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:_____

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

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

DAY 0

MED-B
BONE MARROW FAILURE SYNDROME
(INCLUDING APLASTIC ANAEMIA)

INITIAL DIAGNOSIS

USE THIS FORM TO REGISTER:
1) IMMUNOSUPPRESSION THERAPY FOR PATIENTS THAT DO NOT PROCEED TO HSCT
2) IMMUNOSUPPRESSION THERAPY AND HSCT FOR PATIENTS THAT RECEIVE IMMUNOSUPPRESSION AND THEN PROCEED TO HSCT
3) HSCT FOR PATIENTS THAT DO NOT RECEIVE PRIOR IMMUNOSUPPRESSION THERAPY

FOR IMMUNOSUPPRESSION THERAPY GIVEN POST-HSCT, PLEASE USE THE MED-B FOLLOW UP FORM

TYPE OF TREATMENT BEING REGISTERED WITH THIS FORM
If patients have undergone immunosuppression prior to HSCT ***tick both boxes***

☐ Includes HSCT registration
☐ Immunosuppressive therapy (IS)

SUBCLASSIFICATION
(check one box in each column as necessary)

	TYPE:	ETIOLOGY:
☐ Acquired	☐ Aplastic anaemia ☐ Moderate ☐ Severe ☐ Very severe ☐ Pure red cell aplasia *(non congenital PRCA)* ☐ Paroxysmal nocturnal haemoglobinuria (PNH) Presentation: Haemolytic ☐ No ☐ Yes Aplastic ☐ No ☐ Yes Thrombotic ☐ No ☐ Yes Other, specify ..... ☐ Pure white cell aplasia ☐ Amegakaryocytosis / thrombocytopaenia *(non congenital)* ☐ Other acquired cytopenic syndrome, specify:	☐ Idiopathic ☐ Secondary to hepatitis ☐ Secondary to toxin / other drug ☐ Other, specify.....
☐ Genetic	☐ Fanconi: FANC complementation group .... ☐ Diamond-Blackfan *(congenital PRCA)* ☐ Shwachman-Diamond Syndrome ☐ Dyserythropoietic Anaemia ☐ Dyskeratosis congenita ☐ Amegakaryocytosis / thrombocytopaenia *(congenital)* ☐ Other:	

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

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

CYTOGENETICS

Chromosome analysis

If done: Technique used ☐ Conventional ☐ FISH ☐ Both

☐ Normal: Number of metaphases examined: .....

☐ Abnormal: Number of metaphases with anomalies: .....

& Number of metaphases examined: .....

If abnormal, indicate abnormalities found:

trisomy 8	☐ Absent	☐ Present
trisomy 3 *(for Fanconi)*	☐ Absent	☐ Present

Other or associated abnormalities (specify).....……

☐ Not done or failed

☐ Unknown

Chromosomal breakage test ☐ Negative ☐ Positive ☐ Not evaluated
(for Fanconi)

HAEMATOLOGICAL VALUES

Haemoglobin	.... -	g/dL	☐ Not evaluated	☐ Untransfused	☐ Transfused
Platelets	....	10^9/ L	☐ Not evaluated	☐ Untransfused	☐ Transfused
Neutrophils	....	10^9/ L			
Reticulocytes	....	10^9/ L			
Ferritin	....	ng/ml			

COMPLICATIONS

Haemorrhages	☐ Yes	☐ No	☐ Not evaluated	☐ Unknown
Resistance to random platelets	☐ Yes	☐ No	☐ Not evaluated	☐ Unknown
Systemic infection	☐ Yes	☐ No	☐ Not evaluated	☐ Unknown

PNH TESTS

(To be filled in only for Aplastic anaemia or PNH at diagnosis)

Date of PNH test .... - .... - ....
yyyy *mm* *dd*

PNH diagnostics by flow cytometry ☐ Clone absent
☐ Clone present
☐ Not evaluated
Size of the PNH clone in % :.....

