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

DAY 0

MED-B GENERAL INFORMATION

TEAM

EBMT Centre Identification Code (CIC) ....

Hospital ..... Unit .....

Contact person: .....

e-mail .....

Date of this report .... - .... - ....
yyyy mm dd

STUDY/TRIAL

Patient following national / international study / trial: ☐ No ☐ Yes ☐ Unknown

Name of study / trial .....

PATIENT

Unique Identification Code (UIC) .... *(to be entered only if patient previously reported)*

Hospital Unique <u>Patient</u> 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) – surname(s))

Date of birth .... - .... - ....
yyyy mm dd

Sex: ☐ Male ☐ Female
(at birth)

ABO Group .... Rh factor: ☐ Absent ☐ Present ☐ Not evaluated

DISEASE

Date of 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 (JIA)
  - ☐ Multiple Sclerosis
  - ☐ Systemic Lupus
  - ☐ Systemic Sclerosis
- ☐ Haemoglobinopathy

☐ Other diagnosis, specify:_____

DAY 0

MED-B
ACUTE LEUKAEMIA

INITIAL DIAGNOSIS

Has the information requested in this section been submitted with a previous HSCT registration for this patient?

- ☐ Yes: go to page 11, *Type of HSCT*
- ☐ No: proceed with this section

DIAGNOSIS

- ☐ **Acute Myelogenous Leukaemia (AML)** → ***Go to AML section, page 3***
  (non-lymphoblastic)
- ☐ **Precursor lymphoid neoplasm (old ALL)** → ***Go to PLN section, page 7***
- ☐ **Other acute leukaemias** → ***Go to the other leukaemia section, page 10***

ACUTE LEUKAEMIAS
Acute Myeloid Leukaemia (AML)

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 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* ***MDS Med-B form*** *or the* ***MDS/MPN Med-B form*** *until Status at HSCT, then continue with* ***Predisposing Condition*** *below*

- ☐ AML with 11q23 (MLL) abnormalities
- ☐ AML with BCR-ABL1
- ☐ AML with mutated NPM1
- ☐ AML with biallelic mutation of CEBPA
- ☐ AML with mutated RUNX1

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

- ☐ 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 MPN

  → ***After registering this primary disease classification in AML, please fill in the MDS Med-B form.***
  (If you use Promise it will switch forms automatically during data entry).

PREDISPOSING CONDITION?

Did the recipient have a predisposing condition prior to the diagnosis of leukaemia? ☐ No ☐ Yes:

- ☐ Aplastic anaemia
- ☐ Bloom syndrome
- ☐ Fanconi anaemia
- ☐ 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 MYELOID LEUKAEMIA (AML)

Chromosome analysis at diagnosis (All methods including FISH)

☐ Normal: number of metaphases examined: .....

☐ Abnormal:

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

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

number of metaphases with abnormalities: ..... / number of metaphases examined: .....

☐ Not done or failed ☐ Unknown

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 *Fill only if* 11q23 abnormality *is Present:*	☐ Absent	☐ Present	☐ Not evaluated
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: _ _ _ _ _	☐ Absent	☐ Present	☐ Not evaluated
3q26 (EVI1) abnormality type	☐ Absent	☐ Present	☐ Not evaluated
inv(3) / t(3;3)	☐ Absent	☐ Present	☐ Not evaluated
t(2;3)(p21;q26)	☐ Absent	☐ Present	☐ Not evaluated
Other (3q26)/EVI1 rearrangement, specify: _ _ _ _ _	☐ Absent	☐ Present	☐ Not evaluated
t(6;9)	☐ Absent	☐ Present	☐ Not evaluated
abn 5 type *Fill only if above* abn 5 *is Present:*	☐ Absent	☐ Present	☐ Not evaluated
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 *Fill only if* abn 7 *is Present:*	☐ Absent	☐ Present	☐ Not evaluated
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 MYELOID LEUKAEMIA (AML)

Molecular Markers at Diagnosis

Molecular marker analysis at diagnosis

☐ Not evaluated ☐ Absent ☐ Present ☐ Unknown

Indicate below those **markers** 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:*	☐ Absent	☐ Present	☐ 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: …… MOLOTHER	☐ 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…… MOLOTHER	☐ Absent	☐ Present	☐ Not evaluated

