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

Patient Number in EBMT database (if known): ……..

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:_____

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

Patient Number in EBMT database (if known): ……..

DAY 0

MED-B
MYELODYSPLASTIC SYNDROME (MDS)
OR
THERAPY RELATED MYELOID NEOPLASM

INITIAL DIAGNOSIS

☐ **AML: THERAPY RELATED MYELOID NEOPLASM**

An AML with prior exposure to chemo- or radiotherapy is considered a Therapy related neoplasm (old "Secondary Acute Leukaemia) and the correct subclassification is gathered on the AML form, so you should register it with AML as the primary diagnosis. Once you have registered the disease as AML, please complete this MED-B form for MDS or Therapy Related Myeloid Neoplasm.(If you are using Promise, it will switch forms automatically during data entry).

☐ **MYELODYSPLASTIC SYNDROME** *Please use the WHO subclassification if possible*

(WHO)Subclassification

- ☐ Refractory anaemia (without ring sideroblasts) RA
- ☐ RA with ring sideroblasts (RARS)
- ☐ MDS associated with isolated del(5q)
- ☐ Refractory cytopenia with multilineage dysplasia (RCMD)
- ☐ Refractory cytopenia with multilineage dysplasia and ringed sideroblasts (RCMD-RS)
- ☐ RA with excess of blasts (RAEB-1)
- ☐ RA with excess of blasts (RAEB-2)
- ☐ Childhood myelodysplastic syndrome (*Refractory cytopenia of childhood (RCC)*)
- ☐ Unclassified (MDS-U)

IS THIS A THERAPY RELATED MDS? *(Secondary disease)*

☐ No ☐ Yes ☐ Unknown

For Therapy related MDS or Myeloid Neoplasm:

Cause ☐ Chemotherapy / Radiotherapy treated disease: *(tick all that apply)*
- ☐ Alkylating agent/radiation-related
- ☐ Topoisomerase II inhibitor-related
- ☐ Radiation
- ☐ Unknown

☐ Immune suppression
☐ After stem cell HSCT
☐ Other: .....
☐ Unknown

Primary disease

Date of diagnosis of the primary disease: ..... - .... - .....
yyyy mm dd

☐ AML	☐ ALL	☐ CML	☐ Other chronic leukaemia
☐ NHL	☐ Hodgkin's disease	☐ Multiple myeloma	☐ Other plasma cell disorder
☐ Solid tumour	☐ Aplastic anaemia	☐ PNH	☐ Inherited disorder
☐ Autoimmune	☐ Other		☐ unknown

IF THE PATIENT HAS RECEIVED AN ALLOGRAFT PRIOR TO THE DIAGNOSIS OF MDS OR THERAPY RELATED MYELOID NEOPLASM (*old secondary acute leukaemia*), ANSWER THE FOLLOWING QUESTION

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

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

Patient Number in EBMT database (if known): ……..

CYTOGENETICS DATA

(INCLUDE ALL ANALYSIS BEFORE TREATMENT; DESCRIBE RESULTS OF MOST RECENT COMPLETE ANALYSIS)

Chromosome analysis at diagnosis (All methods including FISH)

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

☐ Abnormal:

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

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**

del Y *(-Y)*	☐ Absent	☐ Present	☐ Not evaluated
abn 5 type *Fill only if* abn 5 *is Present:*	☐ Absent	☐ Present	☐ Not evaluated
del5q *(5q-)*	☐ Absent	☐ Present	☐ Not evaluated
Other abn 5, specify ……	☐ Absent	☐ Present	☐ Not evaluated
del 20q *(20q-)*	☐ Absent	☐ Present	☐ Not evaluated
abn 7 type *Fill only if* abn 7 *is Present:*	☐ Absent	☐ Present	☐ Not evaluated
del 7q (7q-)	☐ Absent	☐ Present	☐ Not evaluated
Other abn 7, specify ……	☐ Absent	☐ Present	☐ Not evaluated
abn 3 type *Fill only if* abn 3 *is Present:*	☐ Absent	☐ Present	☐ Not evaluated
inv(3)	☐ Absent	☐ Present	☐ Not evaluated
t(3q;3q)	☐ Absent	☐ Present	☐ Not evaluated
del(3q)	☐ Absent	☐ Present	☐ Not evaluated
Other abn 3, specify ……	☐ Absent	☐ Present	☐ Not evaluated
del11q	☐ Absent	☐ Present	☐ Not evaluated
trisomy 8	☐ Absent	☐ Present	☐ Not evaluated
trisomy 19	☐ Absent	☐ Present	☐ Not evaluated
i(17q)	☐ Absent	☐ Present	☐ Not evaluated
Other, specify	☐ Absent	☐ Present	☐ Not evaluated

