

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):

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

Chronological number of this HCT/CT/GT/IST event: _____
(It is an order/rank number for this type of treatment event, not the patient's full treatment history. Please Indicate whether this is the 1st, 2nd, 3rd, etc. HCT/CT/GT/IST event recorded for this patient. IST is applicable only for BMF, please don't count IST treatment for other diseases.)

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): _____ ☐ Unknown

ION code of the Donor Registry or Cord Blood Bank (mandatory): _____ ☐ Unknown

EuroCord code for the Cord Blood Bank (if applicable): _____ ☐ Unknown

Name of Donor Registry or Cord Blood Bank: _____ ☐ Unknown

Donor ID given by the Donor Registry or Cord Blood Bank: _____ ☐ Unknown

Patient ID given by the Donor Registry or Cord Blood Bank: _____ ☐ Unknown

***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 $\alpha\beta$ depletion☐ B-cell depletion (CD19+) by MoAB☐ NK cell depletion by MoAB☐ CD34+ enrichment☐ Ex vivo expansion of CD34+ cells: ☐ 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)	_____ ☐ Not evaluated ☐ Unknown	☐ $\times 10^6/\text{kg}$ ☐ $\times 10^7/\text{kg}$ ☐ $\times 10^8/\text{kg}$
CD34+ cells (/kg)	_____ ☐ Not evaluated ☐ Unknown	☐ $\times 10^5/\text{kg}$ ☐ $\times 10^6/\text{kg}$
CD3+ cells (/kg)	_____ ☐ Not evaluated ☐ Unknown	☐ $\times 10^5/\text{kg}$ ☐ $\times 10^6/\text{kg}$ ☐ $\times 10^7/\text{kg}$ ☐ $\times 10^8/\text{kg}$

Was the graft cryopreserved prior to infusion?**☐ No☐ Yes; *Date of cryopreservation: ____/____/____ (YYYY/MM/DD) ☐ Unknown☐ Unknown*Extended datasetCord 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 (<i>Do not use for "Campath in the bag"</i>) ☐ T-cell receptor $\alpha\beta$ depletion ☐ B-cell depletion (CD19+) by MoAB ☐ NK cell depletion by MoAB ☐ CD34+ enrichment ☐ Ex vivo expansion of CD34+ cells: ☐ 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)	_____ ☐ Not evaluated ☐ Unknown	☐ $\times 10^6/\text{kg}$ ☐ $\times 10^7/\text{kg}$ ☐ $\times 10^8/\text{kg}$
CD34+ cells (/kg)	_____ ☐ Not evaluated ☐ Unknown	☐ $\times 10^5/\text{kg}$ ☐ $\times 10^6/\text{kg}$
CD3+ cells (/kg)	_____ ☐ Not evaluated ☐ Unknown	☐ $\times 10^5/\text{kg}$ ☐ $\times 10^6/\text{kg}$ ☐ $\times 10^7/\text{kg}$ ☐ $\times 10^8/\text{kg}$

***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:	☐ 0 (match)	☐ 1	☐ 2	☐ Not evaluated
B:	☐ 0 (match)	☐ 1	☐ 2	☐ Not evaluated
C:	☐ 0 (match)	☐ 1	☐ 2	☐ Not evaluated
DRB1:	☐ 0 (match)	☐ 1	☐ 2	☐ Not evaluated
DQB1:	☐ 0 (match)	☐ 1	☐ 2	☐ Not evaluated
DPB1:	☐ 0 (match)	☐ 1	☐ 2	☐ Not evaluated

if serological typing was done:

*Locus:	*Number of mismatches, antigenic:			
A:	☐ 0 (match)	☐ 1	☐ 2	☐ Not evaluated
B:	☐ 0 (match)	☐ 1	☐ 2	☐ Not evaluated
C:	☐ 0 (match)	☐ 1	☐ 2	☐ Not evaluated
DRB1:	☐ 0 (match)	☐ 1	☐ 2	☐ Not evaluated
DQB1:	☐ 0 (match)	☐ 1	☐ 2	☐ Not evaluated
DPB1:	☐ 0 (match)	☐ 1	☐ 2	☐ 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:	☐ 0 (match) ☐ 1 ☐ 2 ☐ Not evaluated
B:	☐ 0 (match) ☐ 1 ☐ 2 ☐ Not evaluated
C:	☐ 0 (match) ☐ 1 ☐ 2 ☐ Not evaluated
DRB1:	☐ 0 (match) ☐ 1 ☐ 2 ☐ Not evaluated
DQB1:	☐ 0 (match) ☐ 1 ☐ 2 ☐ Not evaluated
DPB1:	☐ 0 (match) ☐ 1 ☐ 2 ☐ Not evaluated

if serological typing was done:

*Locus:	*Number of mismatches, antigenic:
A:	☐ 0 (match) ☐ 1 ☐ 2 ☐ Not evaluated
B:	☐ 0 (match) ☐ 1 ☐ 2 ☐ Not evaluated
C:	☐ 0 (match) ☐ 1 ☐ 2 ☐ Not evaluated
DRB1:	☐ 0 (match) ☐ 1 ☐ 2 ☐ Not evaluated
DQB1:	☐ 0 (match) ☐ 1 ☐ 2 ☐ Not evaluated
DPB1:	☐ 0 (match) ☐ 1 ☐ 2 ☐ 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?