ACUTE MYELOID LEUKAEMIA (AML)

White blood cell count at diagnosis (10^9/l): .... - .... ☐ Not available / unknown

Involvement at Diagnosis

Involvement at diagnosis

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

ACUTE LEUKAEMIAS
Precursor lymphoid neoplasms (old ALL)

Disease

Date of Initial Diagnosis ……..... - ..... - .....
yyyy *mm* *dd*

Classification:

☐ B lymphoblastic leukaemia/lymphoma *(old Precursor B-cell ALL)*
- ☐ Not otherwise specified (NOS)
- ☐ 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*

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

☐ Other Precursor lymphoid neoplasm: .....

Secondary Origin?

Secondary origin

Related to prior exposure to therapeutic drugs or radiation ☐ No ☐ Yes ☐ Unknown

IF THE PATIENT HAS RECEIVED AN ALLOGRAFT OR OTHER ALLOGENEIC CELL PRODUCT PRIOR TO THE DIAGNOSIS OF ACUTE LEUKAEMIA, ANSWER THE FOLLOWING QUESTION

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

PRECURSOR LYMPHOID NEOPLASMS (previously ALL)

Chromosome Analysis at Diagnosis

Chromosome analysis at diagnosis (All methods including FISH)

☐ Normal ☐ Abnormal ☐ Not done or failed ☐ Unknown

If abnormal:

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

You can transcribe the complete karyotype: .....

OR

Indicate below which abnormalities 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: _ _ _ _ _ CHRMABND	☐ 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 number of 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 number of chromosomes	☐ Absent	☐ Present	☐ Not evaluated
Near haploid, 24-31 chromosomes number of chromosomes	☐ Absent	☐ Present	☐ Not evaluated
Monosomy. Specify:	☐ Absent	☐ Present	☐ Not evaluated
Other. number of chromosomes ..... NRCHROMS	☐ 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…… CHRMABND	☐ Absent	☐ Present	☐ Not evaluated

PRECURSOR LYMPHOID NEOPLASMS (previously ALL)

Molecular Markers at Diagnosis

Marker analysis
☐ Not evaluated ☐ Absent ☐ 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

White blood cell count at diagnosis (10^9/l): .... - .... ☐ Not available / unknown

TREATMENT PRE-HSCT

FIRST LINE THERAPY GIVEN

☐ No
☐ Yes: Date started: .... - .... - ....
yyyy *mm* *dd*

Tyrosine kinase receptor antagonist given

☐ No
Yes: ☐ Imatinib
☐ Dasatinib
☐ Other, specify .....

Date started: .... - .... - ....
yyyy *mm* *dd*

Date ended .... - .... - ....
(Enter last date given including today if ongoing) *yyyy* *mm* *dd*

☐ Tick here if ongoing

OTHER ACUTE LEUKAEMIAS

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

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

Chromosome Analysis at Diagnosis

☐ Normal ☐ Abnormal ☐ Not done or failed ☐ Unknown

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

You can transcribe the complete karyotype: .....……

OR

Write below the abnormalities of interest, whether they have been **evaluated** and whether they were **Absent** or **Present**

specify……	☐ Absent	☐ Present	☐ Not evaluated
specify……	☐ Absent	☐ Present	☐ Not evaluated
specify…… CHRMABND	☐ Absent	☐ Present	☐ Not evaluated

Molecular Markers at Diagnosis

Marker analysis

☐ Not evaluated ☐ Absent ☐ Present ☐ Unknown

Write below markers of interest, whether they have been **evaluated** and whether they were **Absent** or **Present**

specify……	☐ Absent	☐ Present	☐ Not evaluated
specify……	☐ Absent	☐ Present	☐ Not evaluated
specify…… CHRMABND	☐ Absent	☐ Present	☐ Not evaluated

White blood cell count at diagnosis (10^9/l): .... - .... ☐ Not available / unknown

ALL ACUTE LEUKAEMIAS

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

DISEASE HISTORY BEFORE 1ST HSCT

FILL IN THIS SECTION ONLY IF THIS IS THE FIRST HSCT FOR THIS DISEASE FOR THIS PATIENT. OTHERWISE, SKIP THIS SECTION AND GO TO TYPE OF HSCT

FIRST REMISSION SINCE DIAGNOSIS AND BEFORE THE 1ST HSCT
FILL IN FOR ALL ACUTE LEUKAEMIAS

Achieved: ☐ No

☐ Yes: Date of first remission: .... - .... - ....
yyyy *mm* *dd*

Number of induction course(s) necessary to reach this first remission: .....

