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: _____

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

ACUTE LEUKAEMIAS (main disease code 1)
Acute Myeloid leukaemia (AML) (1 of 4)

Disease

Date of Initial Diagnosis: _____
yyyy - mm - dd

Classification:

AML with recurrent genetic abnormalities

- ☐ AML with t(8;21)(q22;q22); RUNX1-RUNX1T1
- ☐ AML with inv(16)(p13.1;q22) or t(16;16)(p13.1;q22); CBFB-MYH11
- ☐ Acute promyelocytic leukaemia with t(15;17)(q22;q12); PML/RARA
- ☐ AML with t(9;11) (p22;q23); MLLT3-MLL
- ☐ AML with t(6;9) (p23;q24); DEK-NUP214
- ☐ AML with inv(3) (q21;q26.2) or t(3;3) (q21;q26.2); RPN1-EVI1
- ☐ AML (megakaryoblastic) with t(1;22) (p13;q13); RBM15-MKL1
- ☐ AML with 11q23 (MLL) abnormalities
- ☐ AML with BCR-ABL1
- ☐ AML with mutated NPM1
- ☐ AML with biallelic mutation of CEBPA
- ☐ AML with mutated RUNX1
- ☐ AML with myelodysplasia related changes *(old "Acute leukaemia transformed from MDS or MDS/MPN"):*

Was there a previous diagnosis of MDS or MDS/MPN?

- ☐ No → *Continue to Predisposing condition below*
- ☐ Yes → *Fill in the* MYELODYPLASTIC SYNDROME (MDS) or MDS/MPN *until status at HSCT, then continue with Predisposing Condition below*

AML not otherwise categorised (NOS)

- ☐ AML with minimal differentiation (FAB M0)
- ☐ AML without maturation (FAB M1)
- ☐ AML with maturation (FAB M2)
- ☐ Acute myelomonocytic leukaemia (FAB M4)
- ☐ Acute monoblastic and monocytic leukaemia (FAB M5)
- ☐ Acute erythroid leukaemia (FAB M6)
- ☐ Acute megakaryoblastic leukaemia (FAB M7)
- ☐ Acute basophilic leukaemia
- ☐ Acute panmyelosis with myelofibrosis
- ☐ Myeloid sarcoma (Granulocytic sarcoma)
- ☐ Myeloid proliferations related to Down syndrome
- ☐ Blastic plasmacytoid dendritic cell neoplasm (BPDCN)
- ☐ Therapy related myeloid neoplasia (old "Secondary Acute Leukaemia")
  Related to prior treatment but NOT after a previous diagnosis of MDS or MDS/MPN.

Predisposing Condition?

Skip this question if the AML is a Therapy related neoplasia

Did the recipient have a predisposing condition prior to the diagnosis of leukaemia?

- ☐ No
- ☐ Yes:
  - ☐ Aplastic anaemia
  - ☐ Fanconi anaemia
  - ☐ Bloom syndrome
  - ☐ Unknown

Donor Cell Leukaemia?

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

ACUTE LEUKAEMIAS (main disease code 1)
Acute Myeloid leukaemia (AML) (2 of 4)

Chromosome Analysis at Diagnosis

Chromosome analysis at diagnosis (All methods including FISH)

☐ Done: normal ☐ Done: abnormal ☐ Not done or failed ☐ Unknown

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

Monosomal karyotype: ☐ No ☐ Yes ☐ Unknown
(>= 2 autosomal monosomies or 1 autosomal monosomy + at least 1 structural abnormality)

You can transcribe the complete karyotype: -

OR

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

t(15;17)	☐ Absent ☐ Present ☐ Not evaluated
t(8;21)	☐ Absent ☐ Present ☐ Not evaluated
inv(16)/ t(16;16)	☐ Absent ☐ Present ☐ Not evaluated
11q23 abnormality type	☐ Absent ☐ Present ☐ Not evaluated
Fill only if 11q23 abnormality is Present:	
t(9;11)	☐ Absent ☐ Present ☐ Not evaluated
t(11;19)	☐ Absent ☐ Present ☐ Not evaluated
t(10;11)	☐ Absent ☐ Present ☐ Not evaluated
t(6;11)	☐ Absent ☐ Present ☐ Not evaluated
Other abn(11q23), specify: _ _ _ _ _	
3q26 (EVI1) abnormality type	☐ Absent ☐ Present ☐ Not evaluated
Fill only if 3q26 (EVI1) abnormality is Present:	
inv(3)/ t(3;3)	☐ Absent ☐ Present ☐ Not evaluated
t(2 ;3)(p21 ;q26)	☐ Absent ☐ Present ☐ Not evaluated
Other t(3q26)/EVI1 rearrangement, specify: _ _ _ _ _	☐ Absent ☐ Present ☐ Not evaluated
t(6;9)	☐ Absent ☐ Present ☐ Not evaluated
abn 5 type	☐ Absent ☐ Present ☐ Not evaluated
Fill only if above abn 5 is Present:	
del (5q)	☐ Absent ☐ Present ☐ Not evaluated
monosomy 5	☐ Absent ☐ Present ☐ Not evaluated
add(5q)	☐ Absent ☐ Present ☐ Not evaluated
Other abn(5q); please specify: _ _ _ _ _	☐ Absent ☐ Present ☐ Not evaluated
abn 7 type	☐ Absent ☐ Present ☐ Not evaluated
Fill only if abn 7 is Present:	
del(7q)	☐ Absent ☐ Present ☐ Not evaluated
monosomy 7	☐ Absent ☐ Present ☐ Not evaluated
add(7q)	☐ Absent ☐ Present ☐ Not evaluated
Other abn(7q); please specify: _ _ _ _ _	☐ Absent ☐ Present ☐ Not evaluated
-17	☐ Absent ☐ Present ☐ Not evaluated
abn(17p)	☐ Absent ☐ Present ☐ Not evaluated
t(1;22)	☐ Absent ☐ Present ☐ Not evaluated
trisomy 8	☐ Absent ☐ Present ☐ Not evaluated
Other, specify……………………………………………	☐ Absent ☐ Present

