

ALLOGENEIC HAEMATOPOIETIC CELL TRANSPLANTATION (HCT) Day 0

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

Centre where this HCT took place: _____

Patient UPN for this treatment: _____

Team or unit where treatment took place (select all that apply):

Adults Pediatrics Haematology Oncology Allograft Autograft Other; specify: _____

Unit number: _____ Not applicable

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

Extended dataset

Only for Chronic Myeloid Leukaemia (CML) patients

Reason for HCT (select as many reasons as applicable):

<input type="checkbox"/> Accelerated phase	<input type="checkbox"/> Clonal evolution
<input type="checkbox"/> Blast crisis	<input type="checkbox"/> Poor risk patient or high risk CML
<input type="checkbox"/> TKI intolerance	<input type="checkbox"/> ABL mutation
<input type="checkbox"/> Imatinib resistance	<input type="checkbox"/> Standard indication at diagnosis
<input type="checkbox"/> Dasatinib resistance	<input type="checkbox"/> No engraftment/graft loss
<input type="checkbox"/> Nilotinib resistance	<input type="checkbox"/> Clinical study
<input type="checkbox"/> Asciminib resistance	<input type="checkbox"/> Other, specify : _____
<input type="checkbox"/> Ponatinib resistance	<input type="checkbox"/> Unknown
<input type="checkbox"/> Bosutinib resistance	

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

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

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

ALLOGENEIC HAEMATOPOIETIC CELL TRANSPLANTATION (HCT) Day 0

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

If > 1:

Reason for this HCT:

- Indication diagnosis
- Relapse/progression after previous treatment (HCT/CT/GT/IST)
- Complication after previous treatment (HCT/CT/GT/IST)
- Primary graft failure
- Secondary graft failure
- Secondary malignancy
- Other; specify: _____

Date of the last main treatment before this one: ____/____/____ (YYYY/MM/DD)

A main treatment refers to HCT, cellular therapy, gene therapy and immunosuppressive treatment

Type of the last main treatment before this one:

- Autologous HCT
- Allogeneic HCT
- Cellular therapy (CT)
- Immunosuppressive treatment (IST)
- Gene therapy (GT)

Was the last main 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/GT/IST using the follow up assessment date before this HCT. It is required to capture relapse data and other events between transplants/cellular therapies.



EBMT Centre Identification Code (CIC): _____
Hospital Unique Patient Number (UPN): _____
Patient Number in EBMT Registry: _____

Treatment Type HCT
Treatment Date ____/____/____ (YYYY/MM/DD)

DONOR & GRAFT

Is this HCT part of a (planned) 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 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 4-8)

Yes

Date of birth: ____/____/____ (YYYY/MM/DD)

(year of birth is a mandatory field)

(Skip if the source of stem cells is cord blood)

***Age at time of donation:** _____ years

(optional)

***Age in months:** _____

(optional, if the donor was younger than 2 years)

***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 blood group:**

- A
- B
- AB
- O

***Donor rhesus factor:**

- Negative
- Positive

***Donor EBV status:**

- Negative
- Positive
- Not evaluated
- Unknown

***Donor CMV status:**

- Negative
- Positive
- Not evaluated
- Unknown

Is donor heterozygous? *(Sickle cell disease only)

- No
- Yes

Is donor a carrier for X-linked disease? *(Inborn Errors only)

- No
- Yes
- Not evaluated
- Unknown

***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 5)

DONOR 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 first product collected from this donor.

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

***Graft manipulation ex-vivo 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: UM171 (Zemcelpro; dorocubicel and unexpanded CD34- cells)

Nicotinamide (NAM) (Omisirge; omidubicel-only)

Notch ligand-based expansion

Genetic manipulation

Other; specify: _____

Extended dataset

***Infused cell counts for this product**

*Cell type	*Counts	*Units
Nucleated cells (/kg)	_____ <input type="checkbox"/> Not evaluated <input type="checkbox"/> Unknown	<input type="checkbox"/> x10 ⁶ /kg <input type="checkbox"/> x10 ⁷ /kg <input type="checkbox"/> x10 ⁸ /kg
CD34+ cells (/kg)	_____ <input type="checkbox"/> Not evaluated <input type="checkbox"/> Unknown	<input type="checkbox"/> x10 ⁵ /kg <input type="checkbox"/> x10 ⁶ /kg
CD3+ cells (/kg)	_____ <input type="checkbox"/> Not evaluated <input type="checkbox"/> Unknown	<input type="checkbox"/> x10 ⁵ /kg <input type="checkbox"/> x10 ⁶ /kg <input type="checkbox"/> x10 ⁷ /kg <input type="checkbox"/> x10 ⁸ /kg