FIRST RELAPSE SINCE DIAGNOSIS AND BEFORE THE 1ST HSCT
FILL IN ONLY IF PATIENT HAD A CR PRIOR TO THIS HSCT

Relapsed: ☐ No

☐ Yes: Date of first relapse: .... - .... - ....
yyyy *mm* *dd*

Site of relapse:

Bone marrow	☐ No	☐ Yes	☐ Not evaluated
CNS	☐ No	☐ Yes	☐ Not evaluated
Testis/ovary	☐ No	☐ Yes	☐ Not evaluated
Chloroma *(AML only)*	☐ No	☐ Yes	☐ Not evaluated
Other	☐ No	☐ Yes:	

TYPE OF HSCT

HSCT TYPE ☐ Allogeneic
☐ Autograft:

STATUS AT MOBILISATION (AUTOGRAFTS ONLY)

DATE OF COLLECTION: .... - .... - ....
yyyy *mm* *dd*

TREATMENT

Number of chemotherapy course(s) from last CR to stem cell collection: .....
(fill in only if patient had a CR prior to this HSCT)

Number of chemotherapy course(s) from collection to HSCT: .....

HAEMATOLOGICAL STATUS (CONSIDERING NUMBER OF BLASTS IN BONE MARROW)

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*

STATUS AT HSCT

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*

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

FORMS TO BE FILLED IN

TYPE OF TRANSPLANT

☐ AUTOgraft, **proceed to Autograft day 0 form**

☐ ALLOgraft, **proceed to Allograft day 0 form**

CIC: ..... Hospital UPN: ..... HSCT Date..... .... - ..... - .....
yyyy *mm* *dd*

DAY 100

MED-B
ACUTE LEUKAEMIA

Unique Identification Code (UIC) .... - .... - ..... *(if known)*

Date of this report .... - .... - ....
yyyy *mm* *dd*

Hospital Unique Patient Number .....

Initials: ....._..... (first name(s)_surname(s))

Date of birth .... - .... - ....
yyyy *mm* *dd*

Date of last HSCT for this patient: .... - .... - ....
yyyy *mm* *dd*

Sex: ☐ Male ☐ Female
(at birth)

Date of the most recent transplant before this follow up: ..... - ..... - .....
yyyy *mm* *dd*

BEST DISEASE RESPONSE AT 100 DAYS POST-HSCT

BEST RESPONSE AT 100 DAYS AFTER HSCT

☐ CR (maintained or achieved) If complete response: date of CR .... - .... - ....
yyyy *mm* *dd*

☐ Relapse / progression ☐ Not evaluable

☐ Death ☐ Unknown

FORMS TO BE FILLED IN

TYPE OF TRANSPLANT

☐ AUTOgraft, **proceed to Autograft day 100 form**

☐ ALLOgraft or Syngeneic graft, **proceed to Allograft day 100 form**

CIC: ..... Hospital UPN: ..... HSCT Date..... .... - ..... - .....
yyyy *mm* *dd*

FOLLOW UP | MED-B ACUTE LEUKAEMIA

Unique Identification Code (UIC) .... - .... - ..... *(if known)*

Date of this report .... - .... - ....
yyyy *mm* *dd*

Patient following national / international study / trial: ☐ No ☐ Yes ☐ Unknown

Name of study / trial .....

Hospital Unique Patient Number .....

