CIC: _____ Hospital UPN: _____ Patient UIC _____ HSCT Date: _____
yyyy - mm - dd

HSCT - Minimum Essential Data - A

REGISTRATION - DAY 0

Centre Identification

EBMT Code (CIC): _____ Contact person: _____

Hospital: _____ Unit: _____ Email: _____

Patient Data

Date of this report: _____ First transplant for this patient?: ☐ Yes ☐ No
yyyy - mm - dd

Patient following national / international study / trial:

☐ No ☐ Yes: Name of study / trial _____ ☐ Unknown

Hospital Unique Patient Number or Code (UPN) _____

Compulsory, registrations will not be accepted without this item.

All transplants performed in the same patient must be registered with the same patient identification number or code as this belongs to the patient and <u>not</u> to the transplant.

Initials: _____ _ _____ (first name(s) _family name(s))

Date of birth: _____ Sex: ☐ Male ☐ Female
yyyy - mm - dd ***(at birth)***

Primary Disease Diagnosis

Date of initial diagnosis: _____
yyyy - mm - dd

PRIMARY DISEASE DIAGNOSIS *(CHECK THE DISEASE FOR WHICH THIS TRANSPLANT WAS PERFORMED)*

- ☐ Acute Leukaemia
  - ☐ Acute Myelogenous Leukaemia (AML) related Precursor Neoplasms
  - ☐ Precursor Lymphoid Neoplasms (old ALL)
- ☐ Therapy related myeloid neoplasms (old Secondary Acute Leukaemia)
- ☐ Chronic Leukaemia
  - ☐ Chronic Myeloid Leukaemia (CML)
  - ☐ Chronic Lymphocytic Leukaemia (CLL)
- ☐ Lymphoma
  - ☐ Non Hodgkin
  - ☐ Hodgkin's Disease
- ☐ Myeloma/Plasma cell disorder
- ☐ Solid Tumour
- ☐ Myelodysplastic syndromes / Myeloproliferative neoplasm
  - ☐ MDS
  - ☐ MDS/MPN
  - ☐ Myeloproliferative neoplasm
- ☐ Bone marrow failure including Aplastic anaemia
- ☐ Inherited disorders
  - ☐ Primary immune deficiencies
  - ☐ Metabolic disorders
- ☐ Histiocytic disorders
- ☐ Autoimmune disease
  - ☐ Juvenile Idiopathic Arthritis
  - ☐ Multiple Sclerosis
  - ☐ Systemic Lupus
  - ☐ Systemic Sclerosis
- ☐ Haemoglobinopathy

☐ Other diagnosis, specify: _____

ACUTE LEUKAEMIAS **(main disease code 1)**
Other acute leukaemias

Disease

Date of initial diagnosis: .....
yyyy - mm - dd

Classification:

Acute Leukaemias of ambiguous lineage

- ☐ Acute undifferentiated leukaemia
- ☐ Mixed phenotype NOS
  - ☐ Mixed phenotype B/myeloid, NOS
  - ☐ Mixed phenotype T/myeloid, NOS
- ☐ Natural killer (NK)- cell lymphoblastic leukaemia/lymphoma
- ☐ Other, specify.....

Secondary Origin?

Secondary origin

Related to prior exposure to therapeutic drugs or radiation

- ☐ No
- ☐ Yes
- ☐ Unknown

IF THE PATIENT HAS RECEIVED AN ALLOGRAFT PRIOR TO THE DIAGNOSIS OF ACUTE LEUKAEMIA, ANSWER THE FOLLOWING QUESTION

Is this a donor cell leukaemia ☐ No ☐ Yes ☐ Not evaluated

Status at HSCT

Date of this HSCT: .....
yyyy - mm - dd

STATUS	**NUMBER**	**TYPE OF REMISSION**	
☐ Primary induction failure			
☐ Complete haematological remission (CR)	☐ 1st ☐ 2nd ☐ 3rd or higher	**CYTOGENETIC REMISSION** ☐ No ☐ Yes ☐ Not evaluated ☐ Not Applicable* ☐ Unknown	**MOLECULAR REMISSION** ☐ No ☐ Yes ☐ Not evaluated ☐ Not Applicable* ☐ Unknown
☐ Relapse	☐ 1st ☐ 2nd ☐ 3rd or higher		

** No abnormalities detected prior to this time point*

CIC: ..... Hospital UPN: ..... Patient UIC ..... HSCT Date: .....
yyyy - mm - dd

HSCT

Performance score system used ☐ Karnofsky ☐ Lansky

Score ☐ 10 ☐ 20 ☐ 30 ☐ 40 ☐ 50 ☐ 60 ☐ 70 ☐ 80 ☐ 90 ☐ 100

Weight (kg): ..... **Height (cm):** .....

