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: _____

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

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

		Relapse/progression under this drug		
		Yes	**No**	**Unknown**
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)			
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_____	☐	☐	☐
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 <u>all</u> CR including this one if applicable

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

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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.....

Type of HSCT (Autologous)

☐ **Autologous**

Source of the Stem cells *(check all that apply):*
☐ Bone marrow ☐ Peripheral blood
☐ Cord blood ☐ Other: ----------

Graft manipulation ex-vivo
other than for RBC removal or volume reduction

☐ No ☐ Yes: Genetic manipulation of the graft: ☐ No ☐ Yes:

⇨ **IF AUTOLOGOUS, CONTINUE TO "CHRONOLOGICAL NUMBER OF HSCT"**

CIC: _____ Hospital UPN: _____ Patient UIC _____ HSCT Date: _____
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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, 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

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

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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)

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 .....