Initials: ....._..... (first name(s)_surname(s))

Date of birth ..... - .... - ....
yyyy *mm* *dd*

Sex: ☐ Male ☐ Female
(at birth)

Date of the most recent transplant before this follow up: ..... - ..... - .....
yyyy *mm* *dd*

DATE OF LAST CONTACT

DATE OF LAST CONTACT OR DEATH: .... - .... - ....
yyyy *mm* *dd*

Complications after Transplant (Allografts)

ANSWER IF PATIENT HAS HAD AN ALLOGRAFT AT ANY TIME

ACUTE GRAFT VERSUS HOST DISEASE (AGVHD)

Maximum grade ☐ grade 0 *(Absent)* ☐ grade I ☐ grade II ☐ grade III ☐ grade IV ☐ Not evaluated

If present: ☐ New onset ☐ Recurrent ☐ Persistent

Reason: ☐ Tapering ☐ DLI ☐ Unexplained

Date onset of this episode: ....- .... - .... ☐ Not applicable
(if new or recurrent) *yyyy* *mm* *dd*

Stage:

Skin	☐ 0 (none)	☐ I	☐ II	☐ III	☐ IV
Liver	☐ 0 (none)	☐ I	☐ II	☐ III	☐ IV
Lower GI tract	☐ 0 (none)	☐ I	☐ II	☐ III	☐ IV
Upper GI tract	☐ 0 (none)	☐ I			
Other site affected	☐ No	☐ Yes			

Resolution

☐ No ☐ Yes: Date of resolution: ....- .... - ....
yyyy *mm* *dd*

ANSWER IF PATIENT HAS HAD AN ALLOGRAFT AT ANY TIME

CHRONIC GRAFT VERSUS HOST DISEASE (CGVHD)

Presence of cGvHD

☐ No

☐ Yes: ☐ First episode since last HSCT
☐ Recurrence

Date of onset .... - .... - ....
yyyy mm dd

☐ Continuous since last reported episode

Maximum extent during this period
☐ Limited ☐ Extensive ☐ Unknown

Maximum NIH score during this period
☐ Mild ☐ Moderate ☐ Severe ☐ Not evaluated

Organs affected ☐ Skin ☐ Gut ☐ Liver ☐ Mouth
☐ Eyes ☐ Lung ☐ Other, specify ..... ☐ Unknown

☐ Resolved: Date of resolution: .... - .... - ....
yyyy mm dd

OTHER COMPLICATIONS SINCE LAST REPORT

PLEASE USE THE DOCUMENT "DEFINITIONS OF INFECTIOUS DISEASES AND COMPLICATIONS AFTER STEM CELL TRANSPLANTATION" TO FILL THESE ITEMS.

INFECTION RELATED COMPLICATIONS

☐ No complications
☐ Yes

Type	Pathogen *Use the list of pathogens listed after this table for guidance. Use "**unknown**" if necessary.*	Date *Provide different dates for different episodes of the same complication if applicable.*
Bacteremia / fungemia / viremia / parasites		
SYSTEMIC SYMPTOMS OF INFECTION		
Septic shock		
ARDS		
Multiorgan failure due to infection		
ENDORGAN DISEASES		
Pneumonia		

Type	**Pathogen** *Use the list of pathogens listed after this table for guidance. Use "**unknown**" if necessary.*	**Date** *Provide different dates for different episodes of the same complication if applicable.*
Hepatitis		
CNS infection		
Gut infection		
Skin infection		
Cystitis		
Retinitis		
Other:		
		yyyy *mm* *dd*

DOCUMENTED PATHOGENS *(Use this table for guidance on the pathogens of interest)*

Type	**Pathogen**	**Type**	**Pathogen**
Bacteria		Viruses	
	S. pneumoniae		HSV
	Other gram positive *(i.e.: other streptococci, staphylococci, listeria …)*		VZV
			EBV
	Haemophilus influenzae		CMV
	Other gram negative *(i.e.: E. coli klebsiella, proteus, serratia, pseudomonas …)*		HHV-6
			RSV
	Legionella sp		Other respiratory virus *(influenza, parainfluenza, rhinovirus)*
	Mycobacteria sp		
	Other:		Adenovirus
Fungi			HBV
	Candida sp		HCV
	Aspergillus sp		HIV
	Pneumocystis carinii		Papovavirus
	Other:		Parvovirus
Parasites			Other: .....
	Toxoplasma gondii		
	Other:		

