EBMT FORM GENERAL INFORMATION

TEAM

EBMT Centre Identification Code (CIC) ....

Hospital .... Unit ....

Contact person: ....

Telephone .... Fax ....

e-mail ....

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

UBMID *(only if data is to be sent to CIBMTR):*___________

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 Patient Number ....

Registrations will not be accepted if this item is left blank

Initials .... (first name(s) – surname(s))

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

Sex: ☐ Male ☐ Female

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
- ☐ Myelogenous (AML)
- ☐ Lymphoblastic (ALL)

☐ Secondary Acute Leukaemia
(do not use if transformed from MDS/MPS)

☐ Chronic Leukaemia
- ☐ Chronic Myeloid Leukaemia (CML)
- ☐ Chronic Lymphocytic Leukaemia

☐ Lymphoma
- ☐ Non Hodgkin
- ☐ Hodgkin's Disease

☐ Myeloma /Plasma cell disorder

☐ Solid Tumour

☐ Myelodyspl. / myeloprolifer. syndrome
- ☐ MDS
- ☐ MPS
- ☐ MD/MPS

☐ Aplastic anaemia

☐ Inherited disorders
- ☐ Primary immune deficiencies
- ☐ Metabolic disorders

☐ Hystiocytic disorders

☐ Autoimmune disease
- ☐ Juvenile Idiopathic Arthritis
- ☐ Multiple Sclerosis
- ☐ Rheumatoid Arthritis
- ☐ Systemic Lupus
- ☐ Systemic Sclerosis

☐ Haemoglobinopathy

☐ Other diagnosis, specify:___________________________________

SPECIFICATIONS OF THE DISEASE

INHERITED DISORDERS

INITIAL DIAGNOSIS

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

☐ Yes: go to “Status of Disease at HSCT” on page 3 ☐ No: proceed with this section

CLASSIFICATION

☐ **Primary immune deficiencies**

SCID *(Severe Combined Immune Deficiency)*

T- B- CELLS SCID

- ☐ Artemis
- ☐ Ligase IV
- ☐ Rag-1 or Rag-2
- ☐ T- B- cells SCID, other
- ☐ T- B- cells SCID, unspecified

T- B+ CELLS SCID

- ☐ γc
- ☐ JAK 3
- ☐ IL-7R alpha
- ☐ T- B+ cells SCID, other (CD45, CD3 δ, ε)
- ☐ T- B+ cells SCID, unspecified

☐ ADA

☐ PNP

☐ Reticular dysgenesis

☐ SCID other, specify: ....

CID *(Combined Immune Deficiency)*

- ☐ Omenn syndrome

☐ CID other, specify: ....

Other primary immune deficiencies

- ☐ Agranulocytosis (Kostmann)
- ☐ Ataxia telangiectasia
- ☐ Bare lymphocyte syndrome (lack of HLA ag expression)
- ☐ Cartilage hair hypoplasia / dyskeratosis congenita
- ☐ CD40 Ligand
- ☐ Chediak-Higashi syndrome
- ☐ Chronic granulomatous disease
- ☐ DiGeorge syndrome
- ☐ Familial lymphohistiocytosis
- ☐ Griscelli syndrome
- ☐ Interferon γ
- ☐ IPEX syndrome
- ☐ Leukocyte adhesion
- ☐ Wiskott Aldrich syndrome
- ☐ X-linked lymphoproliferative syndrome (Purtilo)

☐ Inherited disorders of metabolism

☐ Adrenoleukodystrophy	☐ Metachromatic leukodystrophy
☐ Aspartyl glucosaminuria	☐ Morquio (IV)
☐ B-glucuronidase deficiency (VII)	☐ Mucolipidoses, not otherwise specified
☐ Fucosidosis	☐ Mucopolysaccharidosis (V)
☐ Gaucher disease	☐ Mucopolysaccharidosis, not otherwise specified
☐ Glucose storage disease	☐ Niemann-Pick disease
☐ Hunter syndrome (II)	☐ Neuronal ceriod – lipofuscinosis (Batten disease)
☐ Hurler syndrome (IH)	☐ Polysaccharide hydrolase abnormalities, unspecified
☐ I-cell disease	☐ Sanfilippo (III)
☐ Krabbe disease (globoid leukodystrophy)	☐ Scheie syndrome (IS)
☐ Lesch-Nyhan (HGPRT deficiency)	☐ Wolman disease
☐ Mannosidosis	☐ Other, specify: ....
☐ Maroteaux-Lamy (VI)	

☐ Other inherited disorders

- ☐ Glanzmann
- ☐ Platelet defect, not otherwise specified
- ☐ Osteopetrosis
- ☐ Osteoclast defect, not otherwise specified
- ☐ Other, specify ....

