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 Patient 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 not 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 JUVENILE IDIOPATHIC ARTHRITIS (JIA)

Name of Referring Physician _____
Address_____
Fax_____Email_____

INITIAL DIAGNOSIS

Has the information requested in this section been submitted with a previous transplant registration?
☐ Yes: proceed to "Status of disease at mobilisation" on page 4 ☐ No: proceed with this section

SUBCLASSIFICATION AT DIAGNOSIS

☐ Juvenile idiopathic arthritis (JIA), systemic (Stills disease)
☐ Juvenile idiopathic arthritis (JIA), articular: Onset ☐ Oligoarticular
☐ Polyarticular
☐ Juvenile idiopathic arthritis: other, specify:_____

COURSE OF THE DISEASE UNTIL MOBILISATION/TRANSPLANT

(At any time between diagnosis and mobilisation/transplant)

DISEASE STATUS

Systemic JIA with polyarticular course: ☐ No ☐ Yes ☐ Not evaluated ☐ Unknown

Schneider criteria fulfilled? ☐ No ☐ Yes: ☐ Only at diagnosis
- persistent thrombocytosis ☐ At diagnosis and after
- corticosteroids to control fever ☐ Only after
☐ Not evaluated ☐ Unknown

Disease progression on therapy ☐ No ☐ Yes ☐ Not evaluated ☐ Unknown

Corticosteroid dependency to control disease ☐ No ☐ Yes ☐ Not evaluated ☐ Unknown

LABORATORY DATA

Erythrocyte sedimentation rate ..... mm/hr ☐ Not evaluated ☐ Unknown

C-reactive protein ☐ Normal ☐ Elevated

AUTOANTIBODIES

Were tests for autoantibodies done between diagnosis and mobilisation/transplant?
☐ No ☐ Yes ☐ Unknown

Specify antibody:

Anti-nuclear (ANA) ☐ Negative ☐ Positive ☐ Not evaluated ☐ Unknown

Rheumatoid factor ☐ Negative ☐ Positive ☐ Not evaluated ☐ Unknown

Other, specify:_____ ☐ Negative ☐ Positive

FIRST LINE THERAPIES

DISEASE MODIFYING DRUGS AND IMMUNOSUPPRESSANTS

☐ No – *Proceed to "Date of HSCT"*

☐ Yes:

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

☐ Yes, mark appropriate box(es) ☐ Cyclophosphamide ☐ Cyclosporin-A
☐ Methotrexate ☐ Corticosteroids
☐ Non-steroidal anti-inflammatory (NSAIDS)
☐ Anti tumour necrosis factor (*Etarnercept*)
☐ Other drug or agent _____

☐ Unknown

Other treatment ☐ No ☐ Yes: _____ ☐ Unknown

COMPLICATIONS DUE TO TOXICITY FROM CONVENTIONAL TREATMENT

☐ No complications

☐ Yes:

Cataracts	☐ No	☐ Yes	☐ Unknown
Avascular necrosis of femoral head	☐ No	☐ Yes	☐ Unknown
Severe hypertension	☐ No	☐ Yes	☐ Unknown
Renal insufficiency (>30% increase in creatinine)	☐ No	☐ Yes	☐ Unknown
Severe gastrointestinal (GI) toxicity, specify: _____	☐ No	☐ Yes	☐ Unknown
Hepatic dysfunction (≥3 fold increase in liver function tests)	☐ No	☐ Yes	☐ Unknown
Severe gastrointestinal (GI) toxicity, specify: _____	☐ No	☐ Yes	☐ Unknown
Growth delay	☐ No	☐ Yes	☐ Unknown

Other, specify: _____

☐ Unknown

Did severe myelosuppression occurr? ☐ No ☐ Yes ☐ Not evaluated ☐ Unknown

DATE OF HSCT

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

TRANSPLANT TYPE

☐ Allogeneic: *Proceed to* STATUS OF DISEASE AT HSCT *on page 6*

☐ Autologous: Mobilised ☐ No: *Proceed to* STATUS OF DISEASE AT HSCT *on page 6*

☐ Yes: Date of 1st pheresis/collection: .... - .... - ....
yyyy mm dd

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

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

STATUS OF DISEASE AT MOBILISATION

Evaluation should be performed <4 weeks prior to mobilisation for stem cell collection.

