>
<tr>
<td>Genetic manipulation</td>
</tr>
<tr>
<td>Other; specify: ____________</td>
</tr>
</tbody>
</table>

*Donor ____(number) - Product Number 2

If more than one stem cell product, this is the second one infused from this donor.

**Source of stem cells:**
(select only one)
- Bone Marrow:
- Peripheral Blood:
- Cord Blood
- Other; specify: ____________

**Graft manipulation ex-vivo including T-cell depletion:**
(other than for RBC removal or volume reduction)

<table>
<thead>
<tr>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes:</td>
</tr>
<tr>
<td>T-cell receptor αβ depletion</td>
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<tr>
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<td>NK cell depletion by MoAB</td>
</tr>
<tr>
<td>CD34+ enrichment</td>
</tr>
<tr>
<td>Genetic manipulation</td>
</tr>
<tr>
<td>Other; specify: ____________</td>
</tr>
</tbody>
</table>
### DONOR & GRAFT INFORMATION

--- Donor (number) continued ---

*Copy and fill-in this section as many times as necessary, marking if it refers to Donor 1, 2, etc.*

#### *HLA match type and patient/donor relation:*

- □ *Match (both haplotypes matched)*

- □ *Mismatch:*
  - □ *Degree of matching:*
    - □ One haplotype mismatch
    - □ Partial haplotype mismatch, number of mismatched HLA alleles:
      - □ 1
      - □ 2
      - □ 3
      - □ 4
      - □ 5
      - □ 6
  - □ *Mismatch at locus:* (check all that apply)
    - □ A
    - □ DRB1
    - □ B
    - □ DQB1
    - □ C
    - □ DPB1

- □ *Both haplotypes confirmed by family studies? (for both matched and mismatched related donors)*
  - □ No
  - □ Yes
  - □ Unknown

**Relationship to patient (for both matched and mismatched related donors):**

- □ Syngeneic (monozygotic twin) (option only for matched related donors)
- □ Sibling (may include non-monozygotic twin)
- □ Other related: □ Parents
  - □ Child
  - □ Aunt/Uncle
  - □ Cousin
  - □ Grand Parents
  - □ Other; specify: ____________________________

- □ *Unrelated donor:

<table>
<thead>
<tr>
<th>*Degree of HLA matching:</th>
<th>HLA-DPB1 matching:</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Full match (10/10)</td>
<td>□ Match</td>
</tr>
<tr>
<td>□ Single HLA mismatch (9/10)</td>
<td>□ At least 1 mismatch</td>
</tr>
<tr>
<td>□ &gt;=2 HLA mismatches (&lt;9/10)</td>
<td>□ Not typed</td>
</tr>
</tbody>
</table>

* □ *Mismatch at locus:* (check all that apply)
  - □ A
  - □ DRB1
  - □ B
  - □ DQB1
  - □ C
  - □ DPB1

---

*Please enter the LABORATORY RESULTS WITH HLA TYPING into the database for all the donors.*

Index: Registry 97 | Title: DRAFT_AlioHCT_Day0 | Version: 0.0 | Effective Date: | THIS IS AN UNCONTROLLED COPY
ADDITIONAL ASSESSMENTS
(All diagnoses)

Are there Donor-Specific Antibodies (DSA) against HLA?

☐ No

☐ Yes: HLA loci the DSA are directed against: ☐ A ☐ DRB1
☐ B ☐ DQB1
☐ C ☐ DPB1

Did the patient have desensibilisation therapy? ☐ No

(Haemoglobinopathies only)
☐ Yes; specify: ________________________________

Are the DSA red cell antibodies? ☐ No

(Haemoglobinopathies only)
☐ Yes: Are they cross-reacting with the red cells of the donor? ☐ No
☐ Yes

☐ Not evaluated

☐ Unknown

PATIENT SEROLOGICAL STATUS
(All diagnoses)

Patient EBV status: Patient CMV status:
☐ Negative ☐ Negative
☐ Positive ☐ Positive
☐ Not evaluated ☐ Not evaluated
☐ Unknown ☐ Unknown

