

HSCT - Minimum Essential Data - A

REGISTRATION - DAY 0

Centre Identification

EBMT Code (CIC): Contact person:

Hospital: Unit: Email:

Patient DataDate 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 not 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)

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

 Other diagnosis, specify:

LYMPHOMAS (main disease code 3)**T-Cell Non Hodgkin Lymphomas (NHL)****Disease**Date of Initial Diagnosis:
yyyy - mm - dd

Mature T-cell & NK-cell Neoplasms	
<input type="checkbox"/> T-cell large granular lymphocytic leukaemia	
<input type="checkbox"/> Aggressive NK-cell leukaemia	
<input type="checkbox"/> Systemic EBV positive T-cell lymphoproliferative disease of childhood	
<input type="checkbox"/> Hydroa vacciniforme-like lymphoma	
<input type="checkbox"/> Adult T-cell leukaemia/lymphoma	
<input type="checkbox"/> Extranodal NK/T-cell lymphoma, nasal type	
<input type="checkbox"/> Enteropathy-associated T-cell lymphoma	
<input type="checkbox"/> Hepatosplenic T-cell lymphoma	
<input type="checkbox"/> Subcutaneous panniculitis-like T-cell lymphoma	
<input type="checkbox"/> Mycosis fungoides (MF)	ISCL/EORTC <input type="checkbox"/> I A <input type="checkbox"/> I B <input type="checkbox"/> II A <input type="checkbox"/> II B <input type="checkbox"/> III A <input type="checkbox"/> III B <input type="checkbox"/> IVA1 <input type="checkbox"/> IVA2 <input type="checkbox"/> IVB <input type="checkbox"/> Not evaluated
<input type="checkbox"/> Sézary syndrome	
<input type="checkbox"/> Lymphomatoid papulosis	
<input type="checkbox"/> Primary cutaneous anaplastic large cell lymphoma	
<input type="checkbox"/> Primary cutaneous gamma-delta T-cell lymphoma	
<input type="checkbox"/> Primary cutaneous CD8 positive aggressive epidermotropic cytotoxic T-cell lymphoma	
<input type="checkbox"/> Primary cutaneous CD4 positive small/medium T-cell lymphoma	
<input type="checkbox"/> Peripheral T-cell lymphoma NOS (PTCL)	International Prognostic Index (IPI) <input type="checkbox"/> Low risk (0-1 score points) <input type="checkbox"/> Low-Intermediate risk (2) <input type="checkbox"/> High-intermediate risk (3) <input type="checkbox"/> High risk (4 or 5) <input type="checkbox"/> Not evaluated
<input type="checkbox"/> Angioimmunoblastic T-cell lymphoma	
<input type="checkbox"/> Anaplastic large-cell lymphoma (ALCL), ALK-positive	
<input type="checkbox"/> Anaplastic large-cell lymphoma (ALCL), ALK-negative	
<input type="checkbox"/> Other T-cell, specify: _____	

ALL LYMPHOMAS**Treatment Pre-HSCT****Treatment pre-HSCT***Enter first day of treatment and mark all drugs from that date until conditioning* No Yes Date of treatment.....
yyyy - mm - dd**Drugs given**Antibodies:

- Alemtuzumab (MabCampath) (CD52)
 Brentuximab (Adcetris) (CD30)
 Obinutuzumab (Gyzeva) (CD20)
 Ofatumumab (Azerra) (CD20)
 Rituximab (Mabthera) (CD20)
 other antibody, specify _____

Radioimmunotherapy:

- Bexxar (CD20) (radiolabelled MoAB)
 Zevalin (CD20) (radiolabelled MoAB)

Relapse/progression under this drug**Yes No Unknown**Specific inhibitors:

- ABT-199 (BCL2-Inhibitor)
 Crizotinib (ALK-Inhibitor)
 CC-292 (B cell receptor kinase inhibitor)
 Ibrutinib (B cell receptor kinase inhibitor)
 Idelalisib (B cell receptor kinase inhibitor)
 other inhibitor, specify _____

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Other:

- Bortezomib (Velcade)
 Lenalidomide (Revlimid)
 Other, specify _____

ALL LYMPHOMAS

Status at HSCT

Date of this HSCT: _____
yyyy - mm - dd

Number of prior lines of treatment 1 2 3 or more:___ none Unknown
(since diagnosis if 1st transplant, or since last reported transplant)

Technique used for disease assessment:

CT scan done No Yes
PET Negative Positive Not evaluated

STATUS

- Never treated
- Complete remission (CR)
 - Unconfirmed (CRU*) Confirmed
 - *CRU – complete response with persistent scan abnormalities of unknown significance
- Partial response (PR) – (with or without a prior CR)
- Stable disease
- Untreated relapse (from a previous CR) / untreated progression (from a previous PR)
- Chemorefractory relapse or progression, including primary refractory disease
- Disease status unknown