DISEASE STATUS

Number of painful/tender joints : ..... ☐ Not evaluated ☐ Unknown
(Eular/ACR 28 joint count, which comprises bilateral shoulders, elbows, wrists, MCPs, PIPs and knees. Appendix B.2)

Number of swollen/effused joints : ..... ☐ Not evaluated ☐ Unknown
(Eular/ACR 28 joint count, see above)

Pediatric EPM-Range of motion final score (0-3) : ..... -..... ☐ Not evaluated ☐ Unknown
(Appendix B.3)

Was morning stiffness present?
☐ Yes, specify duration: ..... hours ..... minutes ☐ No ☐ Not evaluated ☐ Unknown

Patient's weight: ..... Kg ☐ Not evaluated ☐ Unknown
Patient's height: ..... cm ☐ Not evaluated ☐ Unknown

Patient's weight **one year** prior to time of mobilisation: ..... Kg ☐ Not evaluated ☐ Unknown
Patient's height **one year** prior to time of mobilisation: ..... cm ☐ Not evaluated ☐ Unknown

HAEMATOLOGICAL VALUES

Haemoglobin	.....	g/dL	☐ Not evaluated	☐ Unknown
Erythrocyte sedimentation rate	.....	mm/hr	☐ Not evaluated	☐ Unknown
Platelets:	.....	(10^9/ l)	☐ Not evaluated	☐ Unknown
WBC	..... -	(10^9/ l)	☐ Not evaluated	☐ Unknown
DIFFERENTIAL:				
Segs: %	..... -		☐ Not evaluated	☐ Unknown
Bands: %	..... -		☐ Not evaluated	☐ Unknown
Lymphocytes: %	..... -		☐ Not evaluated	☐ Unknown
Basophils: %	..... -		☐ Not evaluated	☐ Unknown
Monocytes: %	..... -		☐ Not evaluated	☐ Unknown
Eosinophils: %	..... -		☐ Not evaluated	☐ Unknown

CLINICAL AND LABORATORY DATA

Serum creatinine	..... -	µmol/l	☐ Not evaluated	☐ Unknown
Serum AST	.....	(IU/l)	☐ Not evaluated	☐ Unknown
Serum ALT	.....	(IU/l)	☐ Not evaluated	☐ Unknown
Serum albumin	.....	(g/dl)	☐ Not evaluated	☐ Unknown
Serum alkaline phosphatase	.....	(IU/l)	☐ Not evaluated	☐ Unknown
Total serum bilirubin	.....	(mg/dl)	☐ Not evaluated	☐ Unknown
C-reactive protein	☐ Normal	☐ Elevated	☐ Not evaluated	☐ Unknown

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

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

AUTOANTIBODIES

Were tests for autoantibodies done between diagnosis and mobilisation/transplant?

☐ No ☐ Yes ☐ Unknown

Specify antibody:

Anti-nuclear (ANA)	☐ Negative	☐ Positive	☐ Not evaluated	☐ Unknown
Rheumatoid factor	☐ Negative	☐ Positive	☐ Not evaluated	☐ Unknown
Other, specify:_____	☐ Negative	☐ Positive		

RADIOGRAPHIC EVALUATION

Were radiographic bone erosions present? ☐ Negative ☐ Positive ☐ Not evaluated ☐ Unknown

Was advanced skeletal age of affected joints noted radiographically?

☐ No ☐ Yes ☐ Not evaluated ☐ Unknown

Presence of osteoporotic fractures ☐ Never ☐ Previously but not now ☐ Currently ☐ Not evaluated ☐ Unknown

HEALTH ASSESSMENT QUESTIONNAIRE OR SURVEY COMPLETED

☐ No ☐ Yes ☐ unknown

PATIENT'S SELF ASSESSMENT	**Done**	**Not done**	**Unknown**
Childhood Health Assessment Questionnaire (**CHAQ**) completed? *(see Appendix B.4)*	☐	☐	☐

If yes: Specify range of possible scores for the **CHAQ pain** sub-scale:

Patient's score: ..... - .....
Worst possible score: ..... - .....
Best possible score: ..... - .....

Specify range of possible scores for the **CHAQ disability** sub-scale:

Patient's score: ..... - .....
Worst possible score: ..... - .....
Best possible score: ..... - .....

