

CIC:

Unique Patient Number (UPN): .....

SCT Date.....  
yyyy mm dd

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

SPECIFICATIONS  
OF THE DISEASE

## SOLID TUMOURS

## INITIAL DIAGNOSIS

- |   |  |
|---|--|
| <input type="checkbox"/> Bone sarcoma (excluding Ewing sarcoma/PNET)      | <input type="checkbox"/> Breast              |
| <input type="checkbox"/> Central nervous system tumors (include CNS PNET) | <input type="checkbox"/> Neuroblastoma       |
| <input type="checkbox"/> Colorectal                                       | <input type="checkbox"/> Ovarian             |
| <input type="checkbox"/> Ewing sarcoma/PNET, extra-skeletal               | <input type="checkbox"/> Pancreas            |
| <input type="checkbox"/> Ewing sarcoma/PNET, skeletal                     | <input type="checkbox"/> Prostate            |
| <input type="checkbox"/> Germ cell tumour, extragonadal only              | <input type="checkbox"/> Renal cell          |
| <input type="checkbox"/> Hepatobiliary                                    | <input type="checkbox"/> Retinoblastoma      |
| <input type="checkbox"/> Lung cancer, non-small cell                      | <input type="checkbox"/> Rhabdomyosarcoma    |
| <input type="checkbox"/> Lung cancer, small cell                          | <input type="checkbox"/> Soft tissue sarcoma |
| <input type="checkbox"/> Medulloblastoma                                  | <input type="checkbox"/> Testicular          |
| <input type="checkbox"/> Melanoma   | <input type="checkbox"/> Thymoma             |
| <input type="checkbox"/> Other, specify .....                             | <input type="checkbox"/> Wilms tumour        |

Histological grading: ..... (1 to 4)

 Not evaluated Unknown

Clinical TNM classification	0	1	2	3	4	X	Not evaluated	Unknown
Tumour	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Nodes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Metastases*	<input type="checkbox"/>	<input type="checkbox"/>				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

\*For metastases, 0 indicates "No metastasis", 1 indicates "Metastasis" and X indicates "Not evaluable"

**OR**

Disease-specific staging	1	2	3	4
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

.....

## HISTOLOGICAL SUBCLASSIFICATION

Describe

.....

.....



## TREATMENT GIVEN BEFORE THIS HSCT

*Treatment refers to any non HSCT treatment given before the first HSCT if the HSCT being reported is the 1<sup>st</sup> HSCT for this patient. If you are reporting a subsequent HSCT, treatment refers to any non HSCT treatment given after the last HSCT reported.*

Treatment given:  No: Includes a) Patients who have no surgery and go on to have high dose chemotherapy followed immediately by HSCT, or sequential chemotherapy, as the 1<sup>st</sup> line treatment; or

b) Subsequent HSCT within a multiple/ sequential chemotherapy HSCT procedure

*If No proceed to Status of disease at HSCT on page 5*

Yes: Includes surgery or any other treatment, including chemotherapy, given prior to the HSCT and which is not considered part of the preparative (*conditioning*) regimen

*If this is a subsequent HSCT, and the information on 1<sup>st</sup> line treatment has already been reported, go to Treatment history before HSCT on page 5 Otherwise, continue below.*

### FIRST LINE TREATMENT

Date 1<sup>st</sup> line treatment started ..... - .....  
yyyy mm dd

Did the first-line treatment include HSCT?  Yes:  Upfront (*treatment started with a program including high dose chemotherapy followed by HSCT or high dose sequential chemotherapy; adjuvant excluded*)  
 Adjuvant (*HSCT done in adjuvant-setting*)  
 No

#### Modality

Chemotherapy:  Adjuvant Chemotherapy  
 Neoadjuvant Chemotherapy

**Drugs** (*tick as many as applicable*)

<input type="checkbox"/> Anthracyclines	<input type="checkbox"/> Cyclophosphamide or other alkylating agents
<input type="checkbox"/> Taxanes	<input type="checkbox"/> Vinca alkaloids
<input type="checkbox"/> Platinum compounds	<input type="checkbox"/> Etoposide
<input type="checkbox"/> Antimetabolites	<input type="checkbox"/> Other (specify): .....

Surgery

If breast cancer, type of surgery:  Mastectomy  
 Conservative

Radiotherapy

Other: .....

#### Status of disease after first line treatment (best response)

<input type="checkbox"/> Complete Remission	<input type="checkbox"/> Stable Disease
<input type="checkbox"/> Partial Remission	<input type="checkbox"/> Refractory Disease
<input type="checkbox"/> Not Evaluable	

Criteria used for evaluation  WHO criteria  
 RECIST criteria

**ADDITIONAL LINES OF TREATMENT BEFORE THIS HSCT FOR RELAPSED/REFRACTORY DISEASE**

Treatment given:  No  
 Yes

**TREATMENT HISTORY BEFORE HSCT**

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

**TREATMENT SUMMARY** (if there was no treatment before this HSCT, skip this section and go to Status of disease at HSCT below)

Total number of lines before this HSCT:  1  2  3  4  >4  unknown

**Modality used at least once**

Chemotherapy	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> Unknown
Surgery	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> Unknown
Radiotherapy	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> Unknown
Other	<input type="checkbox"/> No	<input type="checkbox"/> Yes .....	<input type="checkbox"/> Unknown

