

EBMT FORM

GENERAL INFORMATION

TEAM

EBMT Centre Identification Code (CIC) CIBMTR Centre #

Hospital Unit

Contact person:

Telephone Fax

e-mail

Date of this report
yyyy mm dd

CIBMTR patient (recipient) Identification

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

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"/> Myelodysplastic syndromes
<input type="checkbox"/> MDS
<input type="checkbox"/> MD/MPS
<input type="checkbox"/> Myeloproliferative syndrome
<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"/> Systemic Lupus
<input type="checkbox"/> Systemic Sclerosis
<input type="checkbox"/> Haemoglobinopathy |
|--|---|--|

SPECIFICATIONS
OF THE DISEASE

MYELOPROLIFERATIVE SYNDROME

DIAGNOSIS

SUBCLASSIFICATION

Myeloproliferative syndrome

- Chronic idiopathic myelofibrosis or Primary myelofibrosis
- Polycythaemia vera
- Essential thrombocythemia
- Hyper eosinophilic syndrome (HES)
- Chronic eosinophilic leukaemia (CEL):
With blastic transformation No Yes Unknown
- Chronic neutrophilic leukaemia
- Stem cell leukemia-Lymphoma syndrome (8p11 syndrome)
- Systemic mastocytosis
- Secondary myelofibrosis (*disease related to prior exposure to therapeutic drugs or radiation; If the myelofibrosis is the disease evolution of a previous MPS stage, do not report it as **Secondary myelofibrosis**. Use the boxes above for **Polycythaemia vera** or **Essential thrombocythemia** instead with the correct date for those*)

CYTOGENETICS DATA

(INCLUDE ALL ANALYSIS BEFORE TREATMENT; DESCRIBE RESULTS OF MOST RECENT COMPLETE ANALYSIS)

Chromosome analysis

- Not done or failed Done: normal Done: abnormal Unknown

If abnormal: Are there 3 or more abnormalities (*complex karyotype*)? No Yes unknown

If done: number of metaphases with abnormalities: / number of metaphases examined:

Indicate which abnormalities found:

Abnormality chr. 1	<input type="checkbox"/> Absent	<input type="checkbox"/> Present
Abnormality chr. 5	<input type="checkbox"/> Absent	<input type="checkbox"/> Present
Abnormality chr. 7	<input type="checkbox"/> Absent	<input type="checkbox"/> Present
trisomy 8	<input type="checkbox"/> Absent	<input type="checkbox"/> Present
trisomy 9	<input type="checkbox"/> Absent	<input type="checkbox"/> Present
del 20	<input type="checkbox"/> Absent	<input type="checkbox"/> Present
del 13	<input type="checkbox"/> Absent	<input type="checkbox"/> Present

Other abnormalities, specify

MOLECULAR BIOLOGY

Molecular markers : Evaluated: Absent Evaluated: Present
 Not evaluated unknown

If evaluated, fill in table below:

JAK2 mutation	<input type="checkbox"/> Absent	<input type="checkbox"/> Present	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> unknown
BCR/ABL	<input type="checkbox"/> Absent	<input type="checkbox"/> Present	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> unknown
FIP1L1-PDGFR	<input type="checkbox"/> Absent	<input type="checkbox"/> Present	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> unknown

HAEMATOLOGICAL VALUES (at diagnosis)

Peripheral blood

Hb (g/dL) Not evaluated
 Platelets (10⁹/L) Not evaluated
 White Blood Cells (10⁹/L) Not evaluated
 % blasts Not evaluated
 % monocytes Not evaluated
 % neutrophils Not evaluated

Bone marrow

% blasts Not evaluated
 Auer rods present Yes No Not evaluated Unknown

RISK FACTOR SCORE

Lille score

Low Intermediate High Unknown

Cervantes score

Low High Unknown

BM INVESTIGATION (at diagnosis)

Cytology Histology Not available

RESULTS

(at diagnosis; check one box in each column)

CELLULARITY ON BM ASPIRATE / BM BIOPSY

Acellular
 Hypocellular
 Normocellular
 Hypercellular
 Focal cellularity
 Unknown

