

Document Type		Form
Index Number	I	Registry 97
Version Number	I	1.0
Title	I	Allogeneic HCT Day 0
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Authorised By	I	Annelot van Amerongen
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Treatment Date \_ \_ \_ / \_ / \_ (YYY/MM/DD)

# ALLOGENEIC HAEMATOPOIETIC CELL TRANSPLANTATION (HCT) Day 0

<b>Date of this HCT:</b> / / (YYYY/MM/DD) (or planned date of HCT if patient died before treatment)	Center where treatment took place (CIC):
Survival status at HCT:	
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)
<b>Chronological number of this treatment:</b> (all types of treatments for this patient, e.g. HCT, CT, IST	)
<b>Chronological number of this HCT:</b> (all HCTs this patient received in the past)	<b>Chronological number of this allogeneic HCT:</b> (all allogeneic HCTs this patient received in the past)
Complete this section only if the <u>chronological number of</u>	
Reason for this HCT:	<u>If &gt; 1:</u>
☐ Indication diagnosis	
☐ Relapse/progression after previous treatment (HCT/C	т)
Complication after previous treatment (HCT/CT)	
Primary graft failure	Ì
Secondary graft failure	
Secondary malignancy	
Other; specify:	
Date of the last treatment before this one: $\_\_\_$ / _	I(YYYY/MM/DD)
Type of the last treatment before this one:	
Autologous HCT	
Allogeneic HCT	
Cellular therapy	
Was the last treatment performed at another institut	tion?
□ No	
Yes: CIC (if known):	
Name of institution:	
City:	
	7/CT using the follow up assessment date before this HCT. It is required plants/cellular therapies.



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#### **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: \_\_\_\_\_



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## **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?
Yes
Date of birth: * / / (YYYY/MM/DD)
(year of birth is a mandatory field)
*Age at time of donation: years (optional)
<b>*Age in months:</b> (optional, if the donor was younger than 1 year)
<b>*Sex</b> (at birth): □ Male
E 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: *Donor CMV status:
<ul> <li>□ Negative</li> <li>□ Positive</li> <li>□ Positive</li> </ul>
□ Not evaluated □ Not evaluated
Unknown
Is donor an HbS trait carrier? (for Sickle Cell Disease only) INO Yes
Did this donor provide more than one stem cell product:

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) Index: Registry 97 | Title: Allogeneic HCT Day 0 | Version: 1.0 | Effective Date: 2023-08-22 | THIS IS AN UNCONTOLLED COPY

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 Treatment Type 🔲 HCT

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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.
*Donor(number) - Product Number 1
If more than one stem cell product , this is the <u>first</u> product collected from this donor.
*Source of stem cells:
(select only one)
Bone Marrow
Peripheral Blood
Cord Blood
Other; specify:
*Graft manipulation <i>ex-vivo</i> including T-cell depletion:
(other than for RBC removal or volume reduction)
□ No
Yes: T-cell (CD3+) depletion (Do not use for "Campath in the bag".)
T-cell receptor αβ depletion
B-cell depletion (CD19+) by MoAB
□ NK cell depletion by MoAB
CD34+ enrichment
Genetic manipulation
☐ Other; specify:
r
*Donor(number) - Product Number 2
If more than one stem cell product , this is the <u>second</u> one infused from this donor.
*Source of stem cells:
(select only one)
Bone Marrow:
Peripheral Blood:
Cord Blood
Other; specify:
*Graft manipulation <i>ex-vivo</i> including T-cell depletion:
(other than for RBC removal or volume reduction)
Yes:      T-cell (CD3+) depletion (Do not use for "Campath in the bag".)
T-cell receptor αβ depletion
B-cell depletion (CD19+) by MoAB
□ NK cell depletion by MoAB
CD34+ enrichment
Genetic manipulation
Other; specify:
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# 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:

\*Related donor, type:

☐ *Match (both haplotypes	matched)					
□ *Mismatch:						
*Degree of matching	j: 🗌 One hap	otype mismat	ch			
	Partial h (select or	aplotype misr n <i>ly one)</i>	natch, numbe	er of mismato	ched HLA alle	eles:
	1	2	3	4	5	6
*Mismatch at locus:	A	DRB1				
(check all that apply)	В	DQB1				
	СС	DPB1				
*Both haplotypes confirmed	d by family st	udies? (for b	oth matched	and mismatc	hed related o	donors)
☐ No ☐ Yes ☐ Unknown						
Relationship to patient (for				,		
Syngeneic (monozygotic	c twin) (option	only for matcl	ned related do	onors)		
Sibling (may include nor	n-monozygotic	: twin)				
Other related: Parents						
Child						
Aunt/Uncle						
Cousin						
Grand Parents						
Other; specify:						

