FOR ALL DISEASES

AUTOGRAFT

PATIENT

PERFORMANCE SCORE

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)

- ☐ Not evaluated
- ☐ Unknown

Weight (kg) : .... Height (cm) : ....

COLLECTION (harvest) OF MATERIAL ACTUALLY REINFUSED

SOURCE OF STEM CELLS
Check all that apply:

☐ Bone marrow: Total number of collections: ....

☐ Peripheral blood: Total number of mobilisation courses : .... ☐ No mobilisation
(Steady state; e.g. CML at diagnosis)

☐ Cord blood

COLLECTION (HARVEST)

BONE MARROW OR <u>UNMOBILISED</u> PERIPHERAL BLOOD

Date of 1st collection .... - .... - ....
yyyy mm dd

PERIPHERAL BLOOD MOBILISATION
List all drugs: chemotherapy, growth factors, antibodies, etc.

Date of 1st pheresis after this mobilisation	Number of this mobilisation	Drug name	Drug name	Drug name
.... - .... - .... yyyy mm dd	....	.... /	.... /	.... / ....
.... - .... - .... yyyy mm dd	....	.... /	.... /	.... / ....
.... - .... - .... yyyy mm dd	....	.... /	.... /	.... / ....

HSCT

Chronological number of HSCT for this patient ....

If number > 1: Date of previous HSCT: .... - .... - ....
yyyy mm dd

Type of previous HSCT ☐ Allo ☐ Auto

HSCT part of a multiple sequential graft program:

☐ No
☐ Yes:
☐ Specify type of graft programme:_____________________
☐ Yes: Graft number in the program _____ out of _____ total number of HSCTs in the program
☐ Unknown

EX VIVO GRAFT MANIPULATION

MANIPULATION

☐ No ☐ Yes

NEGATIVE SELECTION

☐ No
☐ Yes:
Monoclonal antibodies ± complement *(if yes, write CD in space provided)* :
☐ Yes: .... , ..., ... ☐ No ☐ Unknown
Other, specify ....
☐ Unknown

POSITIVE SELECTION

☐ No
☐ Yes: Monoclonal antibodies: ☐ No
☐ Yes: ☐ CD 34+ ☐ CD 38- ☐ DR –
☐ Thy 1+ ☐ Lin - ☐ Other: ....
☐ Unknown

Long term culture ☐ No ☐ Yes ☐ Unknown
Other: ....
☐ Unknown

EXPANSION

☐ No
☐ Yes
☐ Unknown

GENE MANIPULATION

(gene transfer/transduction)
☐ No ☐ Yes ☐ Unknown

PREPARATIVE TREATMENT *(conditioning)* **AND** INFUSION

PREPARATIVE TREATMENT (CONDITIONING)

Drugs ☐ No ☐ Yes ☐ Unknown
(include any active agent be it chemo, monoclonal antibody, policlonal antibody, serotherapy, etc.)

*NOTE: ONLY AGENTS GIVEN **BEFORE** THE DATE OF THE 1ST CELL INFUSION (DAY 0) SHOULD BE LISTED HERE*

NAME	PRESCRIBED CUMULATIVE DOSE AS PER PROTOCOL (DAILY DOSE BY NUMBER OF DAYS)	UNITS IF NOT RADIOLABELLED MoAB *	UNITS IF RADIOLABELLED MoAB
(1)... Radiolabelled *(MoAB only)* ☐ No ☐ Yes ☐ Unknown	....	☐ mg ☐ mg/m² ☐ mg/Kg	O mCi O mBq
(2)... Radiolabelled *(MoAB only)* ☐ No ☐ Yes ☐ Unknown	....	☐ mg ☐ mg/m² ☐ mg/Kg	O mCi O mBq
(3)... Radiolabelled *(MoAB only)* ☐ No ☐ Yes ☐ Unknown	....	☐ mg ☐ mg/m² ☐ mg/Kg	O mCi O mBq
(4)... Radiolabelled *(MoAB only)* ☐ No ☐ Yes ☐ Unknown	....	☐ mg ☐ mg/m² ☐ mg/Kg	O mCi O mBq
(5)... Radiolabelled *(MoAB only)* ☐ No ☐ Yes ☐ Unknown	....	☐ mg ☐ mg/m² ☐ mg/Kg	O mCi O mBq
(6)... Radiolabelled *(MoAB only)* ☐ No ☐ Yes ☐ Unknown	....	☐ mg ☐ mg/m² ☐ mg/Kg	O mCi O mBq
(7)... Radiolabelled *(MoAB only)* ☐ No ☐ Yes ☐ Unknown	....	☐ mg ☐ mg/m² ☐ mg/Kg	O mCi O mBq