Stored material ☐ No

☐ Yes:

DNA	☐ No	☐ Yes
PBL	☐ No	☐ Yes
B-cell line	☐ No	☐ Yes
Fibroblasts	☐ No	☐ Yes

Other, specify ....

☐ Unknown

INHERITANCE

Tick only one

☐ Autosomal recessive proven ☐ Autosomal recessive suspected

☐ X-linked proven ☐ X-linked suspected ☐ unknown

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

CYTOGENETICS

Chromosome analysis

☐ Normal ☐ Abnormal ☐ Not done or failed ☐ Unknown

Complete only for SCID patients.

If abnormal:
Mutations

☐ γc ☐ JAK 3 ☐ Rag-1 ☐ Rag-2 ☐ ADA
☐ other: ....

Description NUCLEOTIDES *(in clear text)*
Allele 1* ....
Allele 2 ....
PROTEIN *(in clear text)*
Allele 1* ....
Allele 2 ....

**For* γc, *use Allele 1 only*

STATUS OF DISEASE AT HSCT

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

HAEMATOLOGICAL VALUES

Platelets (10^9/L) ....
(non transfused values)
White Blood Cells (10^9/L) ....
Lymphocytes (10^9/L) ....
T cells (CD3+) (10^9/L) ....
CD4+ cells (10^9/L) ....
CD8+ cells (10^9/L) ....
NK cells (CD56+) (10^9/L) ....
B cells (10^9/L) ....
Granulocytes (10^9/L) ....
Reticulocytes (10^9/L) ....

T-CELL FUNCTION

Mixed leukocyte culture (MLC) reactivity

☐ Absent ☐ Partial ☐ Normal ☐ Not evaluated

Mitogen induced lymphocyte proliferation

☐ Absent ☐ Partial ☐ Normal ☐ Not evaluated

Natural killer activity

☐ Absent ☐ Partial ☐ Normal ☐ Not evaluated

IMMUNOGLOBULINS (B-CELL FUNCTION)

Serum IgM (g/L) .... ☐ Not evaluated

Serum IgA (g/L) .... ☐ Not evaluated

Serum IgG (g/L) .... ☐ Not evaluated

Serum IgE (g/L) .... ☐ Not evaluated

Isohemaglutinin ☐ Absent ☐ Decreased ☐ Normal or elevated ☐ Not evaluated

Antibody response
☐ Absent ☐ Decreased ☐ Normal or elevated ☐ Not evaluated

CLINICAL STATUS

GENERAL MANIFESTATIONS

Renal impairment ☐ No ☐ Yes ☐ Not evaluated ☐ Unknown

Malnutrition ☐ No ☐ Yes ☐ Not evaluated ☐ Unknown

Protracted diarrhea ☐ No ☐ Yes ☐ Not evaluated ☐ Unknown

Respiratory impairment ☐ No ☐ Yes ☐ Not evaluated ☐ Unknown

Liver impairment ☐ No ☐ Yes ☐ Not evaluated ☐ Unknown

INFECTIONS ☐ No ☐ Yes ☐ Unknown

If yes:

SITE	PATHOGEN
Septicemia	☐ Mycobacteria ☐ Bacteria, other ☐ Pneumocystis carinii ☐ Cryptosporidia ☐ Fungi, other ☐ Virus ☐ Other .... ☐ Unknown
Pulmonary	☐ Mycobacteria ☐ Bacteria, other ☐ Pneumocystis carinii ☐ Cryptosporidia ☐ Fungi, other ☐ Virus ☐ Other .... ☐ Unknown
Meningeal	☐ Mycobacteria ☐ Bacteria, other ☐ Pneumocystis carinii ☐ Cryptosporidia ☐ Fungi, other ☐ Virus ☐ Other .... ☐ Unknown
Skin infection	☐ Mycobacteria ☐ Bacteria, other ☐ Pneumocystis carinii ☐ Cryptosporidia ☐ Fungi, other ☐ Virus ☐ Other .... ☐ Unknown
Liver	☐ Mycobacteria ☐ Bacteria, other ☐ Pneumocystis carinii ☐ Cryptosporidia ☐ Fungi, other ☐ Virus ☐ Other .... ☐ Unknown
Bone or joints	☐ Mycobacteria ☐ Bacteria, other ☐ Pneumocystis carinii ☐ Cryptosporidia ☐ Fungi, other ☐ Virus ☐ Other .... ☐ Unknown
Gut infection	☐ Mycobacteria ☐ Bacteria, other ☐ Pneumocystis carinii ☐ Cryptosporidia ☐ Fungi, other ☐ Virus ☐ Other .... ☐ Unknown