PREPARATIVE REGIMEN
(All Diagnoses)

Preparative (conditioning) regimen given?
☐ No (Primary Immunodeficiency Disorders only)
☐ Yes

Drugs given? (any active agent, including chemotherapy, monoclonal antibody, polyclonal antibody, serotherapy, etc.)
☐ No
☐ Yes (provide details in the table on pages 7-8)

What type of conditioning regimen was used?
☐ Reduced intensity conditioning (RIC)
☐ Myeloablative conditioning (MAC)
**Specification and dose of the preparative regimen:**

(Report the total prescribed cumulative dose as per protocol. Multiply daily dose by the number of days; e.g. for Busulfan given 4mg/kg daily for 4days, total dose to report is 16mg/kg.)

<table>
<thead>
<tr>
<th>Chemotherapy</th>
<th>Dose</th>
<th>Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bendamustine</td>
<td></td>
<td>mg/m²</td>
</tr>
<tr>
<td></td>
<td></td>
<td>mg/kg</td>
</tr>
<tr>
<td>Bleomycin</td>
<td></td>
<td>mg/m²</td>
</tr>
<tr>
<td></td>
<td></td>
<td>mg/kg</td>
</tr>
<tr>
<td>Busulfan</td>
<td></td>
<td>mg/m²</td>
</tr>
<tr>
<td></td>
<td></td>
<td>mg/kg</td>
</tr>
<tr>
<td>Route of administration:</td>
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<tr>
<td>Oral</td>
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<tr>
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<td></td>
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<tr>
<td>Both</td>
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<tr>
<td>Drug monitoring performed:</td>
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<td></td>
</tr>
<tr>
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<td></td>
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</tr>
<tr>
<td>Yes; total AUC:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>mg x hr/L</td>
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<td></td>
</tr>
<tr>
<td>micromol x min/L</td>
<td></td>
<td></td>
</tr>
<tr>
<td>mg x min/mL</td>
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<td></td>
</tr>
<tr>
<td>Carboplatin</td>
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<td>mg/kg</td>
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<td>Drug monitoring performed:</td>
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<td></td>
<td>mg/kg</td>
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<td>Idarubicin</td>
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**PREPARATIVE REGIMEN continued**

**Specification and dose of the preparative regimen:**
(Report the total prescribed cumulative dose as per protocol. Multiply daily dose by the number of days; e.g. for Busulfan given 4mg/kg daily for 4 days, total dose to report is 16mg/kg.)

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<tr>
<td>Ifosfamide</td>
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<tr>
<td>Imatinib</td>
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<td>Lomustine</td>
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<td>Paclitaxel</td>
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<td>Thiotepa</td>
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<td>mCi</td>
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<tr>
<td>Treosulfan</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other; specify*</td>
<td></td>
<td>mCi</td>
</tr>
</tbody>
</table>

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

**Total body irradiation (TBI):**

- No
- Yes; Total prescribed radiation dose as per protocol: ________ Gy
  
  Number of fractions: _____
  
  Number of radiation days: _____
GvHD prophylaxis or preventive treatment:

- Yes: 
  - Drugs (report in the table below)
  - Extracorporeal photopheresis (ECP)
  - Other; specify: 

- Abatacept
- Alemtuzumab
- Anti-Thymocyte Globulin/Anti-Lymphocyte Globulin
  - Product name: 
  - Origin: 
    - Rabbit
    - Horse
    - Other; specify: 
- Basiliximab
- Corticosteroids:
  - Beclometasone
  - Budesonide
  - Dexamethasone
  - Methylprednisolone
  - Prednisolone
  - Cyclophosphamide
  - Cyclosporine
  - Etanercept
  - Everolimus
  - Infliximab
  - Methotrexate
  - Mycophenolate mofetil
  - Ruxolitinib
  - Sirolimus
  - Tacrolimus
  - Other agent (in vivo); specify: 

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