***Was the graft cryopreserved prior to infusion?**

- No
- Yes; *Date of cryopreservation: ____/____/____ (YYYY/MM/DD) Unknown
- Unknown

Extended dataset

Cord blood

***Cell infusion for this product**

- *Route:** Intravenous (IV)
- Intrabone/intramedullary
- Other; specify: _____
- Unknown

- *Method:** DMSO
- Wash (Rubinstein/New York)
- Other; specify: _____
- Unknown

***Cell viability tests performed at HCT centre:** No

Yes;

***Tests performed after thawing of an aliquot on:**

- Contiguous segment
- Reference bag
- Unknown

- *Method used:** 7-AAD
- Tryptan blue
- Acridine orange-ethidium bromide
- Acridine orange-ethidium iodide
- Other; specify: _____
- Unknown

***Viability of all cells (%):** _____ Unknown

***Viability of CD34+ cells (%):** _____ Unknown

DONOR 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 2

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

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

***Graft manipulation ex-vivo 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: UM171 (Zemcelpro; dorocubicel and unexpanded CD34- cells)
 - Nicotinamide (NAM) (Omisirge; omidubicel-only)
 - Notch ligand-based expansion
- Genetic manipulation
- Other; specify: _____

Extended dataset

***Infused cell counts for this product**

*Cell type	*Counts	*Units
Nucleated cells (/kg)	_____ <input type="checkbox"/> Not evaluated <input type="checkbox"/> Unknown	<input type="checkbox"/> x10 ⁶ /kg <input type="checkbox"/> x10 ⁷ /kg <input type="checkbox"/> x10 ⁸ /kg
CD34+ cells (/kg)	_____ <input type="checkbox"/> Not evaluated <input type="checkbox"/> Unknown	<input type="checkbox"/> x10 ⁵ /kg <input type="checkbox"/> x10 ⁶ /kg
CD3+ cells (/kg)	_____ <input type="checkbox"/> Not evaluated <input type="checkbox"/> Unknown	<input type="checkbox"/> x10 ⁵ /kg <input type="checkbox"/> x10 ⁶ /kg <input type="checkbox"/> x10 ⁷ /kg <input type="checkbox"/> x10 ⁸ /kg

***Was the graft cryopreserved prior to infusion?**

- No
- Yes; ***Date of cryopreservation:** ____/____/____ (YYYY/MM/DD) Unknown
- Unknown

Extended dataset

Cord blood

***Cell infusion for this product**

- *Route:** Intravenous (IV)
 Intrabone/intramedullary
 Other; specify: _____
 Unknown

- *Method:** DMSO
 Wash (Rubinstein/New York)
 Other; specify: _____
 Unknown

***Cell viability tests performed at HCT centre:** No
 Yes;

- *Tests performed after thawing of an aliquot on:** Contiguous segment
 Reference bag
 Unknown

- *Method used:** 7-AAD
 Trypan blue
 Acridine orange-ethidium bromide
 Acridine orange-ethidium iodide
 Other; specify: _____
 Unknown

***Viability of all cells (%):** _____ Unknown

***Viability of CD34+ cells (%):** _____ Unknown

DONOR INFORMATION
--- Donor __ (number) continued ---
Copy and fill-in this section as many times as necessary, marking if it refers to Donor 1, 2, etc.

***Relation between patient and donor:** Related:

- Relationship to patient:** Syngeneic (monozygotic twin)
 Sibling (*may include non-monozygotic twin*)
 Other related: Parents
 Child
 Aunt/Uncle
 Cousin
 Grand Parents
 Other; specify: _____

Unrelated (*proceed to next page*)

Related donor:

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

***HLA match type:**

*Match (both haplotypes matched)

*Mismatch: ***Method used for patient/donor HLA typing:** Molecular
 (*select all that apply*) Serology

if molecular typing was done:

*Locus:	*Number of mismatches, allelic:			
A:	<input type="checkbox"/> 0 (match)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> Not evaluated
B:	<input type="checkbox"/> 0 (match)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> Not evaluated
C:	<input type="checkbox"/> 0 (match)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> Not evaluated
DRB1:	<input type="checkbox"/> 0 (match)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> Not evaluated
DQB1:	<input type="checkbox"/> 0 (match)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> Not evaluated
DPB1:	<input type="checkbox"/> 0 (match)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> Not evaluated

if serological typing was done:

*Locus:	*Number of mismatches, antigenic:			
A:	<input type="checkbox"/> 0 (match)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> Not evaluated
B:	<input type="checkbox"/> 0 (match)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> Not evaluated
C:	<input type="checkbox"/> 0 (match)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> Not evaluated
DRB1:	<input type="checkbox"/> 0 (match)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> Not evaluated
DQB1:	<input type="checkbox"/> 0 (match)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> Not evaluated
DPB1:	<input type="checkbox"/> 0 (match)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> Not evaluated

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

DONOR INFORMATION
--- Donor __ (number) continued ---
Copy and fill-in this section as many times as necessary, marking if it refers to Donor 1, 2, etc.