Comorbidity Index

Sorror et al., Blood, 2005 Oct 15; 106(8): 2912-2919: *http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1895304/*

Was there any ***clinically significant*** co-existing disease or organ impairment at time of patient assessment just prior to the preparative regimen?

☐ No ☐ Yes

Comorbidity	Definitions	No	Yes	N/E
Solid tumour, previously present	Treated at any time point in the patient's past history, excluding non-melanoma skin cancer Indicate type	☐	☐	☐
Infammatory bowel disease	Crohn's disease or ulcerative colitis	☐	☐	☐
Rheumatologic	SLE, RA, polymyositis, mixed CTD, or polymyalgia rheumatica	☐	☐	☐
Infection	Requiring continuation of antimicrobial treatment after day 0	☐	☐	☐
Diabetes	Requiring treatment with insulin or oral hypoglycaemics but not diet alone	☐	☐	☐
Renal: moderate/severe	Serum creatinine > 2 mg/dL or >177 µmol/L, on dialysis, or prior renal transplantation	☐	☐	☐
Hepatic: mild	Chronic hepatitis, bilirubin between Upper Limit Normal (ULN) and 1.5 x the ULN, or AST/ALT between ULN and 2.5 × ULN	☐	☐	☐
moderate/ severe	Liver cirrhosis, bilirubin greater than 1.5 × ULN, or AST/ALT greater than 2.5 × ULN	☐	☐	☐
Arrhythmia	Atrial fibrillation or flutter, sick sinus syndrome, or ventricular arrhythmias	☐	☐	☐
Cardiac	Coronary artery disease, congestive heart failure, myocardial infarction, EF ≤ 50%, or shortening fraction in children (<28%)	☐	☐	☐
Cerebrovascular disease	Transient ischemic attack or cerebrovascular accident	☐	☐	☐
Heart valve disease	Except mitral valve prolapse	☐	☐	☐
Pulmonary: moderate	DLco and/or FEV1 66-80% or dyspnoea on slight activity	☐	☐	☐
severe	DLco and/or FEV1 ≤ 65% or dyspnoea at rest or requiring oxygen	☐	☐	☐
Obesity	Patients with a body mass index > 35 kg/m2	☐	☐	☐
Peptic ulcer	Requiring treatment	☐	☐	☐
Psychiatric disturbance	Depression or anxiety requiring psychiatric consultation or treatment	☐	☐	☐

Were there any other major clinical abnormalities prior to the preparative regimen? Specify.....

CIC: _____ Hospital UPN: _____ Patient UIC _____ HSCT Date: _____
yyyy - mm - dd

Type of HSCT (Allogeneic)

☐ **Allogeneic**

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

Multiple donors *(including multiple CB units)* ☐ No ☐ Yes: Number of donors _____

Donor 1

HLA MATCH TYPE *(DONOR RELATION WITH PATIENT)*

☐ HLA - Identical sibling *(may include non-monozygotic twin)*
☐ Syngeneic *(monozygotic twin)*
☐ HLA - Matched other relative
☐ HLA - Mismatched relative: Degree of mismatch ☐ 1 HLA locus mismatch ☐ >=2 HLA loci mismatch

Donor ID given by the centre _____

HLA MISMATCHES BETWEEN DONOR AND PATIENT
(Mismatched relatives only)

Complete number of mismatches inside each box

A	B	C	DRB1	DQB1	DPB1	
☐	☐	☐	☐	☐	☐	Antigenic
☐	☐	☐	☐	☐	☐	Allelic

0=match; 1=one mismatch; 2=2 mismatches; N/E=not evaluated

☐ Unrelated donor

ION code of the Donor Registry or CB Bank _____

BMDW code of the Donor Registry or CB Bank *(If ION code is unknown)* *(up to 4 characters)* _____

Name of Donor Registry/ CB Bank *(If any of the above codes is unknown)* _____

Donor centre name *(if applicable, optional)* _____

Donor ID given by the Donor Registry or the CB Bank listed above _____

Patient ID given by the Donor Registry or the CB Bank listed above _____

⇨ Please enter the LABORATORY RESULTS WITH HLA TYPING into the database

Donor information

Date of birth _____ *yyyy - mm - dd* OR Age at time of donation *(if date of birth not provided)* _____ _____ *month(s)*