** If the unit you need is not listed, please write it on the side.*

ADDITIONAL DRUG INFORMATION
For Busulphan: Route of administration: ☐ Oral ☐ IV ☐ Both
For ALG, ATG *(ALS, ATS)*: Animal origin: ☐ Horse ☐ Rabbit ☐ Other, specify.... ....

TBI ☐ No ☐ Yes ☐ Unknown
(If yes, complete TBI Form)
Total dose (Gy) : .... - .... Number of fractions .... over .... radiation days

TLI / TNI / TAI ☐ No ☐ Yes: Total dose (Gy) : .... - .... ☐ Unknown

Local radiotherapy ☐ No ☐ Yes ☐ Unknown

CELLS COLLECTED AND INFUSED

(complete the whole table in case of graft manipulation)

	Bone Marrow	Peripheral Blood	Cord Blood
Evaluated before manipulation and cryopreservation : - Total nbr. of nucleated cells (/kg) - CD 34+ (cells/kg)	.... - .... x 10^8 .... - .... x 10^6	.... - .... x 10^8 .... - .... x 10^6	.... - .... x 10^8 .... - .... x 10^6
Evaluated after manipulation and before cryopreservation : - Total nbr. of nucleated cells (/kg) - CD 34+ (cells/kg)	.... - .... x 10^8 .... - .... x 10^6	.... - .... x 10^8 .... - .... x 10^6	.... - .... x 10^8 .... - ....x 10^6
Cells actually infused (after thawing (if thawing) and manipulation (if manipulation)) : - Total nbr. of nucleated cells (/kg) - CD 34+ (cells/kg)	.... - .... x 10^8 .... - .... x 10^6	.... - .... x 10^8 .... - .... x 10^6	.... - .... x 10^8 .... - ....x 10^6

(kg of recipient body weight)*

TREATMENT DURING THE IMMEDIATE POST-TRANSPLANT PERIOD

GROWTH FACTORS *(CYTOKINES)*

(excluding growth factors administered for engraftment failure)

☐ No

☐ Yes, specify .... Date started : .... - .... - ....
yyyy mm dd

☐ Unknown

CELLULAR THERAPY

☐ No

☐ Yes: Date of first infusion: ....
(can be the same as HSCT date) yyyy mm dd

☐ Unknown

IF YES:

☐ Donor lymphocyte infusion (DLI) *Please, fill in relevant information in the* DLI Med-B *insert*

☐ Mesenchymal cells *Please, fill in relevant information in the* Cell Therapy Med-A

☐ 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

CELLULAR THERAPY (CONTINUED)

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)

ENGRAFTMENT

GRAFT PERFORMANCE

☐ Engraftment

Haemopoietic reconstitution *(first of 3 consecutive days)*

Neutrophils > 0.5×10^9/l reached?
☐ Yes: Date Neutrophils > 0.5×10^9/l .... - .... - .... (yyyy mm dd)
☐ No
☐ Never below this level

Platelets > 20×10^9/l reached?
☐ Yes: Date Platelets > 20×10^9/l .... - .... - .... (yyyy mm dd)
☐ No
☐ Never below this level