MOLECULAR MARKERS AT DIAGNOSIS

Marker analysis at diagnosis

☐ Not evaluated ☐ Absent ☐ Present ☐ Unknown

HAEMATOLOGICAL VALUES *(at diagnosis)*

Peripheral blood

Hb (g/dL)	....	☐ Not evaluated
Platelets (10^9/L)	....	☐ Not evaluated
White Blood Cells (10^9/L)	....	☐ Not evaluated
% blasts	....	☐ Not evaluated
% monocytes	....	☐ Not evaluated
% neutrophils	....	☐ Not evaluated

Bone marrow

% blasts .... ☐ Not evaluated

Auer rods present ☐ Yes ☐ No ☐ Not evaluated ☐ Unknown

IPSS score

☐ Low (0) ☐ Intermediate-1 (0.5-1.0) ☐ Intermediate-2 (1.5-2) ☐ High (>2.5) ☐ Unknown

BM INVESTIGATION

☐ Cytology ☐ Histology ☐ Both ☐ Not available

RESULTS

(check one box in each column)

CELLULARITY ON BM ASPIRATE / BM BIOPSY

- ☐ Acellular
- ☐ Hypocellular
- ☐ Normocellular
- ☐ Hypercellular
- ☐ Focal cellularity
- ☐ Not evaluated
- ☐ Unknown

FIBROSIS ON BM BIOPSY

- ☐ No
- ☐ Mild
- ☐ Moderate
- ☐ Severe
- ☐ Not evaluable
- ☐ Not evaluated
- ☐ Unknown

FIRST LINE THERAPY

If this registration pertains to a second or subsequent HSCT the therapy number should be counted since last reported HSCT.

FIRST LINE THERAPY GIVEN

☐ No - *Proceed to page 6,"Subclassification & Status of Disease at HSCT"***.** *Alternatively, If you are entering an* ***AML with myelodysplasia related changes****, return to the* ***Acute Leukaemia Med-B form*** *to continue*

☐ Yes: Date started .... - .... - ....
yyyy mm dd

SUBCLASSIFICATION OF MDS AT PRIMARY TREATMENT

Select only one

WHO Classification at HSCT:

☐ Refractory anaemia (without ring sideroblasts) (RA)
☐ RA with ring sideroblasts (RARS)
☐ MDS associated with isolated del(5q)
☐ Refractory cytopenia with multilineage dysplasia (RCMD)
☐ RCMD with ring sideroblasts (RCMD-RS)
☐ RA with excess of blasts-1 (RAEB-1)
☐ RA with excess of blasts-2 (RAEB-2)
☐ Childhood myelodysplastic syndrome (*Refractory cytopenia of childhood (RCC)*)
☐ MDS Unclassifiable (MDS-U)

TREATMENT

Chemo/drug/agent *(including GF, hormones, etc.)* ☐ No ☐ Yes: ☐ Ara-C ☐ Hydroxyurea ☐ Retinoic acid ☐ Hypomethylating agents ☐ Histondeacetylase Inhibitor ☐ AML like therapy ☐ Other, specify .....

Other: .....

