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)*

- ☐ 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
AL AMYLOIDOSIS

INITIAL DIAGNOSIS

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

☐ Yes: go to page 4, *Pre-HSCT Treatment* ☐ No: proceed with this section.

EVIDENCE OF UNDERLYING PLASMA CELL DISORDER

☐ No

☐ Yes

☐ Monoclonal Gammopathy
☐ Multiple Myeloma
☐ Other B-cell malignancy, specify
.....

Select one as applicable

☐ IgG
☐ IgA
☐ IgD
☐ IgE
☐ IgM
☐ Absent
☐ Not evaluated

Select one as applicable

☐ Kappa
☐ Lambda
☐ Absent
☐ Not evaluated

If Multiple myeloma

Stage Untreated (Salmon and Durie)

	I	II	III
A	☐	☐	☐
B	☐	☐	☐

DIAGNOSIS OF AMYLOIDOSIS

Methods

Hereditary Amyloidosis	☐ Excluded	☐ Not evaluated	
Positive immunohistochemistry	☐ No	☐ Yes	☐ Not evaluated

CLINICAL AND LABORATORY DATA

Hb *(g/dL)*	....	☐ Not evaluated
Serum creatinine	.... Units: ☐ *µmol/L* ☐ *mg/dL*	☐ Not evaluated
Creatinine clearance *(mL/min)*	....	☐ Not evaluated
Total urinary protein excretion *(mg/24 h)*	....	☐ Not evaluated
Total urinary albumin excretion *(mg/24 h)*	....	☐ Not evaluated
Serum calcium *(mmol/L)*	.... -	☐ Not evaluated
Serum albumin *(g/L)*	....	☐ Not evaluated
Serum alkaline phosphatase *(IU/L)*	....	☐ Not evaluated
Serum bilirubin	.... Units: ☐ *µmol/L* ☐ *mg/dL*	☐ Not evaluated
Serum NT-pro-BNP *(ng/L)*	....	☐ Not evaluated
Serum c-Troponin T *(µg/L)*	....	☐ Not evaluated

Bone marrow investigations

BM aspirate: % plasmacytosis	....	☐ Not evaluated
BM trephine: % plasmacytosis	....	☐ Not evaluated

Immunoglobulins

Monoclonal Ig in serum *(g/L)* ....

Immunofixation of serum ☐ Negative ☐ Positive ☐ Not evaluated ☐ Unknown

Free light chains in serum:

Kappa light chains *(mg/L)* .... ☐ Not evaluated.

Lambda light chains *(mg/L)* .... ☐ Not evaluated

Immunofixation of urine ☐ Negative ☐ Positive ☐ Not evaluated ☐ Unknown

Monoclonal light chains in urine *(g/24 h)* ....

Serum β2 microglobulin *(mg/L)* .... - .....

Bone structure (X-ray) ☐ Normal ☐ Lytic lesion present ☐ Not evaluated ☐ Unknown

Typical clinical symptoms

Macroglossy	☐ Absent	☐ Present	☐ Not evaluated	☐ Unknown
Periorbital bleeding	☐ Absent	☐ Present	☐ Not evaluated	☐ Unknown
Shoulder pad sign	☐ Absent	☐ Present	☐ Not evaluated	☐ Unknown

ORGAN INVOLVEMENT UNTREATED

	Dominant organ(s) involved	Additional organ involvement	Biopsy	No involvement
Soft Tissues	☐	☐	☐	☐
Gastrointestinal Tract	☐	☐	☐	☐
Heart	☐	☐	☐	☐
Liver	☐	☐	☐	☐
Kidney	☐	☐	☐	☐
Peripheral nerves	☐	☐	☐	☐
Autonomic nerves	☐	☐	☐	☐
Other	☐	☐	☐	☐

Specify .....…..... .... ……..

ORGAN-SPECIFIC DATA UNTREATED

Liver

Liver span in ultrasound or CT scan *(cm craniocaudal diameter)* .... ☐ Not evaluated

Heart

NYHA class ☐ I ☐ II ☐ III ☐ IV ☐ Unknown

Left ventricular ejection fraction *(%)* .... ☐ Not evaluated

Interventricular septal wall thickness .... ☐ Not evaluated
(mean number of mm in echocardiogram)

Gastrointestinal

Weight loss	☐ No	☐ Yes	☐ Not evaluated	☐ Unknown
Malabsorption	☐ No	☐ Yes	☐ Not evaluated	☐ Unknown
GI bleeding	☐ No	☐ Yes	☐ Not evaluated	☐ Unknown

Other evidence of gastrointestinal involvement: ……..

