CIC: Hospital Unique Patient Number (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)*

- ☐ Primary 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 HAEMOGLOBINOPATHY

PRIMARY DISEASE

DIAGNOSIS

☐ Thalassaemia: ☐Beta 0 ☐Beta + ☐Beta E ☐Beta S (sickle cell + thalassaemia)
% sickle cell = ...

☐ Sickle cell disease

☐ Other haemoglobinopathy, specify: _____

PRE-HSCT BIOLOGICAL FEATURES

Molecular marker test: ☐ Done ☐ Not evaluated

PRE-HSCT MAIN CLINICAL FEATURES

Splenomegaly ☐ Absent ☐ Present : Spleen size *(cm under costal margin)* : .... ☐ Not applicable

Hepatomegaly ☐ Absent ☐ Present: Liver size *(cm under costal margin)* : ....

Diabetes ☐ No ☐ Yes : ☐ Insulin required occasionally
☐ Insulin required regularly

OTHER CLINICAL FEATURES AND COMPLICATIONS

	Absent	Present	Not evaluated	Unknown
Gonadal dysfunction	☐	☐	☐	☐
Substitutional hormonal therapy	☐	☐	☐	☐
Growth impairment	☐	☐	☐	☐
Red blood cell immunization	☐	☐	☐	☐
Sickle nephropathy (glomerular filtration rate 30-50% predicted)	☐	☐	☐	☐
Stroke or central nervous system haemorrhage	☐	☐	☐	☐
Recurrent acute chest syndrome	☐	☐	☐	☐
Impaired neuropsychologic function and abnormal Magnetic Resonance Imaging scan	☐	☐	☐	☐
Bilateral proliferative retinopathy and visual impairment	☐	☐	☐	☐
Osteonecrosis of multiple joints	☐	☐	☐	☐

OTHER CLINICAL ABNORMALITIES INDICATING THE SEVERITY OF THE PRIMARY DISEASE :

If present, specify

.....

.....

MAJOR DISEASES NOT RELATED TO THE TREATMENT OF HAEMOGLOBINOPATHY

If present, specify

.....

.....

.....

CHELATION TREATMENT PRE-HSCT

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

☐ Irregular ☐ Regular *(Subcutaneous continuous infusion, at least 5 days per week)*

☐ No

STATUS OF DISEASE AT HSCT

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

Splenectomy ☐ No ☐ Yes, Date : .... - .... - ....

RBC Transfusions: ☐ No ☐ Yes: Age at transfusion *(months)* : ....
Total number of RBC units transfused : ....

Enzymes :

LDH : ☐ Normal ☐ Elevated ☐ Not evaluated ☐ Unknown

	Value	Unit	Times Upper Limit *(of the normal range)*	
AST (SGOT)	....	.....	.... -	☐ Not Evaluated
ALT (SGPT)	....	.....	.... -	☐ Not Evaluated
Gamma (γ) GT	....	.....	.... -	☐ Not evaluated

Albumin	....	(g/dl)	☐ Not evaluated
Bilirubin :			
Total serum bilirubin	....	(mg/dl)	☐ Not evaluated
Direct bilirubin	....	(mg/dl)	☐ Not evaluated
Ferritin	....	(ng/ml)	☐ Not evaluated
Total Transferrin	....	(mg/dl)	☐ Not evaluated
Unbounded Transferrin	....	(mg/dl)	☐ Not evaluated

LIVER FUNCTION

Evidence of hepatitis or other liver disease

☐ No Yes: ☐ Hepatitis B ☐ Hepatitis C
☐ Hepatitis unspecified ☐ Other, specify.....

Liver biopsy performed

☐ No ☐ Yes

RESULTS OF LIVER BIOPSY

Hepatitis ☐ Chronic <u>persistent</u> hepatitis
☐ Chronic <u>active</u> hepatitis
☐ Absent

Siderosis ☐ Present : ☐ Mild ☐ Moderate ☐ Severe
☐ Absent

Fibrosis ☐ Present :
☐ Present without bridging
☐ Present with complete porto-portal and/or porto-central bridging
☐ Present with cirrhosis
☐ Absent

Liver iron concentration : .... - .... mg/g dry weight ☐ Not evaluated

CARDIAC FUNCTION

History of cardiac insufficiency: ☐ No
☐ Yes: Therapy : ☐ No ☐ Yes ☐ Unknown

Left ventricular ejection fraction: % = ... ☐ Not evaluated

OTHER CLINICALLY SIGNIFICANT ORGAN INVOLVEMENT:

☐ No ☐ Yes: Specify

.....

.....

.....

.....

CLASS

☐ 1 : No hepatomegaly (or < 3 cm), No fibrosis, Regular chelation
☐ 2 : One or two of these conditions
☐ 3 : Hepatomegaly (= 3 cm), Fibrosis, and Irregular chelation

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

FOLLOW UP

MED-B HAEMOGLOBINOPATHY

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.*
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
	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**

CIC: Hospital Unique Patient Number (UPN): ..... HSCT Date..... .... - .... - ....
yyyy mm dd

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 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: ☐ Prophylaxis / preemptive / preventive *(planned before the transplant took place)*
☐ For relapse / progression or persistent disease *(not planned)*

LAST DISEASE AND PATIENT STATUS

LAST DISEASE STATUS

REASON NO TRANSFUSION

☐ No transfusion required
- ☐ Full engraftment (100% donor cells)
- ☐ Mixed chimera
- ☐ Unknown

☐ Transfusions required (= autologous reconstitution, 0% donor cells)

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 .....

.....

.....

IDENTIFICATION & SIGNATURE

.....

_____