Flow cytometry assessment done on:
☐ Granulocytes ☐ RBC ☐ Both
☐ Other, specify .....

PNH diagnostics by other test, specify:.....
(if type of test unknown, write "unknown" here)
☐ Clone absent
☐ Clone present
☐ Not done

Clinical manifestations of PNH ☐ No ☐ Yes

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

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

IMMUNOSUPPRESSIVE TREATMENT EPISODE

WAS THE PATIENT TREATED BEFORE THE HSCT PROCEDURE?

(only if HSCT registration)

☐ No treatment (except transfusions) *Please proceed to "Status at HSCT" on page 8*
☐ Yes

FIRST TREATMENT EPISODE FOR THIS REGISTRATION

(All types of registration)

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

SEQUENTIAL NUMBER OF THIS TREATMENT EPISODE .....
Count ALL treatment episodes including those that may have been registered for this patient with previous data submissions

IF 1ST TREATMENT EPISODE EVER FOR THE PATIENT

NUMBER OF TRANSFUSIONS BEFORE THE 1ST TREATMENT

RBC ☐ <20 units ☐ 20-50 units ☐ >50 units ☐ None ☐ unknown
RBC irradiated ☐ No ☐ Yes ☐ unknown

Platelets ☐ <20 units ☐ 20-50 units ☐ >50 units ☐ None ☐ unknown
Platelets irradiated ☐ No ☐ Yes ☐ unknown

OR

IF PATIENT HAS BEEN TREATED BEFORE (Immunosuppressive therapy or HSCT)

REASON FOR THIS TREATMENT

☐ Failure of first line therapy ☐ Relapse ☐ PR to previous treatment
☐ Secondary clonal disorder ☐ Other ..... ☐ Unknown

HAEMATOLOGICAL VALUES *(Data must have been collected within 3 months prior to the treatment)*

Haemoglobin .... - ..... g/dL ☐ Not evaluated ☐ Untransfused ☐ Transfused
Platelets .... 10^9/ L ☐ Not evaluated ☐ Untransfused ☐ Transfused
Neutrophils .... 10^9/ L
Reticulocytes .... 10^9/ L

Ferritin .... ng/ml

Check at least one

	Origin	Brand	Dose (*mg/kg*)	Start date	End date
☐ ATG	☐ horse ☐ rabbit	....		.... - .... - .... (yyyy mm dd)	.... - .... - .... (yyyy mm dd)
☐ Cyclosporin A					
☐ Cyclophosphamide					
☐ Mycophenolate mofetil					
☐ G-CSF					
☐ Erythropoietin					
☐ Corticosteroid					
☐ Androgens					
☐ Rituximab *(Mabthera)*					
☐ Alemtuzumab *(Campath)*					
☐ Other, specify ……					

RESPONSE TO THIS IMMUNOSUPPRESSIVE TREATMENT EPISODE

☐ Complete remission ☐ Partial remission *(transfusion and growth factor independent)*
☐ No response ☐ Progression ☐ Not evaluable
☐ Other, specify ……

Date response evaluated .... - .... -..... .....
yyyy mm dd

SECONDARY CLONAL COMPLICATIONS

☐ No
☐ Yes:

FILL ONLY IF MDS HAS NOT BEEN REPORTED BEFORE

Date of diagnosis of MDS .... - .... -..... ..... ☐ Not applicable
(if applicable) yyyy mm dd

MDS WHO classification ……

FILL ONLY IF PNH HAS NOT BEEN REPORTED BEFORE

Date of diagnosis of PNH .... - .... -..... ..... ☐ Not applicable
(if applicable) yyyy mm dd

PNH diagnostics by flow cytometry ☐ Clone absent
☐ Clone present Size of the PNH clone in % :.....
☐ Not evaluated

Flow cytometry assessment done on:
☐ Granulocytes ☐ RBC ☐ Both
☐ Other, specify .....