……

Peripheral neuropathy

Neurological exam ☐ Normal ☐ Abnormal ☐ Not evaluated or failed ☐ Unknown

If abnormal:

Specify abnormality ….……..……

PNP severity ☐ grade I ☐ grade II ☐ grade III ☐ grade IV

Autonomic neuropathy

Orthostatic hypotension	☐ Yes	☐ No	☐ Not evaluated	☐ Unknown
Intractable diarrhoea	☐ Yes	☐ No	☐ Not evaluated	☐ Unknown
Inflexible pulse rate	☐ Yes	☐ No	☐ Not evaluated	☐ Unknown

Other sites

Clinical evidence for involvement of other sites:……..

PRE-HSCT TREATMENT

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

WAS THE PATIENT TREATED BEFORE THE HSCT PROCEDURE?

☐ No

☐ Yes:

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

Modality: Chemotherapy ☐ No ☐ Yes: Chemotherapy regimen .....
Number of cycles .....

Other .....

HSCT

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

HSCT TYPE

☐ Allogeneic: *proceed to "Status at Start of Conditioning" on page 5*

Autologous: Date of 1st collection or aphaeresis: .... - .... - ....
yyyy mm dd

STATUS OF DISEASE AT COLLECTION (AUTOGRAFTS ONLY)

IMMEDIATELY PRIOR TO MOBILISING CHEMOTHERAPY AND/OR GROWTH FACTOR IF USED

Haematological status

☐ Untreated / At diagnosis

☐ Complete remission (CR) NUMBER OF THIS COMPLETE REMISSION
- ☐ 1st
- ☐ 2nd
- ☐ 3rd or higher

☐ PR NUMBER OF THIS PARTIAL REMISSION
- ☐ 1st
- ☐ 2nd
- ☐ 3rd or higher

☐ Minimal response

☐ Stable disease (*no change)*

☐ Progression

☐ Unknown

Organ status ☐ Untreated ☐ Response ☐ No change ☐ Progression ☐ Unknown

STATUS OF DISEASE AT START OF CONDITIONING FOR BMT

Haematological status

- ☐ Untreated / At diagnosis
- ☐ Complete remission (CR) NUMBER OF THIS COMPLETE REMISSION
  - ☐ 1st
  - ☐ 2nd
  - ☐ 3rd or higher
- ☐ PR NUMBER OF THIS PARTIAL REMISSION
  - ☐ 1st
  - ☐ 2nd
  - ☐ 3rd or higher
- ☐ Minimal response
- ☐ Stable disease (*no change)*
- ☐ Progression
- ☐ Unknown

Organ status ☐ Untreated ☐ Response ☐ No change ☐ Progression ☐ Unknown

CLINICAL AND LABORATORY DATA

Hb *(g/dL)*	....	☐ Not evaluated
Serum creatinine	.... Units: ☐ *µmol/L* ☐ *mg/dL*	☐ Not evaluated
Creatinine clearance *(mL/min)*	....	☐ Not evaluated
Total urinary protein excretion *(mg/24 h)*	....	☐ Not evaluated
Total urinary albumin excretion *(mg/24 h)*	....	☐ Not evaluated
Serum calcium *(mmol/L)*	.... -	☐ Not evaluated
Serum albumin *(g/L)*	....	☐ Not evaluated
Serum alkaline phosphatase *(IU/L)*	....	☐ Not evaluated
Serum bilirubin	.... Units: ☐ *µmol/L* ☐ *mg/dL*	☐ Not evaluated
Serum NT-pro-BNP *(ng/L)*	....	☐ Not evaluated
Serum c-Troponin T *(µg/L)*	....	☐ Not evaluated

Bone marrow investigations

- BM aspirate: % plasmacytosis .... ☐ Not evaluated
- BM trephine: % plasmacytosis .... ☐ Not evaluated

Immunoglobulins

- Monoclonal Ig in serum *(g/L)* ....
- Immunofixation of serum ☐ Negative ☐ Positive ☐ Not evaluated ☐ Unknown
- Free light chains in serum:
  - Kappa light chains *(mg/L)* .... ☐ Not evaluated.
  - Lambda light chains *(mg/L)* .... ☐ Not evaluated
- Immunofixation of urine ☐ Negative ☐ Positive ☐ Not evaluated ☐ Unknown
  - Monoclonal light chains in urine *(g/24 h)* ....
- Serum β2 microglobulin *(mg/L)* .... - .....