Specify range of possible scores for the **CHAQ severity** sub-scale:

Patient's score: ..... - .....
Worst possible score: ..... - .....
Best possible score: ..... - .....

PHYSICIAN'S ASSESSMENT	**Done**	**Not done**	**Unknown**
Did the physician complete a **Global** Assessment of the patient's state?	☐	☐	☐

If yes: Specify range of possible scores for Physician Rated Global Assessment:

Patient's score: ..... - .....
Worst possible score: ..... - .....
Best possible score: ..... - .....

DISEASE RESPONSE TO THE MOBILISATION

☐ Response ☐ Transient ☐ No response ☐ Not evaluated

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

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

STATUS OF DISEASE AT HSCT

Evaluation should be performed <2 weeks prior to conditioning

DISEASE STATUS

Number of painful/tender joints : ..... ☐ Not evaluated ☐ Unknown
(Eular/ACR 28 joint count, which comprises bilateral shoulders, elbows, wrists, MCPs, PIPs and knees. Appendix B.2)

Number of swollen/effused joints : ..... ☐ Not evaluated ☐ Unknown
(Eular/ACR 28 joint count, see above)

Pediatric EPM-Range of motion final score (0-3) : ..... -..... ☐ Not evaluated ☐ Unknown
(Appendix B.3)

Was morning stiffness present?
☐ Yes, specify duration: ..... hours ..... minutes ☐ No ☐ Not evaluated ☐ Unknown

Patient's weight **one year** prior to time of transplant: ..... Kg ☐ Not evaluated ☐ Unknown
Patient's height **one year** prior to time of transplant: ..... cm ☐ Not evaluated ☐ Unknown

HAEMATOLOGICAL VALUES		**Units**	**Not evaluated**	**Unknown**
Haemoglobin	.....	g/dL	☐ Not evaluated	☐ Unknown
Erythrocyte sedimentation rate	.....	mm/hr	☐ Not evaluated	☐ Unknown
Platelets:	.....	(10^9/ l)	☐ Not evaluated	☐ Unknown
WBC	..... -	(10^9/ l)	☐ Not evaluated	☐ Unknown
DIFFERENTIAL:				
Segs: %	..... -		☐ Not evaluated	☐ Unknown
Bands: %	..... -		☐ Not evaluated	☐ Unknown
Lymphocytes: %	..... -		☐ Not evaluated	☐ Unknown
Basophils: %	..... -		☐ Not evaluated	☐ Unknown
Monocytes: %	..... -		☐ Not evaluated	☐ Unknown
Eosinophils: %	..... -		☐ Not evaluated	☐ Unknown

CLINICAL AND LABORATORY DATA

Serum albumin	.....	(g/dl)	☐ Not evaluated	☐ Unknown
Serum alkaline phosphatase	.....	(IU/l)	☐ Not evaluated	☐ Unknown
C-reactive protein	☐ Normal	☐ Elevated	☐ Not evaluated	☐ Unknown

AUTOANTIBODIES

Were tests for autoantibodies done between diagnosis and mobilisation/transplant?
☐ No ☐ Yes ☐ Unknown

Specify antibody:

Anti-nuclear (ANA)	☐ Negative	☐ Positive	☐ Not evaluated	☐ Unknown
Rheumatoid factor	☐ Negative	☐ Positive	☐ Not evaluated	☐ Unknown
Other, specify:_____	☐ Negative	☐ Positive		

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

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

RADIOGRAPHIC EVALUATION

Were radiographic bone erosions present? ☐ Negative ☐ Positive ☐ Not evaluated ☐ Unknown

Was advanced skeletal age of affected joints noted radiographically?

☐ No ☐ Yes ☐ Not evaluated ☐ Unknown

Presence of osteoporotic fractures ☐ Never ☐ Previously but not now ☐ Currently
☐ Not evaluated ☐ Unknown

HEALTH ASSESSMENT QUESTIONNAIRE OR SURVEY COMPLETED

☐ No ☐ Yes ☐ unknown

PATIENT'S SELF ASSESSMENT	**Done**	**Not done**	**Unknown**
Childhood Health Assessment Questionnaire (**CHAQ**) completed? *(see Appendix B.4)*	☐	☐	☐

If yes: Specify range of possible scores for the **CHAQ pain** sub-scale:

Patient's score: ..... - .....
Worst possible score: ..... - .....
Best possible score: ..... - .....

