

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 Sex: Male Female
yyyy mm dd

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)

- | | | |
|--|---|---|
| <input type="checkbox"/> Acute Leukaemia
<input type="checkbox"/> Myelogenous (AML)
<input type="checkbox"/> Lymphoblastic (ALL)
<input type="checkbox"/> Secondary Acute Leukaemia
<i>(do not use if transformed from MDS/MPS)</i>
<input type="checkbox"/> Chronic Leukaemia
<input type="checkbox"/> Chronic Myeloid Leukaemia (CML)
<input type="checkbox"/> Chronic Lymphocytic Leukaemia
<input type="checkbox"/> Lymphoma
<input type="checkbox"/> Non Hodgkin
<input type="checkbox"/> Hodgkin's Disease
<input type="checkbox"/> Other diagnosis, specify: _____ | <input type="checkbox"/> Myeloma /Plasma cell disorder
<input type="checkbox"/> Solid Tumour
<input type="checkbox"/> Myelodyspl. / myeloprolifer. syndrome
<input type="checkbox"/> MDS
<input type="checkbox"/> MPS
<input type="checkbox"/> MD/MPS
<input type="checkbox"/> Aplastic anaemia
<input type="checkbox"/> Inherited disorders
<input type="checkbox"/> Primary immune deficiencies
<input type="checkbox"/> Metabolic disorders | <input type="checkbox"/> Histiocytic disorders
<input type="checkbox"/> Autoimmune disease
<input type="checkbox"/> Juvenile Idiopathic Arthritis
<input type="checkbox"/> Multiple Sclerosis
<input type="checkbox"/> Rheumatoid Arthritis
<input type="checkbox"/> Systemic Lupus
<input type="checkbox"/> Systemic Sclerosis
<input type="checkbox"/> Haemoglobinopathy |
|--|---|---|

SPECIFICATIONS
OF THE DISEASE

SYSTEMIC SCLEROSIS

Name of Referring Physician _____

Address _____

Fax _____ Email _____

INITIAL DIAGNOSIS

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

 Yes: proceed to "Date of HSCT" on page 2 No: proceed with this section

MAIN DIAGNOSIS

Extent of cutaneous Systemic Sclerosis at diagnosis:

- Limited (cutaneous thickening distal to elbows or knees, but not proximal)
- Diffuse
- Other

LABORATORY VALUES

Units

Serum creatinine: (µmol/l) Not evaluated unknownCreatinine clearance: (ml/min) Not evaluated unknownCreatinine phosphokinase: (IU/l) Not evaluated unknownProteinuria: Absent Present Not evaluated Unknown

AUTOANTIBODIES

Were tests for autoantibodies done at diagnosis? No Yes Unknown

SPECIFY ANTIBODY:

- Anti-DNA topoisomerase I (Scl-70): Negative Positive Not evaluated unknown
- Anti-centromere (ACA) Negative Positive Not evaluated unknown
- Anti-nuclear (ANA) Negative Positive Not evaluated unknown
- Other, specify..... Negative Positive

FIRST LINE THERAPIES

THERAPIES

No *If allograft, proceed to "Date of HSCT" on page 2*

Yes:

Date started
yyyy mm dd

Chemotherapy No

Yes: Cyclophosphamide Yes: total cumulative dose

Cyclosporine

Methotrexate

Prednisone or equivalent

Mycophenolate Mofetil

Tacrolimus/FK506

D-penicillamine

Non-steroidal anti-inflammatory (NSAIS)

Prostanoids/Prostaglandin analogs

Other _____

unknown

Phototherapy No Yes unknown

Other No

Yes, specify:

unknown

DATE OF HSCT

DATE OF HSCT :
yyyy mm dd

HSCT TYPE

Allogeneic: *Proceed to STATUS OF DISEASE AT HSCT on page 4*

Autologous: Mobilised No: *Proceed to STATUS OF DISEASE AT HSCT on page 4*

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

STATUS OF DISEASE AT MOBILISATION

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

DISEASE STATUS

- Limited (cutaneous thickening distal to elbows or knees, but not proximal)
 Diffuse
 Other

SKIN THICKNESS

Total modified Rodnan Skin Score (max 51). : Not evaluated Unknown
(Appendix B. 10)

LABORATORY VALUES

Units

Serum creatinine: (µmol/l) Not evaluated unknown
 Creatinine clearance: (ml/min) Not evaluated unknown
 Creatinine phosphokinase: (IU/l) Not evaluated unknown
 Proteinuria: Absent Present Not evaluated Unknown