FIBROSIS/OSTEOSCLEROSIS ON BM BIOPSY

No
 Mild (Grade 1)
 Moderate (Grade 2)
 Severe (Grade 3)
 Not evaluable
 Unknown

CONSTITUTIONAL SYMPTOMS (at diagnosis)

Night sweat Yes No Unknown

Palpable splenomegaly Absent Present Not evaluated Unknown

Physical examination: cm (below costal margin) Not evaluated

Spleen span in ultrasound or CT scan: cm (maximum diameter) Not evaluated

Weight loss Yes No Unknown

FIRST LINE THERAPY

If this registration pertains to a second or subsequent HSCT the therapy number should be counted since last reported transplant.

FIRST LINE THERAPY GIVEN

- No - Proceed to "Subclassification & Status of Disease at HSCT"
- Yes: Date started
 yyyy mm dd

SUBCLASSIFICATION AT PRIMARY TREATMENT

- MPS (as registered at diagnosis)
- Transformed to secondary myelofibrosis
- Transformed to secondary acute leukaemia

If transformed into Secondary myelofibrosis or acute leukaemia, date of transformation:
 yyyy mm dd

TREATMENT

- Chemo/drug/agent No Yes: Ara-C Hydroxyurea Thalidomide
(including GF, hormones, etc.) Androgens AML like therapy Lenalidomide
 Tyrosine kinase inhibitor Interferon Steroids
 Other, specify
- Radiotherapy No Yes: To the spleen No Yes Unknown
- Other :

Response: Complete remission(CR)*, date of first CR
If subsequent HSCT, indicate the date of the 1st CR after this treatment yyyy mm dd

Never in CR

* CR must include all three conditions:
 1. Resolution of disease –related symptoms and signs including palpable hepato-splenomegaly
 2. Hb >11gr/dL, Platelet >100 x10⁹/L and neutrophils >1 x 10⁹/L.
 3. normal bone marrow histology, and fibrosis grade no higher than 1

SUBCLASSIFICATION & STATUS OF DISEASE AT HSCT

TO BE EVALUATED JUST BEFORE STARTING CONDITIONING

DATE OF HSCT:
 yyyy mm dd

Splenectomy No Yes, Date :
 yyyy mm dd

Transfusional status at HSCT
 No transfusions With transfusions Never transfused

SUBCLASSIFICATION AT HSCT

- MPS (as registered at diagnosis)
- Transformed to secondary myelofibrosis
- Transformed to secondary acute leukaemia

If transformed into Secondary myelofibrosis or acute leukaemia, date of transformation:
yyyy mm dd

STATUS OF DISEASE AT HSCT

- | | |
|--|--|
| <ul style="list-style-type: none"> <input type="checkbox"/> Primary refractory phase (no change) <input type="checkbox"/> Complete remission (CR) <input type="checkbox"/> Improvement but no CR <input type="checkbox"/> Relapse (after CR) <input type="checkbox"/> Progression/worse <input type="checkbox"/> Untreated (Supportive care or treatment without chemotherapy) | <p>NUMBER OF STATUS
 NUMBER (complete for CR or relapse)</p> <ul style="list-style-type: none"> <input type="checkbox"/> 1st <input type="checkbox"/> 2nd <input type="checkbox"/> 3rd or higher |
|--|--|

CYTOGENETICS DATA (Within 2 months of the preparative -conditioning- regimen)

Chromosome analysis

- Not done or failed Done: normal Done: abnormal Unknown

If abnormal: Are there 3 or more abnormalities (complex karyotype)? No Yes unknown

Indicate which abnormalities found:

Abnormality chr. 1	<input type="checkbox"/> Absent	<input type="checkbox"/> Present
Abnormality chr. 5	<input type="checkbox"/> Absent	<input type="checkbox"/> Present
Abnormality chr. 7	<input type="checkbox"/> Absent	<input type="checkbox"/> Present
trisomy 8	<input type="checkbox"/> Absent	<input type="checkbox"/> Present
trisomy 9	<input type="checkbox"/> Absent	<input type="checkbox"/> Present
del 20	<input type="checkbox"/> Absent	<input type="checkbox"/> Present
del 13	<input type="checkbox"/> Absent	<input type="checkbox"/> Present