Specify range of possible scores for the **CHAQ disability** sub-scale:

Patient's score: ..... - .....
Worst possible score: ..... - .....
Best possible score: ..... - .....

Specify range of possible scores for the **CHAQ severity** sub-scale:

Patient's score: ..... - .....
Worst possible score: ..... - .....
Best possible score: ..... - .....

PHYSICIAN'S ASSESSMENT	**Done**	**Not done**	**Unknown**
Did the physician complete a **Global** Assessment of the patient's state?	☐	☐	☐

If yes: Specify range of possible scores for Physician Rated Global Assessment:

Patient's score: ..... - .....
Worst possible score: ..... - .....
Best possible score: ..... - .....

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 JUVENILE IDIOPATHIC ARTHRITIS (JIA)

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

BEST DISEASE STATUS AT 100 DAYS AFTER TRANSPLANTATION

To be completed 100 days post transplant, or at time of death if death occurred <100 days post transplant, or immediately prior to start of high-dose therapy (conditioning) for second transplant if second transplant done <100 days after first transplant.

☐ Response ☐ Transient ☐ No response ☐ Not evaluated

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

DISEASE STATUS

Number of painful/tender joints : ..... ☐ Not evaluated ☐ Unknown
(Eular/ACR 28 joint count, which comprises bilateral shoulders, elbows, wrists, MCPs, PIPs and knees. Appendix B.2)

Number of swollen/effused joints : ..... ☐ Not evaluated ☐ Unknown
(Eular/ACR 28 joint count, see above)

Pediatric EPM-Range of motion final score (0-3) : ..... -..... ☐ Not evaluated ☐ Unknown
(Appendix B.3)

Was morning stiffness present?
☐ Yes, specify duration: ..... hours ..... minutes ☐ No ☐ Not evaluated ☐ Unknown

Patient's weight: ..... Kg ☐ Not evaluated ☐ Unknown

Patient's height: ..... cm ☐ Not evaluated ☐ Unknown

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

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

CLINICAL AND LABORATORY DATA

Erythrocyte sedimentation rate ..... mm/hr ☐ ☐

C-reactive protein ☐ Normal ☐ Elevated ☐ ☐

RADIOGRAPHIC EVALUATION

Were radiographic bone erosions present? ☐ Negative ☐ Positive ☐ Not evaluated ☐ Unknown

Was advanced skeletal age of affected joints noted radiographically?

☐ No ☐ Yes ☐ Not evaluated ☐ Unknown

Presence of osteoporotic fractures ☐ Never ☐ Previously but not now ☐ Currently
☐ Not evaluated ☐ Unknown

HEALTH ASSESSMENT QUESTIONNAIRE OR SURVEY COMPLETED

PATIENT'S SELF ASSESSMENT	**Done**	**Not done**	**Unknown**
Childhood HEALTH ASSESSMENT QUESTIONNAIRE (CHAQ) completed? *(see Appendix B.4)*	☐	☐	☐

If yes: Specify range of possible scores for the CHAQ PAIN sub-scale:

Patient's score: ..... - .....
Worst possible score: ..... - .....
Best possible score: ..... - .....

Specify range of possible scores for the CHAQ DISABILITY sub-scale:

Patient's score: ..... - .....
Worst possible score: ..... - .....
Best possible score: ..... - .....

Specify range of possible scores for the CHAQ SEVERITY sub-scale:

Patient's score: ..... - .....
Worst possible score: ..... - .....
Best possible score: ..... - .....

PHYSICIAN'S ASSESSMENT	**Done**	**Not done**	**Unknown**
Did the physician complete a GLOBAL ASSESSMENT of the patient's state?	☐	☐	☐

If yes: Specify range of possible scores for PHYSICIAN RATED GLOBAL ASSESSMENT:

Patient's score: ..... - .....
Worst possible score: ..... - .....
Best possible score: ..... - .....

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 JUVENILE IDIOPATHIC ARTHRITIS (JIA)**

Please use this form for annual follow up only and not data at 100 days, which is already included in the first report

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

GRAFT VERSUS HOST DISEASE (GvHD) SINCE LAST REPORT

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	☐ 1	☐ 2	☐ 3	☐ 4	☐ Not evaluated	☐ unknown
Stage liver	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ Not evaluated	☐ unknown
Stage gut	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ Not evaluated	☐ unknown

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

LATE GRAFT FAILURE ☐ No ☐ Yes

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
(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 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 .....