AUTOANTIBODIES

Were tests for autoantibodies done at mobilisation? No Yes Unknown

SPECIFY ANTIBODY:

Anti-DNA topoisomerase I (Scl-70): Negative Positive Not evaluated unknown
 Anti-centromere (ACA) Negative Positive Not evaluated unknown
 Anti-nuclear (ANA) Negative Positive Not evaluated unknown
 Other, specify..... Negative Positive

PHYSICAL EXAMINATION RESULTS

Dyspnea on exertion No Yes Not evaluated Unknown
 DLCO (% predicted) Not evaluated Unknown
 Restrictive pulmonary function pattern No Yes Not evaluated Unknown
 Fibrosis on CXR No Yes Not evaluated Unknown
 Pulmonary artery hypertension (ECHO) No Yes Not evaluated Unknown
 Mean PAP:mm/Hg Not evaluated Unknown
 Systemic hypertension requiring treatment No
 Yes: With IACE Inhibitor
 With other, specify:
 Not evaluated
 Unknown
 Arrhythmia / conduction blocks No Yes Not evaluated Unknown

STATUS OF DISEASE AT HSCT

Evaluation should be performed <2 weeks prior to conditioning

DISEASE STATUS

- Limited (cutaneous thickening distal to elbows or knees, but not proximal)
- Diffuse
- Other

SKIN THICKNESS

Total modified Rodnan Skin Score (max 51). : Not evaluated Unknown
(Appendix B. 10)

LABORATORY VALUES

Units

Serum creatinine:	(µmol/l)	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> unknown
Creatinine clearance:	(ml/min)	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> unknown
Creatinine phosphokinase:	(IU/l)	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> unknown
Proteinuria: <input type="checkbox"/> Absent <input type="checkbox"/> Present <input type="checkbox"/> Not evaluated <input type="checkbox"/> Unknown			

AUTOANTIBODIES

Were tests for autoantibodies done at conditioning? No Yes Unknown

SPECIFY ANTIBODY:

Anti-DNA topoisomerase I (Scl-70):	<input type="checkbox"/> Negative	<input type="checkbox"/> Positive	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> unknown
Anti-centromere (ACA)	<input type="checkbox"/> Negative	<input type="checkbox"/> Positive	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> unknown
Anti-nuclear (ANA)	<input type="checkbox"/> Negative	<input type="checkbox"/> Positive	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> unknown
Other, specify.....	<input type="checkbox"/> Negative	<input type="checkbox"/> Positive		

PHYSICAL EXAMINATION RESULTS

Dyspnea on exertion	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> Unknown
DLCO (% predicted)			<input type="checkbox"/> Not evaluated	<input type="checkbox"/> Unknown
Restrictive pulmonary function pattern	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> Unknown
Fibrosis on CXR	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> Unknown
Pulmonary artery hypertension (ECHO)	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> Unknown
Mean PAP:mm/Hg			<input type="checkbox"/> Not evaluated	<input type="checkbox"/> Unknown
Systemic hypertension requiring treatment	<input type="checkbox"/> No			
	<input type="checkbox"/> Yes: <input type="checkbox"/> With IACE Inhibitor			
	<input type="checkbox"/> With other, specify:			
	<input type="checkbox"/> Not evaluated			
	<input type="checkbox"/> Unknown			
Arrhythmia / conduction blocks	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> Unknown

CIC:

Unique Patient Number (UPN):

SCT Date..... - -
yyyy mm dd

INVOLVEMENT AND INDICATION FOR HSCT

Disease involvement

(check all that apply):

YES

*Check here if this involvement was the **Reason for HSCT***

GI tract

Heart

Lungs

Skin

Other, specify: _____

Severe functional impairment

No

Yes

Not evaluated

Unknown

ADDITIONAL TREATMENT POST-HSCT

ADDITIONAL DISEASE TREATMENT

No

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

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

FOLLOW UP

SYSTEMIC SCLEROSIS

Unique Identification Code (UIC) (if known)

Date of this report
yyyy mm ddPatient 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 ddDate 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 HSCT" TO FILL THESE ITEMS. THE DOCUMENT IS AVAILABLE FROM www.ebmt.org, INFECTIOUS DISEASES WORKING PARTY.

