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)**
Precursor lymphoid neoplasms (old ALL) (1 of 3)

Disease

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

Classification:

B lymphoblastic leukaemia/lymphoma (old Precursor B-cell ALL)

- ☐ with t(9;22)(q34;q11.2); BCR-ABL1
- ☐ with t(v;11q23); MLL rearranged
- ☐ with t(1;19)(q23;p13.3); E2A-PBX1
- ☐ with t(12;21)(p13;q22); TEL-AML1 (ETV-RUNX1)
- ☐ with hyperdiploidy
- ☐ with hypodiploidy
- ☐ with t(5;14)(q31;q32); IL3-IGH
- ☐ Not otherwise specified (NOS)
- ☐ Other._____

☐ T lymphoblastic leukaemia/lymphoma (old Precursor T-cell ALL)

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

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ACUTE LEUKAEMIAS **(main disease code 1)**
Precursor lymphoid neoplasms (old ALL) 2 of 3

Chromosome Analysis at Diagnosis

Chromosome analysis at diagnosis (All methods including FISH)

☐ Not done or failed ☐ Done: Normal ☐ Done: Abnormal ☐ Unknown

If abnormal:

Complex kariotype: *(3 or more abnormalities)* ☐ No ☐ Yes ☐ Unknown

You can transcribe the complete karyotype: _____

OR

Indicate below those abnormalities that have been **evaluated** and whether they were **Absent** or **Present**

t(9;22)	☐ Absent	☐ Present	☐ Not evaluated
11q23 abnormalities *Fill only if 11q23 abnormalities is Present:*	☐ Absent	☐ Present	☐ Not evaluated
t(4;11)	☐ Absent	☐ Present	☐ Not evaluated
Other abn(11q23); please specify: _ _ _ _ _	☐ Absent	☐ Present	☐ Not evaluated
t(12;21)	☐ Absent	☐ Present	☐ Not evaluated
Hyperdiploidy (>46 chromosomes) *Fill only if hyperdiploidy is Present:*	☐ Absent	☐ Present	☐ Not evaluated
50 – 66 chromosomes	☐ Absent	☐ Present	☐ Not evaluated
Trisomy: Specify extra chromosome: _ _ _ _ _	☐ Absent	☐ Present	☐ Not evaluated
Other hyperdiploid karyotype ..... number of chromosomes .....:	☐ Absent	☐ Present	☐ Not evaluated
Hypodiploidy (<46 chromosomes): *specify the number of missing chromosomes:*	☐ Absent	☐ Present	☐ Not evaluated
Low hypodiploid, 32-39 chromosomes	☐ Absent	☐ Present	☐ Not evaluated
Near haploid, 24-31 chromosomes	☐ Absent	☐ Present	☐ Not evaluated
Monosomy. Specify: _ _ _ _ _	☐ Absent	☐ Present	☐ Not evaluated
Other. number of chromosomes _____	☐ Absent	☐ Present	☐ Not evaluated
t(5;14)(q31;q32)	☐ Absent	☐ Present	☐ Not evaluated
t(1;19)	☐ Absent	☐ Present	☐ Not evaluated
trisomy 8	☐ Absent	☐ Present	☐ Not evaluated
Other, specify	☐ Absent	☐ Present	☐ Not evaluated

Molecular Markers at Diagnosis

Marker analysis

☐ Not evaluated ☐ Evaluated: Absent ☐ Evaluated: Present ☐ Unknown

Indicate below those markers that have been **evaluated** and whether they were **Absent** or **Present**

BCR-ABL molecular product of t(9;22)(q34;q11.2)	☐ Absent	☐ Present	☐ Not evaluated
MLL-rearrangement/mutation:	☐ Absent	☐ Present	☐ Not evaluated
Fill only if MLL-rearrangement/mutation is Present:			
AFF1(AF4)-MLL molecular product of t(4;11)(q21;q23)	☐ Absent	☐ Present	☐ Not evaluated
MLLT1(ENL)-MLL molecular product of t(11;19)(q23;p13.3)	☐ Absent	☐ Present	☐ Not evaluated
MLLT3(AF9)-MLL molecular product of t(9;11)(p22;q23)	☐ Absent	☐ Present	☐ Not evaluated
Other MLL-rearrangement, specify: ……	☐ Absent	☐ Present	☐ Not evaluated
TEL(ETV6)-AML1(RUNX1) molecular product of t(12;21)(p13;q22)	☐ Absent	☐ Present	☐ Not evaluated
IL3-IGH molecular product of translocation t(5;14)(q31;q32)	☐ Absent	☐ Present	☐ Not evaluated
TCF3-PBX1 Molecular product of translocation (1;19)(q23 ;p13.3)	☐ Absent	☐ Present	☐ Not evaluated
IKZF1 (IKAROS)	☐ Absent	☐ Present	☐ Not evaluated
NOTCH1 & FBXW7	☐ Absent	☐ Present	☐ Not evaluated
Other, specify……	☐ Absent	☐ Present	☐ Not evaluated

ACUTE LEUKAEMIAS **(main disease code 1)**
Precursor lymphoid neoplasms (old ALL) 3 of 3

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*

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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 .....