Is this secondary malignancy a donor cell leukaemia**?** ☐ No ☐ Yes ☐ Not applicable

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

A boost is an infusion of cells from the same donor without conditioning, in the presence of engraftment (neutrophils > 5 x 10e9), with the same donor being present in a proportion higher than 10%

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	
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 / HSCT)*:

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

ADDITIONAL DISEASE TREATMENT FOR JIA

☐ No *Proceed to* FIRST EVIDENCE OF DISEASE WORSENING SINCE LAST HSCT
☐ Yes: ☐ Preemptive / preventive *(planned before the transplant took place)*
☐ For relapse / progression or persistent disease *(not planned)*

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

Drugs or agents:

☐ No
☐ Yes, mark appropriate box(es)

Cyclophosphamide ☐
Cyclosporin-A ☐
Methotrexate ☐
Corticosteroids ☐
Non-steroidal anti-inflammatory (NSAIDS) ☐
Anti tumour necrosis factor (*Etarnercept*) ☐
Other drug or agent ☐ _____

☐ Unknown

Other treatment ☐ No ☐ Yes: _____ ☐ 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

LAST DISEASE AND PATIENT STATUS

DISEASE STATUS

Fill in this section only if the evaluation has been performed less than 2 weeks prior to the* DATE OF LAST CONTACT OR DEATH *in this form.

Number of painful/tender joints : ..... ☐ Not evaluated ☐ Unknown
(Eular/ACR 28 joint count, which comprises bilateral shoulders, elbows, wrists, MCPs, PIPs and knees. Appendix B.2)

Number of swollen/effused joints : ..... ☐ Not evaluated ☐ Unknown
(Eular/ACR 28 joint count, see above)

Pediatric EPM-Range of motion final score (0-3) : ..... -..... ☐ Not evaluated ☐ Unknown
(Appendix B.3)

Was morning stiffness present?
☐ Yes, specify duration: ..... hours ..... minutes ☐ No ☐ Not evaluated ☐ Unknown

Patient's weight: ..... Kg ☐ Not evaluated ☐ Unknown

Patient's height: ..... cm ☐ Not evaluated ☐ Unknown

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

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

CLINICAL AND LABORATORY DATA			**Units**	**Not evaluated**	**Unknown**
Erythrocyte sedimentation rate			mm/hr	☐	☐
C-reactive protein	☐ Normal	☐ Elevated		☐	☐

RADIOGRAPHIC EVALUATION

Were radiographic bone erosions present? ☐ Negative ☐ Positive ☐ Not evaluated ☐ Unknown

Was advanced skeletal age of affected joints noted radiographically?

☐ No ☐ Yes ☐ Not evaluated ☐ Unknown

Presence of osteoporotic fractures ☐ Never ☐ Previously but not now ☐ Currently
☐ Not evaluated ☐ Unknown

SURVEYS COMPLETED

☐ No

☐ Yes ***Only if the surveys have been performed less than 2 weeks prior to the* DATE OF LAST CONTACT OR DEATH *in this form.***

☐ unknown

PATIENT'S SELF ASSESSMENT	**Done**	**Not done**	**Unknown**
Childhood HEALTH ASSESSMENT QUESTIONNAIRE (CHAQ) completed? *(see Appendix B.4)*	☐	☐	☐

If yes: Specify range of possible scores for the CHAQ PAIN sub-scale:

Patient's score: ..... - .....
Worst possible score: ..... - .....
Best possible score: ..... - .....

Specify range of possible scores for the CHAQ DISABILITY sub-scale:

Patient's score: ..... - .....
Worst possible score: ..... - .....
Best possible score: ..... - .....

Specify range of possible scores for the CHAQ SEVERITY sub-scale:

Patient's score: ..... - .....
Worst possible score: ..... - .....
Best possible score: ..... - .....

PHYSICIAN'S ASSESSMENT	**Done**	**Not done**	**Unknown**
Did the physician complete a GLOBAL ASSESSMENT of the patient's state?	☐	☐	☐

If yes: Specify range of possible scores for PHYSICIAN RATED GLOBAL ASSESSMENT:

Patient's score: ..... - .....
Worst possible score: ..... - .....
Best possible score: ..... - .....

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

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

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

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