PNH diagnostics by other test, specify:..... ☐ Clone absent
(if type of test unknown, write "unknown" here) ☐ Clone present
☐ Not done

Clinical manifestations of PNH ☐ No ☐ Yes

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

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

FILL ONLY IF THIS DIAGNOSIS HAS NOT BEEN REPORTED BEFORE

Date of diagnosis of other .... - .... -..... ..... ☐ Not applicable
(if applicable) *yyyy mm dd*

Other, specify ……

HAS THE PATIENT UNDERGONE AN ADDITIONAL EPISODE OF IMMUNOSUPPRESSIVE TREATMENT?

☐ No additional therapy except transfusions: *If HSCT registration also, please proceed to "Status at HSCT" on page 8*
If only Immunosuppressive treatment, this is the end of the form

☐Yes

ADDITIONAL IMMUNOSUPPRESSIVE TREATMENT EPISODE

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

SEQUENTIAL NUMBER OF THIS TREATMENT EPISODE: .....

REASON FOR THIS TREATMENT

☐ Failure of first line therapy ☐ Relapse ☐ PR to previous treatment
☐ Secondary clonal disorder ☐ Other ..... ☐ Unknown

HAEMATOLOGICAL VALUES *(Data must have been collected within 3 months prior to the treatment)*

Haemoglobin	.... -	g/dL	☐ Not evaluated	☐ Untransfused	☐ Transfused
Platelets	....	10^9/ L	☐ Not evaluated	☐ Untransfused	☐ Transfused
Neutrophils	....	10^9/ L			
Reticulocytes	....	10^9/ L			
Ferritin	....	ng/ml			

Modality: Chemo/drug/agent

Check at least one

	Origin	**Brand**	**Dose** (*mg/kg*)	**Start date**	**End date**
☐ ATG	☐ horse ☐ rabbit	....	.....	.... - .... - .... *yyyy mm dd*	.... - .... - .... *yyyy mm dd*
☐ Cyclosporin A					
☐ Cyclophosphamide					
☐ Mycophenolate mofetil					
☐ G-CSF					
☐ Erythropoietin					
☐ Corticosteroid					
☐ Androgens					
☐ Rituximab *(Mabthera)*					
☐ Alemtuzumab *(Campath)*					

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

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

☐ Other, specify ……..……

RESPONSE TO THIS IMMUNOSUPPRESSIVE TREATMENT EPISODE

☐ Complete remission ☐ Partial remission *(transfusion and growth factor independent)*
☐ No response ☐ Progression ☐ Not evaluable
☐ Other, specify ……

Date response evaluated .... - .... -..... .....
yyyy mm dd

SECONDARY CLONAL COMPLICATIONS

☐ No
☐ Yes:

FILL ONLY IF MDS HAS NOT BEEN REPORTED BEFORE
Date of diagnosis of MDS .... - .... -..... ..... ☐ Not applicable
(if applicable) *yyyy mm dd*

MDS WHO classification ……

FILL ONLY IF PNH HAS NOT BEEN REPORTED BEFORE
Date of diagnosis of PNH .... - .... -..... ..... ☐ Not applicable
(if applicable) *yyyy mm dd*

PNH diagnostics by flow cytometry ☐ Clone absent
☐ Clone present Size of the PNH clone in % :.....
☐ Not evaluated

Flow cytometry assessment done on:
☐ Granulocytes ☐ RBC ☐ Both
☐ Other, specify .....

PNH diagnostics by other test, specify:..... ☐ Clone absent
(if type of test unknown, write "unknown" here) ☐ Clone present
☐ Not done

Clinical manifestations of PNH ☐ No ☐ Yes

FILL ONLY IF THIS DIAGNOSIS HAS NOT BEEN REPORTED BEFORE
Date of diagnosis of other .... - .... -..... ..... ☐ Not applicable
(if applicable) *yyyy mm dd*

Other, specify ……..……

HAS THE PATIENT UNDERGONE AN ADDITIONAL EPISODE OF IMMUNOSUPPRESSIVE TREATMENT?