**STATUS OF DISEASE AT HSCT**

**STATUS OF DISEASE AT HSCT**

<input type="checkbox"/> Adjuvant <input type="checkbox"/> Never treated (upfront) <input type="checkbox"/> Primary refractory <input type="checkbox"/> Complete remission (CR) <input type="checkbox"/> Confirmed <input type="checkbox"/> Unconfirmed (CRU*) <input type="checkbox"/> Unknown <input type="checkbox"/> 1 <sup>st</sup> Partial response (PR1) <input type="checkbox"/> Relapse <input type="checkbox"/> Local <input type="checkbox"/> Metastatic <input type="checkbox"/> Progressive disease (PD) <small>*CRU – complete response with persistent scan abnormalities of unknown significance</small>	<p><b>NUMBER</b></p> <p>(complete only for CR or relapse)</p> <input type="checkbox"/> 1 <sup>st</sup> <input type="checkbox"/> 2 <sup>nd</sup> <input type="checkbox"/> 3 <sup>rd</sup> or higher	<p><b>SENSITIVITY TO CHEMOTHERAPY</b></p> <p>(complete only for relapse)</p> <input type="checkbox"/> Sensitive (SR:>50% response) <input type="checkbox"/> Resistant (RR:<50% response) <input type="checkbox"/> Untreated
--	--	---

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**Organ(s) involved**

- Nodes Below Diaphragm
- Bone marrow
- CNS
- Mediastinum
- Soft Tissue
- Gastrointestinal tract
- Liver
- Other: .....
- Nodes Above Diaphragm
- Bone
- Lungs
- Heart
- Skin
- Urogenital tract
- Ovaries/Testes

Primary site affected:  Yes  No

**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**

**BEST RESPONSE AT 100 DAYS AFTER HSCT**

- Complete Remission
- Very Good Partial Remission
- Partial Remission (>50%)
- Not Evaluable
- Stable Disease
- Progressive Disease
- Minor Response (>25% and <50%)

DATE OF EVALUATION: .....  
yyyy mm dd

**FORMS TO BE FILLED IN**

- AUTOgraft, proceed to Autograft form
  - ALLOgraft or Syngeneic graft, proceed to Allograft form
- If Cord Blood, fill in the section in Forms Appendix
- If Other: ....., contact the EBMT Central Registry Office for instructions

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SCT Date.....

yyyy mm dd

## FOLLOW UP

## SOLID TUMOURS

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](http://www.ebmt.org), INFECTIOUS DISEASES WORKING PARTY.

## INFECTIOUS 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		
<b>SYSTEMIC SYMPTOMS OF INFECTION</b>		
Septic shock		
ARDS		
Multiorgan failure due to infection		

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<b>Type</b>	<b>Pathogen</b> <i>Use the list of pathogens listed after this table for guidance. Use "unknown" if necessary.</i>	<b>Date</b> <i>Provide different dates for different episodes of the same complication if applicable.</i>
<b>ENDORGAN DISEASES</b>		
Pneumonia		
Hepatitis		
CNS infection		
Gut infection		
Skin infection		
Cystitis		
Retinitis		
Other: .....	VOTINCOM	
		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 INFECTIOUS 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"/>	
HSCT-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

## EVENTS SINCE LAST FOLLOW UP

### 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 MYELOPROLIFERATIVE 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 TREATMENT

- 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 <sup>8</sup> <input type="checkbox"/> Not evaluated <input type="checkbox"/> unknown
CD 34+ (cells/kg*) (DLI only)	..... - ..... x 10 <sup>6</sup> <input type="checkbox"/> Not evaluated <input type="checkbox"/> unknown
CD 3+ (cells/kg*) (DLI only)	..... - ..... x 10 <sup>6</sup> <input type="checkbox"/> Not evaluated <input type="checkbox"/> unknown
Total number of cells infused	
All cells (cells/kg*) (non DLI only)	..... - ..... x 10 <sup>6</sup> <input type="checkbox"/> Not evaluated <input type="checkbox"/> 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 / HSCT):

- 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)
  
- Chemo, specify .....
  
- Radiotherapy, specify .....
  
- Surgery, specify.....

**RELAPSE OR PROGRESSION**

- Previously reported
- No
- Yes; date diagnosed: ..... - ..... - .....

**Organs involved at relapse or progression**

- Local
- Distant:  CNS  bone marrow  lung
- liver  bone  pleura
- nodes  soft tissue  other: .....
- Continuous progression since HSCT
- Unknown

**LAST DISEASE AND PATIENT STATUS**

**LAST DISEASE STATUS**

- Complete Remission
- Stable disease
- Relapse
- Progression

**CONCEPTION**

Has patient or partner become pregnant after this HSCT?

- Yes
- No
- Unknown

**SURVIVAL STATUS**

- Alive
- Dead

**PERFORMANCE SCORE** (if alive)

- |                           |   |   |
|---------------------------|---|---|
| <b>Type of score used</b> | <input type="checkbox"/> Karnofsky<br><input type="checkbox"/> Lansky | <b>SCORE</b> <input type="checkbox"/> 100 (Normal, NED) <input type="checkbox"/> Not evaluated<br><input type="checkbox"/> 90 (Normal activity) <input type="checkbox"/> Unknown<br><input type="checkbox"/> 80 (Normal with effort)<br><input type="checkbox"/> 70 (Cares for self)<br><input type="checkbox"/> 60 (Requires occasional assistance)<br><input type="checkbox"/> 50 (Requires assistance)<br><input type="checkbox"/> 40 (Disabled)<br><input type="checkbox"/> 30 (Severely disabled)<br><input type="checkbox"/> 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 ttoxicity	<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**

.....