☐ No

☐ Yes: HLA loci the DSA are directed against:

☐ A	☐ DQB1
☐ B	☐ DPB1
☐ C	☐ Other; specify: _____
☐ DRB1	_____

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

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
☐ Bendamustine	_____	☐ mg/m ² ☐ mg/kg
☐ Bleomycin	_____	☐ mg/m ² ☐ mg/kg
☐ Busulfan Route of administration: ☐ Oral ☐ IV ☐ Both Drug monitoring performed: ☐ No ☐ Yes; total AUC: _____ ☐ mg x hr/L ☐ micromol x min/L ☐ mg x min/mL	_____	☐ mg/m ² ☐ mg/kg
☐ Carboplatin Drug monitoring performed: ☐ No ☐ Yes; total AUC: _____ ☐ mg x hr/L ☐ micromol x min/L ☐ mg x min/mL	_____	☐ mg/m ² ☐ mg/kg
☐ Carmustine	_____	☐ mg/m ² ☐ mg/kg
☐ Cisplatin	_____	☐ mg/m ² ☐ mg/kg
☐ Clofarabine	_____	☐ mg/m ² ☐ mg/kg
Corticosteroids: ☐ Beclometasone ☐ Budesonide ☐ Dexamethasone ☐ Methylprednisolone ☐ Prednisolone	_____ _____ _____ _____ _____	☐ mg/m ² ☐ mg/kg ☐ mg/m ² ☐ mg/kg ☐ mg/m ² ☐ mg/kg ☐ mg/m ² ☐ mg/kg ☐ mg/m ² ☐ mg/kg
☐ Cyclophosphamide	_____	☐ mg/m ² ☐ mg/kg
☐ Cytarabine	_____	☐ mg/m ² ☐ mg/kg
☐ Daunorubicin	_____	☐ mg/m ² ☐ mg/kg
☐ Doxorubicin	_____	☐ mg/m ² ☐ mg/kg
☐ Epirubicin	_____	☐ mg/m ² ☐ mg/kg
☐ Etoposide	_____	☐ mg/m ² ☐ mg/kg
☐ Fludarabine	_____	☐ mg/m ² ☐ mg/kg
☐ Gemtuzumab ozogamicin	_____	☐ mg/m ² ☐ mg/kg
☐ Ibritumomab tiuxetan	_____	☐ mCi ☐ MBq
☐ Idarubicin	_____	☐ mg/m ² ☐ 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
☐ Ifosfamide	_____	☐ mg/m ² ☐ mg/kg
☐ Imatinib	_____	☐ mg/m ² ☐ mg/kg
☐ Lomustine	_____	☐ mg/m ² ☐ mg/kg
☐ Melphalan	_____	☐ mg/m ² ☐ mg/kg
☐ Mitoxantrone	_____	☐ mg/m ² ☐ mg/kg
☐ Paclitaxel	_____	☐ mg/m ² ☐ mg/kg
☐ Anti-CD20 antibodies	_____	☐ mg/m ² ☐ mg/kg
☐ Teniposide	_____	☐ mg/m ² ☐ mg/kg
☐ Thiotepa	_____	☐ mg/m ² ☐ mg/kg
☐ Tositumomab	_____	☐ mCi ☐ MBq
☐ Treosulfan	_____	☐ mg/m ² ☐ mg/kg
☐ Other; specify*: _____	_____	☐ mg/m ² ☐ 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: _____

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: _____



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

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

GvHD PREVENTIVE TREATMENT

GvHD preventive treatment:

- ☐ No
☐ Yes: indicate the drugs

☐ Abatacept
☐ Alemtuzumab
☐ Anti-Thymocyte Globulin (ATG) Anti-Lymphocyte Globulin Product name: _____ Origin: ☐ Rabbit Anti-Thymocyte Globulin (ATG) total cumulative dose (mg/kg): _____ ☐ Horse ☐ Unknown ☐ Other; specify: _____
☐ Basiliximab
Corticosteroids: ☐ Beclometasone ☐ Budesonide ☐ Dexamethasone ☐ Methylprednisolone ☐ Prednisolone
☐ Cyclophosphamide Post Transplant Cyclophosphamide (PTCY) cumulative dose (mg/kg): _____ ☐ Unknown Post Transplant Cyclophosphamide (PTCY) timing schedule: ☐ Single dose on day 3 ☐ Single dose on day 5 ☐ Doses on days 3 and 4 ☐ Doses on days 3 and 5 ☐ Other, specify: _____
☐ Cyclosporine
☐ Etanercept
☐ Everolimus
☐ Infliximab
☐ Methotrexate
☐ Mycophenolate mofetil
☐ Ruxolitinib
☐ Sirolimus
☐ Tacrolimus
☐ Other agent (in vivo); specify*: _____

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

END OF THE ALLO-HCT DAY 0 REPORT
proceed to form DISEASE STATUS AT HCT/CT/GT/IST