Donor Sex ***(at birth)*** ☐ Male ☐ Female

Donor CMV status ☐ Negative ☐ Positive ☐ Not evaluated ☐ Unknown

Did this donor provide more than one stem cell product

☐ No - *(please fill "Donor 1 – Product Number 1" on next page*
☐ Yes: Number of different stem cell products infused from this donor _____
(If 2 products e.g. BM PB, please fill "Donor 1 – Product Number 1 AND 2" on next page)

Donor 1 - Product Number 1

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

Source of Stem Cells for **this product** , select only **one**

☐ Bone marrow ☐ Peripheral blood

☐ Cord blood ☐ Other: ----------

Graft manipulation ex-vivo of this product including T-cell depletion
other than for RBC removal or volume reduction

☐ No

☐ Yes Negative: ☐ No ☐ Yes:

☐ *T-cell (CD3+) depletion (do not use for "Campath in bag")*
☐ T-cell receptor αβ depletion
☐ B-cell depletion (CD19+) by MoAB
☐ NK cell depletion by MoAB
☐ Other ----------

Positive: ☐ No ☐ Yes
☐ CD34+ enrichment

Genetic manipulation ☐ No ☐ Yes

⇨ Please enter the LABORATORY RESULTS WITH HLA TYPING into the database

Donor 1 - Product Number 2

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

Source of Stem Cells for **this product** , select only **one**

☐ Bone marrow ☐ Peripheral blood

☐ Cord blood ☐ Other: ----------

Graft manipulation ex-vivo of this product including T-cell depletion
other than for RBC removal or volume reduction

☐ No

☐ Yes Negative: ☐ No ☐ Yes:

☐ *T-cell (CD3+) depletion (do not use for "Campath in bag")*
☐ T-cell receptor αβ depletion
☐ B-cell depletion (CD19+) by MoAB
☐ NK cell depletion by MoAB
☐ Other ----------

Positive: ☐ No ☐ Yes
☐ CD34+ enrichment

Genetic manipulation ☐ No ☐ Yes

⇨ Please enter the LABORATORY RESULTS WITH HLA TYPING into the database

CIC: ..... Hospital UPN: ..... Patient UIC ..... HSCT Date: .....
yyyy - mm - dd

Donor 2

HLA MATCH TYPE *(DONOR RELATION WITH PATIENT)*

- ☐ HLA - Identical sibling *(may include non-monozygotic twin)*
- ☐ Syngeneic *(monozygotic twin)*
- ☐ HLA - Matched other relative
- ☐ HLA - Mismatched relative Degree of mismatch ☐ 1 HLA locus mismatch ☐ >=2 HLA loci mismatch

.....

HLA MISMATCHES BETWEEN DONOR AND PATIENT
(Mismatched relatives only)

Complete number of mismatches inside each box

A	B	C	DRB1	DQB1	DPB1	
☐	☐	☐	☐	☐	☐	Antigenic
☐	☐	☐	☐	☐	☐	Allelic

0=match; 1=one mismatch; 2=2 mismatches; N/E=not evaluated

☐ Unrelated donor

ION code of the Donor Registry or CB Bank .....

BMDW code of the Donor Registry or CB Bank *(If ION code is unknown)* *(up to 4 characters)* .....

Name of Donor Registry/ CB Bank *(If any of the above codes is unknown)* .....

Donor centre name *(if applicable, optional)* .....

Donor ID given by the Donor Registry or the CB Bank listed above .....

Patient ID given by the Donor Registry or the CB Bank listed above .....

⇨ **Please enter the LABORATORY RESULTS WITH HLA TYPING into the database**

Donor information

Date of birth ..... OR Age at time of donation *(if date of birth not provided)*
yyyy - mm - dd
.....*year(s)* .....*month(s)*

Donor Sex ***(at birth)*** ☐ Male ☐ Female

Donor CMV status ☐ Negative ☐ Positive ☐ Not evaluated ☐ Unknown

Did this donor provide more than one stem cell product

- ☐ No *(please fill "Donor 1 – Product Number 1" on next page*
- ☐ Yes: Number of different stem cell products infused from this donor .....