ORGAN INVOLVEMENT AT HSCT

	Dominant organ(s) involved	Additional organ involvement	Biopsy	No involvement
Soft Tissues	☐	☐	☐	☐
Gastrointestinal Tract	☐	☐	☐	☐
Heart	☐	☐	☐	☐
Liver	☐	☐	☐	☐
Kidney	☐	☐	☐	☐
Peripheral nerves	☐	☐	☐	☐
Autonomic nerves	☐	☐	☐	☐
Other	☐	☐	☐	☐

Specify ....

ORGAN-SPECIFIC DATA AT HSCT

Liver

Liver span in ultrasound or CT scan *(cm craniocaudal diameter)* .... ☐ Not evaluated

Heart

NYHA class ☐ I ☐ II ☐ III ☐ IV ☐ Unknown

Left ventricular ejection fraction *(%)* .... ☐ Not evaluated

Interventricular septal wall thickness .... ☐ Not evaluated
(mean number of mm in echocardiogram)

Gastrointestinal

Weight loss ☐ No ☐ Yes ☐ Not evaluated ☐ Unknown

Malabsorption ☐ No ☐ Yes ☐ Not evaluated ☐ Unknown

GI bleeding ☐ No ☐ Yes ☐ Not evaluated ☐ Unknown

Other evidence of gastrointestinal involvement: ……..
……

Peripheral neuropathy

Neurological exam ☐ Normal ☐ Abnormal ☐ Not evaluated or failed ☐ Unknown

If abnormal:

Specify abnormality …..…….....……..

PNP severity ☐ grade I ☐ grade II ☐ grade III ☐ grade IV ☐ Unknown

Autonomic neuropathy

Orthostatic hypotension ☐ Yes ☐ No ☐ Not evaluated ☐ Unknown

Intractable diarrhoea ☐ Yes ☐ No ☐ Not evaluated ☐ Unknown

Inflexible pulse rate ☐ Yes ☐ No ☐ Not evaluated ☐ Unknown

Other sites

Clinical evidence for involvement of other sites:……..

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
AL AMYLOIDOSIS

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

STATUS OF DISEASE AT 100 DAYS AFTER HSCT

BEST HAEMATOLOGICAL RESPONSE TO HSCT AT 100 DAYS

☐ CR1 ☐ CR2 ☐ >CR2
☐ PR1 ☐ PR2 ☐ >PR2 ☐ MR
☐ No change ☐ Progression ☐ Not evaluable ☐ Unknown

DATE RESPONSE ACHIEVED OR ASSESSED :..... .... - .... - ....
yyyy mm dd

CLINICAL AND LABORATORY DATA

Hb *(g/dL)*	....	☐ Not evaluated
Serum creatinine	.... Units: ☐ *µmol/L* ☐ *mg/dL*	☐ Not evaluated
Creatinine clearance *(mL/min)*	....	☐ Not evaluated
Total urinary protein excretion *(mg/24 h)*	....	☐ Not evaluated
Total urinary albumin excretion *(mg/24 h)*	....	☐ Not evaluated
Serum calcium *(mmol/L)*	.... -	☐ Not evaluated
Serum albumin *(g/L)*	....	☐ Not evaluated
Serum alkaline phosphatase *(IU/L)*	....	☐ Not evaluated
Serum bilirubin	.... Units: ☐ *µmol/L* ☐ *mg/dL*	☐ Not evaluated
Serum NT-pro-BNP *(ng/L)*	....	☐ Not evaluated
Serum c-Troponin T *(µg/L)*	....	☐ Not evaluated

Bone marrow investigations

BM aspirate: % plasmacytosis .... ☐ Not evaluated
BM trephine: % plasmacytosis .... ☐ Not evaluated

Immunoglobulins

Monoclonal Ig in serum *(g/L)* ....

Immunofixation of serum ☐ Negative ☐ Positive ☐ Not evaluated ☐ Unknown

Free light chains in serum:

Kappa light chains *(mg/L)* .... ☐ Not evaluated

Lambda light chains *(mg/L)* .... ☐ Not evaluated

Immunofixation of urine ☐ Negative ☐ Positive ☐ Not evaluated ☐ Unknown

Monoclonal light chains in urine *(g/24 h)* ....