Unrelated donor:

***HLA match type:**

***Method used for patient/donor HLA typing:** Molecular
 (select all that apply) Serology

if molecular typing was done:

*Locus:	*Number of mismatches, allelic:
A:	<input type="checkbox"/> 0 (match) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> Not evaluated
B:	<input type="checkbox"/> 0 (match) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> Not evaluated
C:	<input type="checkbox"/> 0 (match) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> Not evaluated
DRB1:	<input type="checkbox"/> 0 (match) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> Not evaluated
DQB1:	<input type="checkbox"/> 0 (match) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> Not evaluated
DPB1:	<input type="checkbox"/> 0 (match) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> Not evaluated

if serological typing was done:

*Locus:	*Number of mismatches, antigenic:
A:	<input type="checkbox"/> 0 (match) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> Not evaluated
B:	<input type="checkbox"/> 0 (match) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> Not evaluated
C:	<input type="checkbox"/> 0 (match) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> Not evaluated
DRB1:	<input type="checkbox"/> 0 (match) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> Not evaluated
DQB1:	<input type="checkbox"/> 0 (match) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> Not evaluated
DPB1:	<input type="checkbox"/> 0 (match) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> Not evaluated

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

ADDITIONAL ASSESSMENTS
(All diagnoses)

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

<input type="checkbox"/> No							
<input type="checkbox"/> Yes: HLA loci the DSA are directed against: <table style="margin-left: 20px; border: none;"> <tr> <td><input type="checkbox"/> A</td> <td><input type="checkbox"/> DRB1</td> </tr> <tr> <td><input type="checkbox"/> B</td> <td><input type="checkbox"/> DQB1</td> </tr> <tr> <td><input type="checkbox"/> C</td> <td><input type="checkbox"/> DPB1</td> </tr> </table>		<input type="checkbox"/> A	<input type="checkbox"/> DRB1	<input type="checkbox"/> B	<input type="checkbox"/> DQB1	<input type="checkbox"/> C	<input type="checkbox"/> DPB1
<input type="checkbox"/> A	<input type="checkbox"/> DRB1						
<input type="checkbox"/> B	<input type="checkbox"/> DQB1						
<input type="checkbox"/> C	<input type="checkbox"/> DPB1						
<p>Did the patient have desensibilisation therapy? <input type="checkbox"/> No <i>(Haemoglobinopathies only)</i> <input type="checkbox"/> Yes; specify: _____</p>							
<p>Are the DSA red cell antibodies? <input type="checkbox"/> No <i>(Haemoglobinopathies only)</i> <input type="checkbox"/> Yes: Are they cross-reacting with the red cells of the donor? <input type="checkbox"/> No <input type="checkbox"/> Yes</p>							
<input type="checkbox"/> Not evaluated							
<input type="checkbox"/> Unknown							

PREPARATIVE REGIMEN
(All Diagnoses)

Preparative (conditioning) regimen given?

- No
 Yes

Drugs given? *(any active agent, including chemotherapy, monoclonal antibody, polyclonal antibody, serotherapy, etc.)*

- No
 Yes (provide details in the table on pages 10-11)

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.
Report dosages and units only for individual drugs.)*