INFECTION RELATED COMPLICATIONS

- No complications
 Yes

Type	Pathogen <i>Use the list of pathogens listed after this table for guidance. Use "unknown" if necessary.</i>	Date <i>Provide different dates for different episodes of the same complication if applicable.</i>
Bacteremia / fungemia / viremia / parasites		
SYSTEMIC SYMPTOMS OF INFECTION		
Septic shock		
ARDS		
Multiorgan failure due to infection		

CIC:

Unique Patient Number (UPN):

SCT Date.....

yyyy mm dd

Type	Pathogen <i>Use the list of pathogens listed after this table for guidance. Use "unknown" if necessary.</i>	Date <i>Provide different dates for different episodes of the same complication if applicable.</i>
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	S. pneumoniae	Viruses	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	Candida sp		Adenovirus
	Aspergillus sp		HBV
	Pneumocystis carinii		HCV
	Other:		HIV
			Papovavirus
Parasites	Toxoplasma gondii		Parvovirus
	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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
VOD	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
EBV lymphoproliferative disease	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Cataract	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Haemorrhagic cystitis, non infectious	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
ARDS, non infectious	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Multiorgan failure, non infectious	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Transplant-associated microangiopathy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Renal failure requiring dialysis	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Haemolytic anaemia due to blood group	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Aseptic bone necrosis	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Other:	<input type="checkbox"/>			

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 (never)
- 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

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

Number of relapses/progressions since last HSCT..... Unknown

LAST DISEASE AND PATIENT STATUS

Only if evaluation has been performed <2 weeks prior to this follow up including death

DISEASE STATUS

- Limited (cutaneous thickening distal to elbows or knees, but not proximal)
- Diffuse
- Other

SKIN THICKNESS

Total modified Rodnan Skin Score (max 51). : Not evaluated Unknown
(Appendix B. 10)

LABORATORY VALUES

Units

Serum creatinine:	(µmol/l)	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> unknown
Creatinine clearance:	(ml/min)	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> unknown
Creatinine phosphokinase:	(IU/l)	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> unknown
Proteinuria: <input type="checkbox"/> Absent <input type="checkbox"/> Present <input type="checkbox"/> Not evaluated <input type="checkbox"/> Unknown			

AUTOANTIBODIES

Were tests for autoantibodies done since last follow up? Yes No Unknown

SPECIFY ANTIBODY:

Anti-DNA topoisomerase I (Scl-70):	<input type="checkbox"/> Negative	<input type="checkbox"/> Positive	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> unknown
Anti-centromere (ACA)	<input type="checkbox"/> Negative	<input type="checkbox"/> Positive	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> unknown
Anti-nuclear (ANA)	<input type="checkbox"/> Negative	<input type="checkbox"/> Positive	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> unknown
Other, specify.....	<input type="checkbox"/> Negative	<input type="checkbox"/> Positive		

PHYSICAL EXAMINATION RESULTS

- Dyspnea on exertion No Yes Not evaluated Unknown
 DLCO (% predicted) Not evaluated Unknown
- Restrictive pulmonary function pattern No Yes Not evaluated Unknown
- Fibrosis on CXR No Yes Not evaluated Unknown
- Pulmonary artery hypertension (ECHO) No Yes Not evaluated Unknown
 Mean PAP:mm/Hg Not evaluated Unknown
- Systemic hypertension requiring treatment No
 Yes: With IACE Inhibitor
 With other, specify:
 Not evaluated
 Unknown
- Arrhythmia / conduction blocks No Yes Not evaluated Unknown

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) Not evaluated
 90 (Normal activity) Unknown
 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)

CAUSE OF DEATH (if dead)

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

(check as many as appropriate)

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

Unknown

Other :

ADDITIONAL NOTES IF APPLICABLE

COMMENTS

.....

IDENTIFICATION & SIGNATURE

.....

APPENDIX B

AUTOIMMUNE DISEASES

1. Poser CM, Paty DW, Scheinber L, et al, Ann Neurol, 1983, 13:227-231
2. Fuchs and Pincus, Arthritis Rheum, 1994, 37:470
3. Len. C, et al, J Rheum, 1999, 26(4):909-913
4. Singh G, Athreya B, Fries J, Goldsmith DP. Measurement of health status in children with rheumatoid arthritis. "Arthritis Rheum" 1994, 37:1761-69)
5. Giannini EH, et al, "Arthritis Rheum" 1997, Jul; 40 (7): 1202-9)
6. Arnett et al, "Arthritis Rheum" 1988, 31:315)
7. Felson et al, "Arthritis Rheum" 1995, 38:727)
8. Pinals et al, "Arthritis Rheum" 1981, 24:1308)
9. Austin HA III, et al, Kidney Int, 1984, 25:689)
10. Clements P, et al, J Rheumatol, 1995, 22:1281-5)
11. Steen VD, Arthritis Rheum, 1997, Nov; 40 (11): 1984-91