SITE	PATHOGEN		
Undetermined	☐ Mycobacteria ☐ Pneumocystis carinii ☐ Virus ☐ Other	☐ Bacteria, other ☐ Cryptosporidia	 ☐ Fungi, other ☐ Unknown
Other:	☐ Mycobacteria ☐ Pneumocystis carinii ☐ Virus ☐ Other	☐ Bacteria, other ☐ Cryptosporidia	 ☐ Fungi, other ☐ Unknown

GVHD STATUS PRIOR TO HSCT

☐ Absent ☐ Present ☐ Not evaluated ☐ Unknown

If present:

Manifestation

Organ affected ☐ Gut ☐ Liver ☐ Skin

Lymphadenopathy ☐ No ☐ Yes ☐ Unknown

Cause of the GvHD ☐ Blood transfusion
☐ Maternal engraftment: Number of maternal T cells . ... 10^9/L
Test used ☐ HLA typing
☐ Microsatellite
☐ IL2 T cell line
☐ Unknown ☐ Cytogenetics

Treatment

☐ No ☐ Yes ☐ Unknown

NUMBER OF TRANSFUSIONS BEFORE HSCT

	NONE	< 20 UNITS	20-50 UNITS	> 50 UNITS	UNKNOWN
RBC	☐	☐	☐	☐	☐
Platelets	☐	☐	☐	☐	☐

Non irradiated products infused ☐ No ☐ Yes ☐ Unknown

ADDITIONAL TREATMENT POST-HSCT

ADDITIONAL DISEASE TREATMENT

☐ No
☐ Yes: ☐ Planned *(planned before HSCT took place)*
☐ Not planned *(for relapse/progression or persistent disease)*

BEST DISEASE RESPONSE AT 100 DAYS POST-HSCT

DISEASE STATUS AT 100 DAYS AFTER HSCT

☐ Cured ☐ Improved ☐ No change ☐ Worse ☐ Unknown

Date of assessment ....……. - .... - .... *(As close to the 3rd month interval as possible)*
yyyy mm dd

RECONSTITUTION

CHIMAERISM (*ENGRAFTMENT*)

T-cell ☐ Full: Date achieved ....……. - .... - ....
yyyy mm dd
☐ Mixed ☐ Absent ☐ Not evaluated

B-cell ☐ Full ☐ Partial ☐ Absent ☐ Not evaluated
Granulocyte ☐ Full ☐ Partial ☐ Absent ☐ Not evaluated
Monocyte ☐ Full ☐ Partial ☐ Absent ☐ Not evaluated
Red cell ☐ Full ☐ Partial ☐ Absent ☐ Not evaluated
Platelets ☐ Full ☐ Partial ☐ Absent ☐ Not evaluated

Overall engraftment*:* ☐ Full ☐ Partial ☐ Absent

HAEMATOLOGICAL RECONSTITUTION

Haemoglobin (g/dL) ....
Platelets (10^9/L) ....
T-cells (CD3+) (10^9/L) ....
B-cells (10^9/L) ....
Granulocytes (10^9/L) ....

IMMUNOLOGICAL RECONSTITUTION

T-cells

Mixed leukocyte culture (MLC) reactivity
☐ Absent ☐ Partial ☐ Normal ☐ Not evaluated

Mitogen induced lymphocyte proliferation
☐ Absent ☐ Partial ☐ Normal ☐ Not evaluated

B-cells

Serum IgM (g/L) .... ☐ Not evaluated
Serum IgA (g/L) .... ☐ Not evaluated
Serum IgG (g/L) .... ☐ Not evaluated
Serum IgE (g/L) .... ☐ Not evaluated

Antibody production after vaccination
☐ Absent ☐ Decreased ☐ Normal or elevated ☐ Not evaluated

ON-GOING TREATMENT FOR RECONSTITUTION AT 100 DAYS

☐ No

☐ Yes: Patient still receiving IV Immunoglobulins ☐ No ☐ Yes ☐ Unknown

Growth factors (cytokines) administered to the patient? ☐ No ☐ Yes ☐ Unknown

☐ Unknown

FORMS TO BE FILLED IN

TYPE OF HSCT *(CHECK ALL THAT APPLY)*:

☐ AUTOgraft, proceed to Autograft form

☐ ALLOgraft or Syngeneic graft, proceed to Allograft form

If ☐ Cord Blood, fill in also section in Forms Appendix

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

FOLLOW UP INHERITED DISORDERS

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

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

PATIENT LAST SEEN

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

COMPLICATIONS SINCE LAST REPORT

PLEASE USE THE DOCUMENT "DEFINITIONS OF INFECTIOUS DISEASES AND COMPLICATIONS AFTER STEM CELL TRANSPLANTATION" TO FILL THESE ITEMS. THE DOCUMENT IS AVAILABLE FROM **www.ebmt.org**, ***INFECTIOUS DISEASES WORKING PARTY.***

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		

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.*
ENDORGAN DISEASES		
Pneumonia		
Hepatitis		
CNS infection		
Gut infection		
Skin infection		
Cystitis		
Retinitis		
Other:		
		yyyy mm dd

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

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

NON INFECTION RELATED COMPLICATIONS

☐ No complications
☐ Yes

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

GRAFT ASSESSMENT AND HAEMOPOIETIC CHIMAERISM

GRAFT LOSS (EQUIVALENT TO APLASIA IF AUTO)

☐ No: If allo: Date graft assessed …..... .. …..... - ….... ... - …......
yyyy mm dd

Chimaerism: ☐ Full ☐ Mixed: % donor cells ....

Method used for chimaerism: ☐ FISH ☐ Molecular
(check all that apply) ☐ Cytogenetic ☐ ABO Group

☐ Yes: Date graft loss …..….... …..... - ……….... - …......
yyyy mm dd

If allo: ☐ Aplasia ☐ Autologous reconstitution

☐ Not evaluated

CHRONIC GRAFT VERSUS HOST DISEASE (cGvHD)

(allografts only)

Presence of cGvHD

☐ No

☐ Yes: ☐ First episode
☐ Recurrence

Date of onset of this episode: .... - .... - ....
yyyy mm dd

☐ Present continuously since last reported episode

cGvHD grade ☐ Limited ☐ Extensive

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

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

SECONDARY MALIGNANCY, LYMPHOPROLIFERATIVE OR MYELOPROLIFRATIVE DISORDER DIAGNOSED

☐ Previously reported

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

Diagnosis: ☐ AML ☐ MDS ☐ EBV lymphoproliferative disorder ☐ Other ....

☐ No at date of this follow-up

ADDITIONAL THERAPIES SINCE LAST FOLLOW UP

Treatment given since last report

☐ No

☐ Yes: Date started: ....
yyyy mm dd

☐ Unknown

If yes:

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

If yes:
Type of cells

☐ Donor lymphocyte infusion (DLI)

☐ Mesenchymal 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 / transplant)*:

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

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

☐ No
☐ Yes: ☐ Planned *(planned before HSCT took place)*
☐ Not planned *(for relapse/progression or persistent disease)*

LAST DISEASE AND PATIENT STATUS

LAST DISEASE STATUS

- ☐ Cured
- ☐ Improved
- ☐ Unchanged
- ☐ Worse

CONCEPTION

Has patient or partner become pregnant after this HSCT?

☐ Yes ☐ No ☐ 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

CAUSE OF DEATH *(if dead)*

- ☐ Relapse or progression
- ☐ Secondary malignancy
- ☐ HSCT related cause :

(check as many as appropriate)

	Yes	No	Unknown
GvHD	☐	☐	☐
Interstitial pneumonitis	☐	☐	☐
Pulmonary toxicity	☐	☐	☐
Infection: ☐ bacterial ☐ viral ☐ fungal ☐ parasitic ☐ unknown	☐	☐	☐
Rejection / poor graft function	☐	☐	☐
Veno-Occlusive disease (VOD)	☐	☐	☐
Haemorrhage	☐	☐	☐
Cardiac toxicity	☐	☐	☐
Central nervous system toxicity	☐	☐	☐
Gastro intestinal toxicity	☐	☐	☐
Skin toxicity	☐	☐	☐
Renal failure	☐	☐	☐
Multiple organ failure	☐	☐	☐
EBV lymphoproliferative disease	☐	☐	☐
Other:	☐		

- ☐ Unknown
- ☐ Other : ....

....

ADDITIONAL NOTES IF APPLICABLE

COMMENTS ....

....

....

IDENTIFICATION & SIGNATURE

....