Chemotherapy	Dose	Unit
<input type="checkbox"/> Bendamustine	_____	<input type="checkbox"/> mg/m ² <input type="checkbox"/> mg/kg
<input type="checkbox"/> Bleomycin	_____	<input type="checkbox"/> mg/m ² <input type="checkbox"/> mg/kg
<input type="checkbox"/> Busulfan Route of administration: <input type="checkbox"/> Oral <input type="checkbox"/> IV <input type="checkbox"/> Both Drug monitoring performed: <input type="checkbox"/> No <input type="checkbox"/> Yes; total AUC: _____ <input type="checkbox"/> mg x hr/L <input type="checkbox"/> micromol x min/L <input type="checkbox"/> mg x min/mL	_____	<input type="checkbox"/> mg/m ² <input type="checkbox"/> mg/kg
<input type="checkbox"/> Carboplatin Drug monitoring performed: <input type="checkbox"/> No <input type="checkbox"/> Yes; total AUC: _____ <input type="checkbox"/> mg x hr/L <input type="checkbox"/> micromol x min/L <input type="checkbox"/> mg x min/mL	_____	<input type="checkbox"/> mg/m ² <input type="checkbox"/> mg/kg
<input type="checkbox"/> Carmustine	_____	<input type="checkbox"/> mg/m ² <input type="checkbox"/> mg/kg
<input type="checkbox"/> Cisplatin	_____	<input type="checkbox"/> mg/m ² <input type="checkbox"/> mg/kg
<input type="checkbox"/> Clofarabine	_____	<input type="checkbox"/> mg/m ² <input type="checkbox"/> mg/kg
Corticosteroids:		
<input type="checkbox"/> Beclometasone	_____	<input type="checkbox"/> mg/m ² <input type="checkbox"/> mg/kg
<input type="checkbox"/> Budesonide	_____	<input type="checkbox"/> mg/m ² <input type="checkbox"/> mg/kg
<input type="checkbox"/> Dexamethasone	_____	<input type="checkbox"/> mg/m ² <input type="checkbox"/> mg/kg
<input type="checkbox"/> Methylprednisolone	_____	<input type="checkbox"/> mg/m ² <input type="checkbox"/> mg/kg
<input type="checkbox"/> Prednisolone	_____	<input type="checkbox"/> mg/m ² <input type="checkbox"/> mg/kg
<input type="checkbox"/> Cyclophosphamide	_____	<input type="checkbox"/> mg/m ² <input type="checkbox"/> mg/kg
<input type="checkbox"/> Cytarabine	_____	<input type="checkbox"/> mg/m ² <input type="checkbox"/> mg/kg
<input type="checkbox"/> Daunorubicin	_____	<input type="checkbox"/> mg/m ² <input type="checkbox"/> mg/kg
<input type="checkbox"/> Doxorubicin	_____	<input type="checkbox"/> mg/m ² <input type="checkbox"/> mg/kg
<input type="checkbox"/> Epirubicin	_____	<input type="checkbox"/> mg/m ² <input type="checkbox"/> mg/kg
<input type="checkbox"/> Etoposide	_____	<input type="checkbox"/> mg/m ² <input type="checkbox"/> mg/kg
<input type="checkbox"/> Fludarabine	_____	<input type="checkbox"/> mg/m ² <input type="checkbox"/> mg/kg
<input type="checkbox"/> Gemtuzumab ozogamicin	_____	<input type="checkbox"/> mg/m ² <input type="checkbox"/> mg/kg
<input type="checkbox"/> Ibritumomab tiuxetan	_____	<input type="checkbox"/> mCi <input type="checkbox"/> MBq
<input type="checkbox"/> Idarubicin	_____	<input type="checkbox"/> mg/m ² <input type="checkbox"/> mg/kg

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
<input type="checkbox"/> Ifosfamide	_____	<input type="checkbox"/> mg/m ² <input type="checkbox"/> mg/kg
<input type="checkbox"/> Imatinib	_____	<input type="checkbox"/> mg/m ² <input type="checkbox"/> mg/kg
<input type="checkbox"/> Lomustine	_____	<input type="checkbox"/> mg/m ² <input type="checkbox"/> mg/kg
<input type="checkbox"/> Melphalan	_____	<input type="checkbox"/> mg/m ² <input type="checkbox"/> mg/kg
<input type="checkbox"/> Mitoxantrone	_____	<input type="checkbox"/> mg/m ² <input type="checkbox"/> mg/kg
<input type="checkbox"/> Paclitaxel	_____	<input type="checkbox"/> mg/m ² <input type="checkbox"/> mg/kg
<input type="checkbox"/> Anti-CD20 antibodies	_____	<input type="checkbox"/> mg/m ² <input type="checkbox"/> mg/kg
<input type="checkbox"/> Teniposide	_____	<input type="checkbox"/> mg/m ² <input type="checkbox"/> mg/kg
<input type="checkbox"/> Thiotepa	_____	<input type="checkbox"/> mg/m ² <input type="checkbox"/> mg/kg
<input type="checkbox"/> Tositumomab	_____	<input type="checkbox"/> mCi <input type="checkbox"/> MBq
<input type="checkbox"/> Treosulfan	_____	<input type="checkbox"/> mg/m ² <input type="checkbox"/> mg/kg
<input type="checkbox"/> Other; specify*: _____	_____	<input type="checkbox"/> mg/m ² <input type="checkbox"/> mg/kg <input type="checkbox"/> mCi <input type="checkbox"/> 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:** _____

Total lymphatic irradiation (TLI):

- No
- Yes; **Total prescribed radiation dose as per protocol (Gy):** _____
- Number of fractions:** _____
- Number of radiation days:** _____

Total abdominal irradiation (TAI):

- No
- Yes; **Total prescribed radiation dose as per protocol (Gy):** _____
- Number of fractions:** _____
- Number of radiation days:** _____