Was this patient refractory to any line of chemotherapy before this HSCT? No Yes

Number of Complete (CR, CRu) achieved by the patient prior to this HSCT: _____
Count all CR including this one if applicable

Number of Partial remissions (PR) achieved by the patient prior to this HSCT: _____
Count all PR including this one if applicable

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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Inflammatory bowel disease	Crohn's disease or ulcerative colitis	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Rheumatologic	SLE, RA, polymyositis, mixed CTD, or polymyalgia rheumatica	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Infection	Requiring continuation of antimicrobial treatment after day 0	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Diabetes	Requiring treatment with insulin or oral hypoglycaemics but not diet alone	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Renal: moderate/severe	Serum creatinine > 2 mg/dL or >177 µmol/L, on dialysis, or prior renal transplantation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Hepatic: mild	Chronic hepatitis, bilirubin between Upper Limit Normal (ULN) and 1.5 x the ULN, or AST/ALT between ULN and 2.5 x ULN Liver cirrhosis, bilirubin greater than 1.5 x ULN, or AST/ALT greater than 2.5 x ULN	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
moderate/ severe		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Arrhythmia	Atrial fibrillation or flutter, sick sinus syndrome, or ventricular arrhythmias	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cardiac	Coronary artery disease, congestive heart failure, myocardial infarction, EF ≤ 50%, or shortening fraction in children (<28%)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cerebrovascular disease	Transient ischemic attack or cerebrovascular accident	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Heart valve disease	Except mitral valve prolapse	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Pulmonary: moderate	DLco and/or FEV1 66-80% or dyspnoea on slight activity DLco and/or FEV1 ≤ 65% or dyspnoea at rest or requiring oxygen	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
severe		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Obesity	Patients with a body mass index > 35 kg/m ²	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Peptic ulcer	Requiring treatment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Psychiatric disturbance	Depression or anxiety requiring psychiatric consultation or treatment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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

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

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 $\alpha\beta$ 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 $\alpha\beta$ 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 performed 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		
<input type="checkbox"/> Ara-C (cytarabine)		<input type="checkbox"/> mg/m ²	<input type="checkbox"/> mg/kg	
<input type="checkbox"/> ALG, ATG (ALS/ ATS) Animal origin: <input type="checkbox"/> Horse <input type="checkbox"/> Rabbit <input type="checkbox"/> Other, specify		<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 <input type="checkbox"/> Oral <input type="checkbox"/> IV <input type="checkbox"/> Both		<input type="checkbox"/> mg/m ²	<input type="checkbox"/> mg/kg	<input type="checkbox"/> mg x hr/L <input type="checkbox"/> micromol x min/L <input type="checkbox"/> mg x min/mL
<input type="checkbox"/> BCNU		<input type="checkbox"/> mg/m ²	<input type="checkbox"/> mg/kg	
<input type="checkbox"/> Bexxar (radio labelled MoAB)		<input type="checkbox"/> mCi	<input type="checkbox"/> MBq	
<input type="checkbox"/> CCNU		<input type="checkbox"/> mg/m ²	<input type="checkbox"/> mg/kg	
<input type="checkbox"/> Campath (AntiCD 52)		<input type="checkbox"/> mg/m ²	<input type="checkbox"/> mg/kg	
<input type="checkbox"/> Carboplatin		<input type="checkbox"/> mg/m ²	<input type="checkbox"/> mg/kg	<input type="checkbox"/> mg x hr/L <input type="checkbox"/> micromol x min/L <input type="checkbox"/> mg x min/mL
<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	
<input type="checkbox"/> Corticosteroids		<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"/> Daunorubicin		<input type="checkbox"/> mg/m ²	<input type="checkbox"/> mg/kg	
<input type="checkbox"/> Doxorubicin (adriamycine)		<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 (VP16)		<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		<input type="checkbox"/> mg/m ²	<input type="checkbox"/> mg/kg	
<input type="checkbox"/> Idarubicin		<input type="checkbox"/> mg/m ²	<input type="checkbox"/> mg/kg	
<input type="checkbox"/> Ifosfamide		<input type="checkbox"/> mg/m ²	<input type="checkbox"/> mg/kg	
<input type="checkbox"/> Imatinib mesylate		<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"/> Rituximab (mabthera, antiCD20)		<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"/> Treosulphan		<input type="checkbox"/> mg/m ²	<input type="checkbox"/> mg/kg	
<input type="checkbox"/> Zevalin (radiolabelled MoAB)		<input type="checkbox"/> mCi	<input type="checkbox"/> MBq	
<input type="checkbox"/> Other radiolabelled MoAB Specify		<input type="checkbox"/> mCi	<input type="checkbox"/> MBq	
<input type="checkbox"/> Other MoAB, specify		<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	

*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

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 Venous occlusive disorder (VOD)
- Haemorrhage
- Cardiac toxicity
- Central nervous system (CNS) toxicity
- Gastrointestinal (GI) toxicity
- Skin toxicity
- Renal failure
- Multiple organ failure
- Other, specify