(If 2 products e.g. BM PB, please fill "Donor 1 – Product Number 1 AND 2" on next page)

Donor 2 - Product Number 1

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

Source of Stem Cells for this product, select only one

☐ Bone marrow ☐ Peripheral blood

☐ Cord blood ☐ Other source _____

Graft manipulation ex-vivo including T-Cell depletion

other than for RBC removal or volume reduction

☐ No

☐ Yes Negative: ☐ No ☐ Yes:

☐ *T-cell (CD3+) depletion (do not use for "Campathbag")*
☐ T-cell receptor αβ depletion
☐ B-cell depletion (CD19+) by MoAB
☐ NK cell depletion by MoAB
☐ Other _____

Positive: ☐ No ☐ Yes

☐ CD34+ enrichment

Genetic manipulation ☐ No ☐ Yes

⇨ Please enter the LABORATORY RESULTS WITH HLA TYPING into the database

Donor 2 - Product Number 2

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

Source of Stem Cells for this product, select only one

☐ Bone marrow ☐ Peripheral blood

☐ Cord blood ☐ Other source _____

Graft manipulation ex-vivo including T-Cell depletion

other than for RBC removal or volume reduction

☐ No

☐ Yes Negative: ☐ No ☐ Yes:

☐ *T-cell (CD3+) depletion (do not use for "Campathbag")*
☐ T-cell receptor αβ depletion
☐ B-cell depletion (CD19+) by MoAB
☐ NK cell depletion by MoAB
☐ Other _____

Positive: ☐ No ☐ Yes

☐ CD34+ enrichment

Genetic manipulation ☐ No ☐ Yes

⇨ Please enter the LABORATORY RESULTS WITH HLA TYPING into the database

HSCT (Continued)

Chronological number of HSCT for this patient? | |

If >1, date of last HSCT before this one _____
yyyy - mm - dd

If >1, type of last HSCT before this one ☐ Allo ☐ Auto

If >1 and Allograft, Was the same donor used for all prior and current HSCTs? ☐ No ☐ Yes

If >1, was last HSCT peformed at another institution? ☐ No ☐ Yes: CIC if known _____

Name of the institution _____

City _____

⇨ If >1, please submit an Annual follow up form before proceeding, **giving the date of the subsequent transplant as the date of last contact**
(This is so we can capture relapse data and other events between transplants).

HSCT part of a planned multiple (sequential) graft protocol *(program)**?***

☐ No ☐ Yes

Preparative Regimen

Preparative (conditioning) **regimen given?**

☐ No *(Usually Paed Inherited Disorders only) Go to GvHD Prophylaxis*

☐ Yes

Was this intended to be myeloablative? *(allo only)*

☐ Yes ☐ No: Reason

☐ Age of recipient
☐ Comorbid conditions
☐ Prior HSCT
☐ Protocol driven
☐ Other, specify _____

Drugs ☐ No ☐ Yes ☐ Unknown

(include any active agent be it chemo, monoclonal antibody, polyclonal antibody, serotherapy, etc.)

Specification and dose of the preparative regimen

TOTAL PRESCRIBED CUMULATIVE DOSE*

as per protocol:

DRUG (given before day 0)	DOSE	UNITS		
☐ Ara-C (cytarabine)		☐ mg/m2	☐ mg/kg	
☐ ALG, ATG (ALS/ ATS) Animal origin: ☐ Horse ☐ Rabbit ☐ Other, specify		☐ mg/m2	☐ mg/kg	
☐ Bleomycin		☐ mg/m2	☐ mg/kg	
☐ Busulfan ☐ Oral ☐ IV ☐ Both		☐ mg/m2	☐ mg/kg	☐ mg x hr/L ☐ micromol x min/L ☐ mg x min/mL
☐ BCNU		☐ mg/m2	☐ mg/kg	
☐ Bexxar (radio labelled MoAB)		☐ mCi	☐ MBq	
☐ CCNU		☐ mg/m2	☐ mg/kg	
☐ Campath (AntiCD 52)		☐ mg/m2	☐ mg/kg	
☐ Carboplatin		☐ mg/m2	☐ mg/kg	☐ mg x hr/L ☐ micromol x min/L ☐ mg x min/mL
☐ Cisplatin		☐ mg/m2	☐ mg/kg	
☐ Clofarabine		☐ mg/m2	☐ mg/kg	
☐ Corticosteroids		☐ mg/m2	☐ mg/kg	
☐ Cyclophosphamide		☐ mg/m2	☐ mg/kg	
☐ Daunorubicin		☐ mg/m2	☐ mg/kg	
☐ Doxorubicin (adriamycine)		☐ mg/m2	☐ mg/kg	
☐ Epirubicin		☐ mg/m2	☐ mg/kg	
☐ Etoposide (VP16)		☐ mg/m2	☐ mg/kg	
☐ Fludarabine		☐ mg/m2	☐ mg/kg	
☐ Gemtuzumab		☐ mg/m2	☐ mg/kg	
☐ Idarubicin		☐ mg/m2	☐ mg/kg	
☐ Ifosfamide		☐ mg/m2	☐ mg/kg	
☐ Imatinib mesylate		☐ mg/m2	☐ mg/kg	
☐ Melphalan		☐ mg/m2	☐ mg/kg	
☐ Mitoxantrone		☐ mg/m2	☐ mg/kg	
☐ Paclitaxel		☐ mg/m2	☐ mg/kg	
☐ Rituximab (mabthera, antiCD20)		☐ mg/m2	☐ mg/kg	
☐ Teniposide		☐ mg/m2	☐ mg/kg	
☐ Thiotepa		☐ mg/m2	☐ mg/kg	
☐ Treosulphan		☐ mg/m2	☐ mg/kg	
☐ Zevalin (radiolabelled MoAB)		☐ mCi	☐ MBq	
☐ Other radiolabelled MoAB Specify		☐ mCi	☐ MBq	
☐ Other MoAB, specify		☐ mg/m2	☐ mg/kg	
☐ Other, specify		☐ mg/m2	☐ mg/kg	

**Report the total prescribed cumulative dose as per protocol. Multiply daily dose in mg/kg or mg/m² by the number of days; e.g. for Busulfan given 4mg/kg daily for 4days, total dose to report is 16mg/kg*

**AUC = Area under the curve

CIC: ..... Hospital UPN: ..... Patient UIC ..... HSCT Date: .....
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Total Body Irradiation (TBI) ☐ No ☐ Yes : Total prescribed radiation dose as per protocol ..... Gy

Number of fractions ..... over ..... radiation days

TLI, TNI, TAI ☐ No ☐ Yes : Total prescribed radiation dose as per protocol ..... Gy

(lymphoid, nodal, abdominal)

GvHD prophylaxis or preventive treatment *(Allografts only)*

☐ No ☐ Yes

If Yes: ☐ Drugs (Immunosuppressive chemo)

- ☐ ALG, ALS, ATG, ATS : *(given after day 0)* Animal origin: ☐ Horse ☐ Rabbit ☐ Other, specify .....
- ☐ Anti CD25*(MoAB in vivo)*
- ☐ Campath *(MoAB in vivo; can be "in the bag")*
- ☐ Systemic corticosteroids
- ☐ Cyclosporine
- ☐ Cyclophosphamide *(given after day 0)*
- ☐ Etanercept *(MoAB in vivo)*
- ☐ FK 506 *(Tacrolimus, Prograf)*
- ☐ Infliximab *(MoAB in vivo)*
- ☐ Methotrexate
- ☐ Mycophenolate *(MMF)*
- ☐ Sirolimus
- ☐ Other monoclonal antibody *(in vivo)* , specify .....
- ☐ Other agent (in vivo), specify.....

☐ Extracorporeal photopheresis (ECP)

☐ Other, specify .....

Survival Status

Survival Status on date of HSCT

☐ Alive ☐ Dead

☐ Patient died between administration of the preparative regimen and date of HSCT

Main Cause of Death *(check only one main cause):*

- ☐ Relapse or Progression/Persistent disease
- ☐ HSCT Related Cause
- ☐ Unknown
- ☐ Other .....

Contributory Cause of Death *(check as many as appropriate):*

- ☐ GVHD
- ☐ Interstitial pneumonitis
- ☐ Pulmonary toxicity
- ☐ Infection:
  - ☐ bacterial
  - ☐ viral
  - ☐ fungal
  - ☐ parasitic
  - ☐ Unknown
- ☐ Rejection/Poor graft function
- ☐ History of severe Veno occlusive disorder (VOD)
- ☐ Haemorrhage
- ☐ Cardiac toxicity
- ☐ Central nervous system (CNS) toxicity
- ☐ Gastrointestinal (GI) toxicity
- ☐ Skin toxicity
- ☐ Renal failure
- ☐ Multiple organ failure
- ☐ Other, specify .....