☐ No additional therapy except transfusions: *If HSCT registration also, please proceed to "Status at HSCT" on page 8*
If only Immunosuppressive treatment, this is the end of the form

☐Yes *Photocopy or reprint the* **ADDITIONAL IMMUNOSUPPRESSIVE TREATMENT EPISODE** *section and fill it in as many times as required.*

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

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

STATUS AT HSCT

Fill in only if this is an HSCT report, otherwise report a Follow Up Form for the IS only patient

Date of HSCT .... - .... - ....
yyyy mm dd

CYTOGENETICS

If done: Technique used ☐ Conventional ☐ FISH ☐ Both

☐ Normal: Number of metaphases examined: .....

☐ Abnormal: Number of metaphases with anomalies: .....

& Number of metaphases examined: .....

If abnormal, indicate abnormalities found:

trisomy 8 ☐ Absent ☐ Present

trisomy 3 *(for Fanconi)* ☐ Absent ☐ Present

☐ Other or associated abnormalities (specify).....……

.....…… .....……

☐ Not done or failed

☐ Unknown

HAEMATOLOGICAL VALUES

Haemoglobin	.... -	g/dL	☐ Not evaluated	☐ Untransfused	☐ Transfused
Platelets	....	10^9/ L	☐ Not evaluated	☐ Untransfused	☐ Transfused
Neutrophils	....	10^9/ L			
Reticulocytes	....	10^9/ L			
Ferritin	....	ng/ml			

COMPLICATIONS

Haemorrhages	☐ Yes	☐ No	☐ Not evaluated	☐ Unknown
Resistance to random platelets	☐ Yes	☐ No	☐ Not evaluated	☐ Unknown
Systemic infection	☐ Yes	☐ No	☐ Not evaluated	☐ Unknown

PNH TESTS

(To be filled in only for Aplastic anaemia or PNH at diagnosis)

Date of test .... - .... -..... .....
yyyy mm dd

PNH diagnostics by flow cytometry

If done: ☐ Cone absent
☐ Clone present Size of the PNH clone in % _____

Assessed on: ☐ Granulocytes ☐ RBC ☐ Both
☐ Other, specify ..... ☐ Not done

PNH diagnostics by other test ☐ Clone absent
Specify test :..... ☐ Clone present
(if type of test unknown, write "unknown" here) ☐ Not done

Clinical manifestations ☐ No ☐ Yes

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

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

NUMBER OF TRANSFUSIONS FROM DIAGNOSIS

Report all transfusions including those reported prior to the first immunosuppressive treatment if applicable

RBC ☐ <20 units ☐ 20-50 units ☐ >50 units ☐ None ☐ unknown

RBC irradiated ☐ No ☐ Yes ☐ unknown

Platelets ☐ <20 units ☐ 20-50 units ☐ >50 units ☐ None ☐ unknown

Platelets irradiated ☐ No ☐ Yes ☐ 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

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

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

DAY 100

MED-B
BONE MARROW FAILURE SYNDROME
(INCLUDING APLASTIC ANAEMIA)

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: .... - .... - ....
(if applicable) *yyyy mm dd*

BEST DISEASE RESPONSE AT 100 DAYS POST-HSCT

BEST RESPONSE AT 100 DAYS AFTER HSCT

☐ Complete remission ☐ Partial remission *(transfusion and growth factor independent)*
☐ No response ☐ Progression ☐ Not evaluable
☐ Other, specify ……

Date response evaluated .... - .... -..... .....
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**

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

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

FOLLOW UP	**MED-B** **BONE MARROW FAILURE SYNDROME** **(INCLUDING APLASTIC ANAEMIA)**

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: .... - .... - ....
(if applicable) *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

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

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

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		

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

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

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*

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

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

EVENTS SINCE LAST FOLLOW UP

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

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

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

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 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.