Response: ☐ Complete remission, date of first CR .... - .... - ....
If subsequent HSCT, indicate the date of the 1st CR after this treatment *yyyy mm dd*

☐ Never in CR

NOTE*: If you are submitting an* ***AML with myelodysplasia related changes****, return to the* ***Acute Leukaemia Med-B form*** *to continue*

SUBCLASSIFICATION & STATUS OF DISEASE AT HSCT

TO BE EVALUATED JUST BEFORE STARTING CONDITIONING

DATE OF HSCT: ..... - ..... - .....
yyyy mm dd

TRANSFUSIONS ☐ Red Blood Cells, number: ☐ < 20 units
(erythrocytes) ☐ 20-50 units
☐ > 50 units
☐ Unknown

☐ Platelets

☐ None

☐ Unknown

SUBCLASSIFICATION OF MDS AT HSCT
Select only one
WHO Classification at HSCT:

☐ Refractory anaemia (without ring sideroblasts) (RA)
☐ RA with ring sideroblasts (RARS)
☐ MDS associated with isolated del(5q)
☐ Refractory cytopenia with multilineage dysplasia (RCMD)
☐ RCMD with ring sideroblasts (RCMD-RS)
☐ RA with excess of blasts-1 (RAEB-1)
☐ RA with excess of blasts-2 (RAEB-2)
☐ Childhood myelodysplastic syndrome (*Refractory cytopenia of childhood (RCC)*)
☐ MDS Unclassifiable (MDS-U)

DISEASE STATUS AT HSCT

STATUS	NUMBER
Treated with chemotherapy: ☐ Primary refractory phase (no change)	
☐ Complete remission (CR)	☐ 1st ☐ 2nd ☐ 3rd or higher
☐ Improvement but no CR	
☐ Relapse (after CR)	☐ 1st ☐ 2nd ☐ 3rd or higher
☐ Progression/worse ☐ Never treated (Supportive care or treatment without chemotherapy)	

CYTOGENETICS DATA *(Within 2 months of the preparative -conditioning- regimen)*

Chromosome analysis (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 those abnormalities that have been **evaluated** and whether they were **Absent** or **Present**

del Y *(-Y)*	☐ Absent	☐ Present	☐ Not evaluated
abn 5 type *Fill only if* abn 5 *is Present:*	☐ Absent	☐ Present	☐ Not evaluated
del5q *(5q-)*	☐ Absent	☐ Present	☐ Not evaluated
Other abn 5, specify ……	☐ Absent	☐ Present	☐ Not evaluated
del 20q *(20q-)*	☐ Absent	☐ Present	☐ Not evaluated
abn 7 type *Fill only if* abn 7 *is Present:*	☐ Absent	☐ Present	☐ Not evaluated
del 7q (7q-)	☐ Absent	☐ Present	☐ Not evaluated
Other abn 7, specify ……	☐ Absent	☐ Present	☐ Not evaluated
abn 3 type *Fill only if* abn 3 *is Present:*	☐ Absent	☐ Present	☐ Not evaluated
inv(3)	☐ Absent	☐ Present	☐ Not evaluated
t(3q;3q)	☐ Absent	☐ Present	☐ Not evaluated
del(3q)	☐ Absent	☐ Present	☐ Not evaluated
Other abn 3, specify ……	☐ Absent	☐ Present	☐ Not evaluated
del11q	☐ Absent	☐ Present	☐ Not evaluated
trisomy 8	☐ Absent	☐ Present	☐ Not evaluated
trisomy 19	☐ Absent	☐ Present	☐ Not evaluated
i(17q)	☐ Absent	☐ Present	☐ Not evaluated
Other, specify	☐ Absent	☐ Present	☐ Not evaluated

HAEMATOLOGICAL VALUES *(To be evaluated just before starting the preparative -conditioning- regimen)*

Peripheral blood

Hb (g/dL) ..... ☐ Not evaluated

Platelets (10^9/L) ..... ☐ Not evaluated

White Blood Cells (10^9/L) ..... ☐ Not evaluated

% blasts ..... ☐ Not evaluated

% monocytes ..... ☐ Not evaluated

% neutrophils ..... ☐ Not evaluated

Bone marrow

% blasts ..... ☐ Not evaluated

Auer rods present ☐ Yes ☐ No ☐ Not evaluated ☐ Unknown

IPSS score

☐ Low (0) ☐ Intermediate-1 (0.5-1.0) ☐ Intermediate-2 (1.5-2) ☐ High (>2.5) ☐ Unknown

BM INVESTIGATION *(Within 2 months of the preparative -conditioning- regimen)*

☐ Cytology ☐ Histology ☐ Both ☐ Not available

RESULTS

(check one box in each column)