Other abnormalities, specify

HAEMATOLOGICAL VALUES (To be evaluated just before starting the preparative -conditioning- regimen)

Peripheral blood

- | | |
|--|--|
| Hb (g/dL) | <input type="checkbox"/> Not evaluated |
| Platelets (10 ⁹ /L) | <input type="checkbox"/> Not evaluated |
| White Blood Cells (10 ⁹ /L) | <input type="checkbox"/> Not evaluated |
| % blasts | <input type="checkbox"/> Not evaluated |
| % monocytes | <input type="checkbox"/> Not evaluated |
| % neutrophils | <input type="checkbox"/> Not evaluated |

Bone marrow

- % blasts Not evaluated
- Auer rods present Yes No Not evaluated Unknown

RISK FACTOR SCORE

Lille score

- Low Intermediate High Unknown

Cervantes score

- Low High Unknown

BM INVESTIGATION (Within 2 months of the preparative -conditioning- regimen)

- Cytology Histology Not available

RESULTS

(at diagnosis; check one box in each column)

CELLULARITY ON BM ASPIRATE / BM BIOPSY

- Acellular
 Hypocellular
 Normocellular
 Hypercellular
 Focal cellularity
 Unknown

FIBROSIS/OSTEOSCLEROSIS ON BM BIOPSY

- No
 Mild (Grade 1)
 Moderate (Grade 2)
 Severe (Grade 3)
 Not evaluable
 Unknown

CONSTITUTIONAL SYMPTOMS (Within 2 months of the preparative -conditioning- regimen)

Night sweat Yes No Unknown

Palpable splenomegaly Absent Present Not evaluated Unknown

Physical examination: cm (below costal margin) Not evaluated

Spleen span in ultrasound or CT scan: cm (maximum diameter) Not evaluated

Weight loss Yes No Unknown

ADDITIONAL TREATMENT POST-HSCT

ADDITIONAL DISEASE TREATMENT

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

RESPONSE OF DISEASE

BEST RESPONSE AT 100 DAYS AFTER HSCT

- CR (maintained or achieved) Relapse / Progression
 Improvement but no CR Not evaluable
 Unknown

CIC:

Unique Patient Number (UPN):

SCT Date.....
yyyy mm dd

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 MYELOPROLIFERATIVE SYNDROME

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 <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		

CIC:

Unique Patient Number (UPN):

SCT Date.....
 yyyy mm dd

Multiorgan failure due to infection		
ENDORGAN DISEASES		
Pneumonia		
Hepatitis		
CNS infection		
Gut infection		
Skin infection		
Cystitis		
Retinitis		
Other: VOTINCOM		
		yyyy mm dd

CIC:

Unique Patient Number (UPN):

SCT Date.....

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
Parasites	Toxoplasma gondii		Papovavirus
	Other:		Parvovirus
		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
- 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

ADDITIONAL TREATMENT

- Treatment given since last report
- No
- Yes: Date started:
yyyy mm dd
- Unknown

FIRST EVIDENCE OF RELAPSE OR PROGRESSION SINCE LAST HSCT

RELAPSE OR PROGRESSION

- Previously reported
- No
- Yes; date diagnosed: - -
yyyy mm dd
- Continuous progression since transplant
- Unknown

LAST DISEASE AND PATIENT STATUS

LAST DISEASE STATUS

- Complete Remission
- Stable disease
- Relapse
- Progression

- FIBROSIS/OSTEOSCLEROSIS ON BM BIOPSY**
- No
 - Mild (Grade 1)
 - Moderate (Grade 2)
 - Severe (Grade 3)
 - Not evaluable
 - Unknown

CONCEPTION

Has patient or partner become pregnant after this HSCT?

- No
- Yes
- 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

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IDENTIFICATION & SIGNATURE