#### \*Unrelated donor:

*Degree of HLA matching:	HLA-DPB1 matchir	ng:	
☐ Full match (10/10)	☐ Match	At least 1	mismatch 🔲 Not typed
Single HLA mismatch (9/10)	*Mismatch at locus	<u>, П</u> А П В	DRB1 DQB1
>=2 HLA mismatches (<9/10)	(check all that apply)		DPB1

\*Please enter the LABORATORY RESULTS WITH HLA TYPING into the database for all the donors Index: Registry 97 | Title: Allogeneic HCT Day 0 | Version: 1.0 | Effective Date: 2023-08-22 | THIS IS AN UNCONTOLLED COPY



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### ADDITIONAL ASSESSMENTS

(All diagnoses)

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

Yes: HLA loci the DSA are directed against:
□ B □ DQB1
C DPB1
Did the patient have desensibilisation therapy? 🔲 No
(Haemoglobinopathies only)
Are the DSA red cell antibodies?       No         (Haemoglobinopathies only)       Yes: Are they cross-reacting with the red cells of the donor?         No       Yes: Are they cross-reacting with the red cells of the donor?
Not evaluated

PATIENT	SEROLOGICAL	<b>STATUS</b>
	(All diagnoses)	

(All diagnoses)

#### Patient EBV status:

#### Patient CMV status:

Negative
Positive
Positive
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)



# **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 4days, total dose to report is 16mg/kg.)

Chemotherapy	Dose	Units
Bendamustine		mg/m <sup>2</sup> mg/kg
Bleomycin		mg/m <sup>2</sup> mg/kg
Busulfan		
Route of administration: IV Both		☐ mg/m² ☐ mg/kg
Drug monitoring performed:  No Yes; total AUC: mg x hr/L micromol x min/L mg x min/mL		
Carboplatin		
Drug monitoring performed:  No Yes; total AUC: mg x hr/L micromol x min/L mg x min/mL		☐ mg/m² ☐ mg/kg
		☐ mg/m <sup>2</sup> ☐ mg/kg
Cisplatin		☐ mg/m <sup>2</sup> ☐ mg/kg
Clofarabine		☐ mg/m <sup>2</sup> ☐ mg/kg
Corticosteroids:		
Beclometasone		☐ mg/m <sup>2</sup> ☐ mg/kg
Budesonide		☐ mg/m <sup>2</sup> ☐ mg/kg
Dexamethasone		☐ mg/m <sup>2</sup> ☐ mg/kg
Methylprednisolone		☐ mg/m <sup>2</sup> ☐ mg/kg
		☐ mg/m <sup>2</sup> ☐ mg/kg
Cyclophosphamide		☐ mg/m <sup>2</sup> ☐ mg/kg
Cytarabine		mg/m <sup>2</sup> mg/kg
Daunorubicin		mg/m <sup>2</sup> mg/kg
Doxorubicin		☐ mg/m <sup>2</sup> ☐ mg/kg
		☐ mg/m <sup>2</sup> ☐ mg/kg
Etoposide		☐ mg/m <sup>2</sup> ☐ mg/kg
Fludarabine		☐ mg/m <sup>2</sup> ☐ mg/kg
Gemtuzumab ozogamicin		☐ mg/m <sup>2</sup> ☐ mg/kg
☐ Ibritumomab tiuxetan		🗌 mCi 🔄 MBq
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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 4days, total dose to report is 16mg/kg.)

Chemotherapy	Dose	Units
Ifosfamide		mg/m <sup>2</sup> mg/kg
🔲 Imatinib		☐ mg/m <sup>2</sup> ☐ mg/kg
		☐ mg/m <sup>2</sup> ☐ mg/kg
🔲 Melphalan		☐ mg/m <sup>2</sup> ☐ mg/kg
Mitoxantrone		☐ mg/m <sup>2</sup> ☐ mg/kg
Paclitaxel		mg/m <sup>2</sup> mg/kg
🔲 Rituximab		☐ mg/m² ☐ mg/kg
Teniposide		☐ mg/m² ☐ mg/kg
🔲 Thiotepa		☐ mg/m <sup>2</sup> ☐ mg/kg
🔲 Tositumomab		🗌 mCi 🔄 MBq
🔲 Treosulfan		☐ mg/m <sup>2</sup> ☐ mg/kg
Other; specify*:		☐ mg/m <sup>2</sup> ☐ mg/kg
		🗌 mCi 🔄 MBq

\*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:

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#### **GvHD PROPHYLAXIS**

GvHD prophylaxis or preventive treatment:
□ No
Yes: Drugs (report in the table below)
Extracorporeal photopheresis (ECP)
Other; specify:
Alemtuzumab
Anti-Thymocyte Globulin Anti-Lymphocyte Globulin
Product name: Origin:  Rabbit
☐ Horse ☐ Other; specify:
Corticosteroids:
Methylprednisolone
Cyclophosphamide
🔲 Infliximab
Methotrexate
Mycophenolate mofetil
Tacrolimus
Other agent (in vivo); specify*:

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