CELLULARITY ON BM ASPIRATE / BM BIOPSY

- ☐ Acellular
- ☐ Hypocellular
- ☐ Normocellular
- ☐ Hypercellular
- ☐ Focal cellularity
- ☐ Not evaluated
- ☐ Unknown

FIBROSIS ON BM BIOPSY

- ☐ No
- ☐ Mild
- ☐ Moderate
- ☐ Severe
- ☐ Not evaluable
- ☐ Not evaluated
- ☐ Unknown

FORMS TO BE FILLED IN

TYPE OF HSCT

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

☐ ALLOgraft or Syngeneic graft, **proceed to Allograft day 0 form**

If ☐ Other : ..... , contact the EBMT Central Registry Office for instructions

DAY 100

MED-B
MYELODYSPLASTIC SYNDROME (MDS)

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

Sex: ☐ Male ☐ Female
(at birth)

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

BEST DISEASE RESPONSE AT 100 DAYS POST-HSCT

BEST RESPONSE AT 100 DAYS AFTER HSCT

- ☐ CR (maintained or achieved)
- ☐ Improvement but no CR
- ☐ Not evaluable
- ☐ Relapse
- ☐ Progression
- ☐ Unknown

Date of evaluation :..... ..... - .... - ....
yyyy mm dd

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**

FOLLOW UP | MYELODYSPLASTIC SYNDROME (MDS)

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

PATIENT LAST SEEN

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
☐ Recurrence

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

☐ Present continuously 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.*
Bacteraemia / 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
	Haemophilus influenzae		EBV
	Other gram negative *(i.e.: E. coli klebsiella, proteus, serratia, pseudomonas …)*		CMV
	Legionella sp		HHV-6
	Mycobacteria sp		RSV
	Other:		Other respiratory virus *(influenza, parainfluenza, rhinovirus)*
Fungi			Adenovirus
	Candida sp		HBV
	Aspergillus sp		HCV
	Pneumocystis carinii		HIV
	Other:		Papovavirus
Parasites			Parvovirus
	Toxoplasma gondii		Other: .....
	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

GRAFT ASSESSMENT AND HAEMOPOIETIC CHIMAERISM

Graft loss

☐ No ☐ Yes ☐ Not evaluated

Overall chimaerism ☐ Full *(donor ≥95 %)* ☐ Mixed *(partial)*
☐ Autologous reconstitution *(recipient ≥95 %)* ☐ 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

☐ Previously reported

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

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

Indication *(check all that apply)*

☐ Planned/protocol
☐ Prophylactic
☐ Treatment of GvHD
☐ Loss/decreased chimaerism
☐ Other, specify ....
☐ Treatment for disease
☐ Mixed chimaerism
☐ Treatment viral infection
☐ 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: ☐ Preemptive / preventive *(planned before the transplant took place)*
☐ For relapse / progression or persistent disease *(not planned)*

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

Chemo/drug/agent ..... ☐ Unknown
(including MoAB, vaccination, etc.)
Radiotherapy ☐ No ☐ Yes ☐ Unknown

Other treatment ☐ No ☐ Yes, specify: ..... ☐ Unknown
☐ Unknown

FIRST EVIDENCE OF RELAPSE OR PROGRESSION SINCE LAST HSCT

RELAPSE OR PROGRESSION

☐ Previously reported
☐ No
☐ Yes; date diagnosed: ..... - ..... - .....
yyyy *mm* *dd*
☐ Continuous progression since transplant
☐ Unknown

LAST DISEASE AND PATIENT STATUS

LAST DISEASE STATUS

☐ Complete Remission ☐ Relapse ☐ Treatment failure / progression

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
- ☐ 100 (Normal, NED)
- ☐ 90 (Normal activity)
- ☐ 80 (Normal with effort)
- ☐ 70 (Cares for self)
- ☐ 60 (Requires occasional assistance)
- ☐ 50 (Requires assistance)
- ☐ 40 (Disabled)
- ☐ 30 (Severely disabled)
- ☐ 20 (Very sick)
- ☐ 10 (Moribund)
- ☐ Not evaluated
- ☐ Unknown

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: .....

ADDITIONAL NOTES IF APPLICABLE

COMMENTS .....

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IDENTIFICATION & SIGNATURE

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