Serum β2 microglobulin *(mg/L)* .... - .....

ORGAN-SPECIFIC RESPONSES AT 100 DAYS AFTER HSCT

Kidney

Renal response ☐ Response ☐ No response/stable disease ☐ Progressive disease
☐ Not evaluable ☐ Not evaluated ☐ Not applicable ☐ Unknown

Liver

Liver span in ultrasound or CT scan *(cm craniocaudal diameter)* .... ☐ Not evaluated

Hepatic response ☐ Response ☐ No response/stable disease ☐ Progressive disease
☐ Not evaluable ☐ Not evaluated ☐ Not applicable ☐ Unknown

Heart

NYHA class ☐ I ☐ II ☐ III ☐ IV ☐ Unknown

Left ventricular ejection fraction *(%)* .... ☐ Not evaluated

Interventricular septal wall thickness .... ☐ Not evaluated
(mean number of mm in echocardiogram)

Cardiac response ☐ Response ☐ No response/stable disease ☐ Progressive disease
☐ Not evaluable ☐ Not evaluated ☐ Not applicable ☐ Unknown

Gastrointestinal

Weight loss ☐ No ☐ Yes ☐ Not evaluated ☐ Unknown

Malabsorption ☐ No ☐ Yes ☐ Not evaluated ☐ Unknown

GI bleeding ☐ No ☐ Yes ☐ Not evaluated ☐ Unknown

GI response ☐ Response ☐ No response/stable disease ☐ Progressive disease
☐ Not evaluable ☐ Not evaluated ☐ Not applicable ☐ Unknown

Peripheral neuropathy

(Compare current situation to situation before HSCT)

Neurological exam ☐ Improved ☐ Worsened ☐ Unchanged ☐ Unknown

PNP severity ☐ grade I ☐ grade II ☐ grade III ☐ grade IV

PN response ☐ Response ☐ No response/stable disease ☐ Progressive disease
☐ Not evaluable ☐ Not evaluated ☐ Not applicable ☐ Unknown

Autonomic neuropathy

AN response ☐ Response ☐ No response/stable disease ☐ Progressive disease
☐ Not evaluable ☐ Not evaluated ☐ Not applicable ☐ Unknown

Evidence of new organ involvement

Clinical evidence for involvement of new sites:……..

KARNOFSKY : ....

FORMS TO BE FILLED IN

TYPE OF HSCT

☐ 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

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

FOLLOW UP	MED-B AL AMYLOIDOSIS

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

Complete haematological remission obtained after the HSCT in the absence of additional disease treatment
☐ Previously reported
☐ Yes, date .... - .... - ....
yyyy mm dd
☐ No
☐ Unknown

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		

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

Hepatitis		
CNS infection		
Gut infection		
Skin infection		
Cystitis		
Retinitis		
Other:		
		dd *mm* *yyyy*

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)*	**CTC grade** 0 1 2 3 4	**Date**	**Comments**
Cardiovascular	☐ ☐ ☐ ☐ ☐		
Dermatologic	☐ ☐ ☐ ☐ ☐		
Gastrointestinal	☐ ☐ ☐ ☐ ☐		
Haemorrhage	☐ ☐ ☐ ☐ ☐		
Hepatic	☐ ☐ ☐ ☐ ☐		
Neurologic	☐ ☐ ☐ ☐ ☐		
Pulmonary	☐ ☐ ☐ ☐ ☐		
Renal	☐ ☐ ☐ ☐ ☐		
Other: .....…… VOTHCOMA	☐ ☐ ☐ ☐ ☐		

dd mm yyyy

GRAFT ASSESSMENT AND HAEMOPOIETIC CHIMAERISM

(ALLOS ONLY)

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

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

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 THERAPIES SINCE LAST FOLLOW UP

ADDITIONAL TREATMENT

Treatment given since last report

☐ No

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

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

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.

☐ No

☐ Yes: Disease status before this cellular therapy ☐ CR ☐ Not in CR ☐ Not evaluated

☐ Unknown

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

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 / HSCT)*:

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

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

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

-Chemo / radiotherapy

ADDITIONAL DISEASE TREATMENT GIVEN EXCLUDING CELL INFUSION?