ACUTE LEUKAEMIAS **(main disease code 1)**
Primary Acute Myeloid leukaemia (AML) (3 of 4)

Molecular Markers at Diagnosis

Molecular marker analysis at diagnosis

☐ Not evaluated ☐ Evaluated: absent ☐ Evaluated present ☐ Unknown

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

AML1-ETO (RUNX1/RUNXT1) *Molecular product of t(8;21)*	☐ Absent ☐ Present ☐ Not evaluated
CBFB-MYH11 *Molecular product of inv(16)(p13.1;q22) or (16;16)(p13.1;q22)*	☐ Absent ☐ Present ☐ Not evaluated
PML-RARα *Molecular product of t(15;17)*	☐ Absent ☐ Present ☐ Not evaluated

MLL-rearrangement/mutation: *Fill only if 11q23 abnormality is Present:*	☐ Evaluated at least once	☐ Not evaluated
MLLT3(AF9)-MLL *molecular product of t(9;11)(p22;q23)*	☐ Absent ☐ Present ☐ Not evaluated	
MLL-PTD (partial tandem duplication)	☐ Absent ☐ Present ☐ Not evaluated	
MLLT4(AF6)-MLL *molecular product of t(6;11)(q27;q23)*	☐ Absent ☐ Present ☐ Not evaluated	
ELL-MLL: *molecular product of t(11;19)(q23;p13.1)*	☐ Absent ☐ Present ☐ Not evaluated	
MLLT1(ENL)-MLL: *molecular product of t(11;19)(q23;p13.3)*	☐ Absent ☐ Present ☐ Not evaluated	
MLLT10(AF10)-MLL: *molecular product of t(10;11)(p12;q23)*	☐ Absent ☐ Present ☐ Not evaluated	
Other MLL-rearrangement, specify: _ _ _ _ __ _ _ _ __ ____ _ _ __	☐ Absent ☐ Present ☐ Not evaluated	

DEK-NUP214(CAN) *molecular product of translocation t(6;9)(p23;q34)*	☐ Absent ☐ Present ☐ Not evaluated
RPN1-EVI1 *molecular product of inv(3)(q21q26.2) or t(3;3)(q21q26.2)*	☐ Absent ☐ Present ☐ Not evaluated
RBM15-MKL1 *molecular product of translocation t(1;22)(p13;q13)*	☐ Absent ☐ Present ☐ Not evaluated
NPM1 mutation	☐ Absent ☐ Present ☐ Not evaluated
CEBPA mutation	☐ Absent ☐ Present ☐ Not evaluated
FLT3-ITD (internal tandem duplication)	☐ Absent ☐ Present ☐ Not evaluated
DNMT3A	☐ Absent ☐ Present ☐ Not evaluated
ASXL1	☐ Absent ☐ Present ☐ Not evaluated
TP53	☐ Absent ☐ Present ☐ Not evaluated
RUNX1	☐ Absent ☐ Present ☐ Not evaluated
c-KIT	☐ Absent ☐ Present ☐ Not evaluated
Other, specify _ _ _ _ __ _ _ _ __ _ _ _ __ _ _ _ _	☐ Absent ☐ Present ☐ Not evaluated

Involvement at Diagnosis

Involvement at diagnosis

Bone marrow	☐ No	☐ Yes	☐ Not evaluated
CNS	☐ No	☐ Yes	☐ Not evaluated
Testis/ovary	☐ No	☐ Yes	☐ Not evaluated
Other	☐ No	☐ Yes, specify	

ACUTE LEUKAEMIAS**(main disease code 1)**
Primary Acute Myeloid leukaemia (AML) (4 of 4)

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	**CYTOGENETICS 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*

Date of last relapse before this HSCT: ----------
(If applicable) *yyyy - mm - dd*

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.....

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: _____
yyyy - mm - dd

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 .....