NON INFECTION RELATED COMPLICATIONS

☐ No complications
☐ Yes

Type *(Check all that are applicable for this period)*	**Yes**	**No**	**Unknown**	**Date**
Idiopathic pneumonia syndrome	☐	☐	☐	
VOD	☐	☐	☐	
Cataract	☐	☐	☐	
Haemorrhagic cystitis, non infectious	☐	☐	☐	
ARDS, non infectious	☐	☐	☐	
Multiorgan failure, non infectious	☐	☐	☐	
HSCT-associated microangiopathy	☐	☐	☐	
Renal failure requiring dialysis	☐	☐	☐	
Haemolytic anaemia due to blood group	☐	☐	☐	
Aseptic bone necrosis	☐	☐	☐	
Other: ..... VOTCOMPS	☐			

yyyy *mm* *dd*

ANSWER IF PATIENT HAS HAD AN ALLOGRAFT AT ANY TIME

GRAFT ASSESSMENT AND HAEMOPOIETIC CHIMAERISM

Graft loss

☐ No ☐ Yes ☐ Not evaluated

Overall chimaerism

☐ Full *(donor ≥95 %)*
☐ Patient reconstitution *(recipient ≥95 %)*
☐ Not informative
☐ Mixed *(partial)*
☐ Aplasia
☐ Not evaluated

INDICATE THE DATE(S) AND RESULTS OF ALL TESTS DONE FOR ALL DONORS.

SPLIT THE RESULTS BY DONOR AND BY THE CELL TYPE ON WHICH THE TEST WAS PERFORMED IF APPLICABLE.

COPY THIS TABLE AS MANY TIMES AS NECESSARY.

Date of test	Identification of donor or Cord Blood Unit given by the centre	Number in the infusion order *(if applicable)*	Cell type on which test was performed	% Donor cells	Test used
.... - ..... - .... *yyyy mm dd*	.....	..... ☐ N/A	☐ BM ☐ PB mononuclear cells (PBMC) ☐ T-cell ☐ B-cells ☐ Red blood cells ☐ Monocytes ☐ PMNs (neutrophils) ☐ Lymphocytes, NOS ☐ Myeloid cells, NOS ☐ Other, specify:	..... % ..... …% ..... % ..... % ..... …% ..... % ..... % ..... …% ..... % ..... %	☐ FISH ☐ Molecular ☐ Cytogenetic ☐ ABO group ☐ Other: ..... ☐ unknown
.... - ..... - .... *yyyy mm dd*	....	..... ☐ N/A	☐ BM ☐ PB mononuclear cells (PBMC) ☐ T-cell ☐ B-cells ☐ Red blood cells ☐ Monocytes ☐ PMNs (neutrophils) ☐ Lymphocytes, NOS ☐ Myeloid cells, NOS ☐ Other, specify:	..... % ..... …% ..... % ..... % ..... …% ..... % ..... % ..... …% ..... % ..... %	☐ FISH ☐ Molecular ☐ Cytogenetic ☐ ABO group ☐ Other: ..... ☐ unknown
.... - ..... - .... *yyyy mm dd*	....	..... ☐ N/A	☐ BM ☐ PB mononuclear cells (PBMC) ☐ T-cell ☐ B-cells ☐ Red blood cells ☐ Monocytes ☐ PMNs (neutrophils) ☐ Lymphocytes, NOS ☐ Myeloid cells, NOS ☐ Other, specify:	..... % ..... …% ..... % ..... % ..... …% ..... % ..... % ..... …% ..... % ..... %	☐ FISH ☐ Molecular ☐ Cytogenetic ☐ ABO group ☐ Other: ..... ☐ unknown

SECONDARY MALIGNANCY, LYMPHOPROLIFERATIVE OR MYELOPROLIFRATIVE DISORDER DIAGNOSED

☐ No at date of this follow-up

☐ Yes, date of diagnosis: .... - .... - ....
yyyy *mm* *dd*

Diagnosis: ☐ AML ☐ MDS ☐ Lymphoproliferative disorder ☐ Other .....

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

Is this secondary malignancy a donor cell leukaemia**?** ☐ No ☐ Yes ☐ Not applicable

☐ No

ADDITIONAL TREATMENT SINCE LAST FOLLOW UP INCLUDING CELL THERAPY

Was any additional treatment given for the disease indication for transplant

☐ No

☐ Yes: Start date of the additional treatment since last report: ....
yyyy *mm* *dd*

☐ Unknown

-Cell therapy

Did the disease treatment include additional cell infusions *(**excluding a new HSCT**)*

☐ No

☐ Yes: Is this cell infusion an allogeneic boost? ☐ No ☐ Yes
An allo boost is an infusion of cells from the same donor without conditioning,with no evidence of graft rejection.