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 DLI only	
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 any non DLI infusion	
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 / 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): …….

ADDITIONAL IMMUNOSUPPRESSIVE *(DISEASE)* TREATMENT *(apart from donor cell infusion or other type of cell therapy)*

☐ No additional therapy except transfusions *Proceed to "First evidence of disease worsening" on page 19*

☐ Yes: ☐ Planned *(planned before HSCT took place)*

☐ Not planned *(for relapse/progression or persistent disease)*

FIRST IMMUNOSUPPRESSIVE TREATMENT EPISODE FOR THIS FOLLOW UP

SEQUENTIAL NUMBER OF THIS IMMUNOSUPPRESSIVE TREATMENT EPISODE: .....

REASON FOR THIS TREATMENT

☐ Failure of previous treatment ☐ Relapse ☐ PR to previous treatment
☐ Secondary clonal disorder ☐ Other ..... ☐ Unknown

NUMBER OF TRANSFUSIONS FROM LAST REPORT

RBC ☐ <20 units ☐ 20-50 units ☐ >50 units ☐ None ☐ unknown
RBC irradiated ☐ No ☐ Yes ☐ unknown

Platelets ☐ <20 units ☐ 20-50 units ☐ >50 units ☐ None ☐ unknown
Platelets irradiated ☐ No ☐ Yes ☐ unknown

HAEMATOLOGICAL VALUES *(Data must have been collected within 3 months prior to the treatment)*

Haemoglobin	.... - ..... g/dL	☐ Not evaluated	☐ Untransfused	☐ Transfused
Platelets	.... 10^9/ L	☐ Not evaluated	☐ Untransfused	☐ Transfused
Neutrophils	.... 10^9/ L			
Reticulocytes	.... 10^9/ L			
Ferritin	.... ng/ml			

Chemo/drug/agent *Check at least one*

	Origin	**Brand**	**Dose** (*mg/kg*)	**Start date**	**End date**
☐ ATG	☐ horse ☐ rabbit	....		.... - .... - .... *yyyy mm dd*	.... - .... - .... *yyyy mm dd*
☐ Cyclosporin A					
☐ Cyclophosphamide					
☐ Mycophenolate mofetil					
☐ G-CSF					
☐ Erythropoietin					
☐ Corticosteroid					
☐ Androgens					
☐ Rituximab *(Mabthera)*					
☐ Alemtuzumab *(Campath)*					
☐ Other, specify ……					

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

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

RESPONSE TO THIS IMMUNOSUPPRESSIVE TREATMENT EPISODE

☐ Complete remission ☐ Partial remission *(transfusion and growth factor independent)*
☐ No response ☐ Progression ☐ Not evaluable
☐ Other, specify ……

Date response evaluated .... - .... -..... .....
yyyy *mm* *dd*

HAS THE PATIENT UNDERGONE AN ADDITIONAL EPISODE OF IMMUNOSUPPRESSIVE TREATMENT?

☐ No additional therapy except transfusions
☐ Yes *Photocopy or reprint the* **FIRST IMMUNOSUPPRESSIVE TREATMENT EPISODE FOR THIS FOLLOW UP** *section and fill it in as many times as required.*

FIRST EVIDENCE OF DISEASE WORSENING SINCE LAST HSCT

RELAPSE OR PROGRESSION

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

LAST DISEASE AND PATIENT STATUS

LAST DISEASE STATUS

- ☐ Stable disease / No response
- ☐ Complete Remission
- ☐ Partial Remission
- ☐ Relapse/Progression

PNH TESTS

(To be filled in only for Aplastic anaemia or PNH at diagnosis)

Date of PNH test .... - .... -..... .....
yyyy mm dd

Size of the PNH clone in % :.....

Flow cytometry assessment done on:

- ☐ Granulocytes ☐ RBC ☐ Both
- ☐ Other, specify ..... ☐ Not done

Clinical manifestations of PNH ☐ No ☐ Yes

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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