☐ No

☐ Yes: ☐ Premptive / 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 DISEASE WORSENING SINCE LAST HSCT

EVIDENCE OF DISEASE ACTIVITY

☐ Previously reported

☐ No

☐ Yes; date first noted: ..... - ..... - .....
yyyy mm dd

☐ Continuous worsening since HSCT

☐ Unknown

LAST DISEASE AND PATIENT STATUS

HAEMATOLOGICAL DISEASE STATUS

☐ Complete remission

☐ Partial remission

☐ Stable disease

☐ Progression

☐ Not evaluable

☐ Unknown

ORGAN RESPONSE

☐ Response

☐ Non Response

☐ Progression

☐ Not evaluable

☐ Unknown

CLINICAL AND LABORATORY DATA

Hb *(g/dL)*	....	☐ Not evaluated
Serum creatinine	.... Units: ☐ *µmol/L* ☐ *mg/dL*	☐ Not evaluated
Creatinine clearance *(mL/min)*	....	☐ Not evaluated
Total urinary protein excretion *(mg/24 h)*	....	☐ Not evaluated
Total urinary albumin excretion *(mg/24 h)*	....	☐ Not evaluated
Serum calcium *(mmol/L)*	.... -	☐ Not evaluated
Serum albumin *(g/L)*	....	☐ Not evaluated
Serum alkaline phosphatase *(IU/L)*	....	☐ Not evaluated
Serum bilirubin	.... Units: ☐ *µmol/L* ☐ *mg/dL*	☐ Not evaluated
Serum NT-pro-BNP *(ng/L)*	....	☐ Not evaluated
Serum c-Troponin T *(µg/L)*	....	☐ Not evaluated

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

Bone marrow investigations

BM aspirate: % plasmacytosis .... ☐ Not evaluated

BM trephine: % plasmacytosis .... ☐ Not evaluated

Immunoglobulins

Monoclonal Ig in serum *(g/L)* ....

Immunofixation of serum ☐ Negative ☐ Positive ☐ Not evaluated ☐ Unknown

Free light chains in serum:

Kappa light chains *(mg/L)* .... ☐ Not evaluated.

Lambda light chains *(mg/L)* .... ☐ Not evaluated

Immunofixation of urine ☐ Negative ☐ Positive ☐ Not evaluated ☐ Unknown

Monoclonal light chains in urine *(g/24 h)* ....

Serum β2 microglobulin *(mg/L)* .... - .....

ORGAN-SPECIFIC RESPONSES AT THIS FOLLOW UP

Renal response ☐ Response ☐ No response/stable disease ☐ Progressive disease
☐ Not evaluable ☐ Not evaluated ☐ Not applicable ☐ Unknown

Liver

Liver span in ultrasound or CT scan *(cm craniocaudal diameter)* .... ☐ Not evaluated

Hepatic response ☐ Response ☐ No response/stable disease ☐ Progressive disease
☐ Not evaluable ☐ Not evaluated ☐ Not applicable ☐ Unknown

Heart

NYHA class ☐ I ☐ II ☐ III ☐ IV ☐ Unknown

Left ventricular ejection fraction *(%)* .... ☐ Not evaluated

Interventricular septal wall thickness .... ☐ Not evaluated
(mean number of mm in echocardiogram)

Cardiac response ☐ Response ☐ No response/stable disease ☐ Progressive disease
☐ Not evaluable ☐ Not evaluated ☐ Not applicable ☐ Unknown

Gastrointestinal

Weight loss ☐ No ☐ Yes ☐ Not evaluated ☐ Unknown

Malabsorption ☐ No ☐ Yes ☐ Not evaluated ☐ Unknown

GI bleeding ☐ No ☐ Yes ☐ Not evaluated ☐ Unknown

GI response ☐ Response ☐ No response/stable disease ☐ Progressive disease
☐ Not evaluable ☐ Not evaluated ☐ Not applicable ☐ Unknown

Peripheral neuropathy

(Compare current situation to situation before HSCT)

Neurological exam ☐ Not done ☐ Improved ☐ Worsened ☐ Unchanged ☐ Unknown

PNP severity ☐ grade I ☐ grade II ☐ grade III ☐ grade IV

PN response ☐ Response ☐ No response/stable disease ☐ Progressive disease
☐ Not evaluable ☐ Not evaluated ☐ Not applicable ☐ Unknown

Autonomic neuropathy

AN response ☐ Response ☐ No response/stable disease ☐ Progressive disease
☐ Not evaluable ☐ Not evaluated ☐ Not applicable ☐ Unknown

Evidence of new organ involvement

Clinical evidence for involvement of new sites:……..

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

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

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

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

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