Is this cell infusion an autologous boost? ☐ No ☐ Yes

⇨ **If cell infusion is <u>not</u> a boost, please complete CELLULAR THERAPY on the following page**

CELLULAR THERAPY

One cell therapy regimen is defined as any number of infusions given within 10 weeks for the same indication. If more than one regimen of cell therapy has been given since last report, copy this section and complete it as many times as necessary.

Date of first infusion: ....
yyyy *mm* *dd*

Disease status before this cellular therapy ☐ CR ☐ Not in CR ☐ Not evaluated ☐ Unknown

Source of cells: ☐ Allo ☐ Auto
(check all that apply)

Type of cells *(check all that apply)*

☐ Donor lymphocyte infusion (DLI)

☐ Mesenchymal cells

☐ Fibroblasts

☐ Dendritic cells

☐ NK cells

☐ Regulatory T-cells

☐ Gamma/delta cells

☐ Other .....

☐ Unknown

Number of cells infused by type	
Nucleated cells (/kg*) *(DLI only)*	.... - .... x 10^8 ☐ Not evaluated ☐ unknown
CD 34+ (cells/kg*) *(DLI only)*	.... - .... x 10^6 ☐ Not evaluated ☐ unknown
CD 3+ (cells/kg*) *(DLI only)*	.... - .... x 10^6 ☐ Not evaluated ☐ unknown
Total number of cells infused	
All cells (cells/kg*) *(non DLI only)*	.... - .... x 10^6 ☐ Not evaluated ☐ unknown

Chronological number of this cell therapy for this patient .....

Indication *(check all that apply)*

☐ Planned/protocol
☐ Prophylactic
☐ Treatment of aGvHD
☐ Treatment viral infection
☐ Other, specify ....
☐ Treatment for disease
☐ Mixed chimaerism
☐ Treatment of cGvHD
☐ Loss/decreased chimaerism
☐ Treatment PTLD, EBV lymphoma

Number of infusions within 10 weeks .....
(count only infusions that are part of same regimen and given for the same indication)

Acute Graft Versus Host Disease *(after this infusion but before any further infusion / transplant)*:

Maximum grade ☐ grade 0 (absent) ☐ grade 1 ☐ grade 2
☐ grade 3 ☐ grade 4 ☐ present, grade unknown

-Chemo / radiotherapy

ADDITIONAL DISEASE TREATMENT GIVEN EXCLUDING CELL INFUSION?

☐ No
☐ Yes: ☐ Prophylaxis / preemptive / preventive *(planned before the transplant took place)*
☐ For relapse / progression or persistent disease *(not planned)*

Date started ..... - ..... - .....
yyyy *mm* *dd*

Chemo/drug ☐ No
☐ Yes:

Tick here if continuous from last follow up report

ABL TKI inhibitor:	
☐ Imatinib mesylate (Gleevec, Glivec)	☐
☐ Dasatinib (Sprycel)	☐
☐ Nilotinib (Tasigna)	☐
☐ Other TKI inhibitor: …….	☐

FLT3 inhibitor:	
☐ Sorafenib	☐
☐ Midostaurin	☐
☐ Quizartinib	☐
☐ Crenolanib	☐
☐ Other TKI inhibitor: …….	☐

HDAC inhibitor:	
☐ Panobinosta	☐

IDH1-2 inhibitor:	
☐ Other HDAC inhibitor: …….	☐

Hypomethylating agents:	
☐ Azacytidine	☐
☐ Decitabine	☐

Other:	
☐ Other drug/chemotherapy, specify …….....	☐

FIRST EVIDENCE OF RELAPSE OR PROGRESSION SINCE LAST HSCT

RELAPSE OR PROGRESSION AFTER HSCT *(detected by any method)*

☐ No

☐ Yes; date first seen: .... - .... - .....
yyyy *mm* *dd*

Method of detection	Date of the assessment	Site
Cinical/haematological relapse or progression	☐ No: Date assessed ..... - ..... - ..... *yyyy mm dd* DHEMREL	
VRELLEUK	☐ Yes: Date first seen ..... - ..... - ..... *yyyy mm dd*	☐ marrow – blood ☐ extramedullary
	☐ Not evaluated	VRELLEU2
Cytogenetic relapse or progression	☐ No: Date assessed ..... - ..... - ..... *yyyy mm dd*	
	☐ Yes: Date first seen ..... - ..... - ..... *yyyy mm dd*	☐ marrow – blood ☐ extramedullary
	☐ Not evaluated	
Molecular relapse or progression	☐ No: Date assessed ..... - ..... - ..... *yyyy mm dd* DMOLREL	
VRELLEU5	☐ Yes: Date first seen ..... - ..... - ..... *yyyy mm dd*	☐ marrow – blood ☐ extramedullary
	☐ Not evaluated	VRELLEU6

☐ Continuous progression since transplant

LAST DISEASE AND PATIENT STATUS

LAST DISEASE STATUS

☐ Complete Remission ☐ Stable disease ☐ Relapse ☐ Progression

Method	Disease detected (record the most recent status and date for each method)	
Clinical/haematological	☐ No ☐ Yes	
DISCLI DISCLID	Last date evaluated ..... - ..... - ..... (yyyy mm dd)	☐ Not evaluated
Cytogenetic/FISH	☐ No ☐ Yes: Considered disease relapse/progression	☐ No ☐ Yes
	Last date assessed ..... - ..... - ..... (yyyy mm dd)	☐ Not evaluated
Molecular	☐ No ☐ Yes: Considered disease relapse/progression	☐ No ☐ Yes
DISMOL DISMOLDR DISMOLD	Last date assessed ..... - ..... - ..... (yyyy mm dd)	☐ Not evaluated

PREGNANCY AFTER HSCT

Has patient or partner become pregnant after this HSCT?

☐ No
☐ Yes: Did the pregnancy result in a live birth? ☐ No ☐ Yes ☐ Unknown
☐ Unknown

SURVIVAL STATUS

☐ Alive
☐ Dead

PERFORMANCE SCORE *(if alive)*

Type of score used ☐ Karnofsky ☐ Lansky

SCORE *(For more detailed description, see manual)*

☐ 100	Normal, NED	Normal, NED
☐ 90	Normal activity; minor signs and symptoms of disease	Minor restrictions in physically strenuous activity
☐ 80	Normal with effort	Active, but tires more quickly
☐ 70	Cares for self, unable to perform normal activity	Both greater restriction of and less time spent in play activity
☐ 60	Requires occasional assistance	Up and around, but minimal active play; keeps busy with quieter activities
☐ 50	Requires considerable assistance	Gets dressed but lies around much of the day, no active play but able to participate in all quiet play and activities
☐ 40	Requires special care; disabled	Mostly in bed; participates in quiet activities
☐ 30	Severely disabled	In bed; needs assistance even for quiet play
☐ 20	Very sick	Often sleeping; play entirely limited to very passive activities

☐ Not evaluated

CIC: ..... Hospital UPN: ..... HSCT Date..... .... - ..... - .....
yyyy *mm* *dd*

MAIN CAUSE OF DEATH *(check only one main cause)*

- ☐ Relapse or progression / persistent disease
- ☐ Secondary malignancy *(including lymphoproliferative disease)*
- ☐ HSCT related cause
- ☐ Cell therapy (non HSCT) Related Cause *(if applicable)*
- ☐ Other: .....
- ☐ Unknown

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

	Yes	No	Unknown
GvHD *(if previous allograft)*	☐	☐	☐
Interstitial pneumonitis	☐	☐	☐
Pulmonary toxicity	☐	☐	☐
Infection	☐	☐	☐
bacterial	☐	☐	☐
viral	☐	☐	☐
fungal	☐	☐	☐
parasitic	☐	☐	☐
Rejection / poor graft function	☐	☐	☐
History of severe Veno-Occlusive disorder (VOD)	☐	☐	☐
Haemorrhage	☐	☐	☐
Cardiac toxicity	☐	☐	☐
Central nervous system toxicity	☐	☐	☐
Gastro intestinal toxicity	☐	☐	☐
Skin toxicity	☐	☐	☐
Renal failure	☐	☐	☐
Multiple organ failure	☐	☐	☐

Other: .....

COMMENTS .....

.....

.....

IDENTIFICATION & SIGNATURE

.....