Platelets > 50×10^9/l reached?
☐ Yes: Date Platelets > 50×10^9/l .... - .... - .... (yyyy mm dd)
☐ No
☐ Never below this level

Date of last platelet transfusion .... - .... - .... (yyyy mm dd)

☐ No engraftment: Date last assessment .... - .... - .... (yyyy mm dd)

☐ Lost graft, date of graft failure .... - .... - .... (yyyy mm dd)

TREATMENT FOR FAILURE

(If engraftment failure)

☐ No

☐ Growth factors

☐ Subsequent transplant *(please complete a new transplant form)*:

Date : .... - .... - .... (yyyy mm dd)
☐ AUTOgraft *(must have prior conditioning)*
☐ ALLOgraft

☐ Autologous PBSC re-infusion *(no prior conditioning)*

☐ Autologous BM re-infusion *(no prior conditioning)*

☐ Other : ....

COMPLICATIONS WITHIN THE FIRST 100 DAYS.

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		
Septic shock		
ARDS		
Multiorgan failure due to infection		
ENDORGAN DISEASES		
Pneumonia		
Hepatitis		
CNS infection		
Gut infection		
Skin infection		
Cystitis		

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.*
Retinitis		
Other: .... VOTINCOM		
		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	☐	☐	☐	
Aseptic bone necrosis	☐	☐	☐	
Other: ....……	☐			
				yyyy mm dd

STATUS AT 100 DAYS

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

RELAPSE OR PROGRESSION

☐ No

☐ Yes; date diagnosed: .... - .... - ....
yyyy mm dd

FILL IN ONLY FOR ACUTE AND CHRONIC LEUKAEMIAS:

Method of detection			Site
Cinical/haematological relapse or progression	☐ No: Date assessed	.... - .... - .... *yyyy mm dd*	
☐ Not evaluated	☐ Yes: Date first seen	.... - .... - .... *yyyy mm dd*	☐ marrow – blood ☐ extramedullary
Cytogenetic relapse or progression	☐ No: Date assessed	.... - .... - .... *yyyy mm dd*	
☐ Not evaluated	☐ Yes: Date first seen	.... - .... - .... *yyyy mm dd*	☐ marrow – blood ☐ extramedullary
Molecular/marker relapse or progression	☐ No: Date assessed	.... - .... - .... *yyyy mm dd*	
☐ Not evaluated	☐ Yes: Date first seen	.... - .... - .... *yyyy mm dd*	☐ marrow – blood ☐ extramedullary

☐ Continuous progression since transplant

☐ Unknown

LAST DISEASE STATUS *(record the most recent status and date for each method, depending on the disease)*

Method	Disease detected
Clinical/haematological	☐ No ☐ Yes
☐ Not evaluated	Last date evaluated .... - .... - .... *yyyy mm dd*
FILL IN ONLY FOR ACUTE AND CHRONIC LEUKAEMIAS	
Cytogenetic/FISH	☐ No ☐ Yes: Considered disease relapse/progression ☐ No ☐ Yes
☐ Not evaluated	Last date assessed .... - .... - .... *yyyy mm dd*
Molecular/marker	☐ No ☐ Yes: Considered disease relapse/progression ☐ No ☐ Yes
☐ Not evaluated	Last date assessed .... - .... - .... *yyyy mm dd*

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, including EBV lymphoproliferative disease
- ☐ Transplantation related cause :

(check as many as appropriate)

	Yes	No	Unknown
GvHD *(if previous allograft)*	☐	☐	☐
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	☐	☐	☐
Other:	☐		

- ☐ Unknown
- ☐ Other : ....

....

ADDITIONAL NOTES IF APPLICABLE

COMMENTS ....

....

....

IDENTIFICATION & SIGNATURE

....

FOR ALL DISEASES

AUTOGRAFT APPENDIX

PATIENT ETHNIC OR RACIAL ORIGIN

Only compulsory for USA centres or HSCT performed with USA donors. USA Federal socio-political standards used. Contact the CIBMTR if clarification is needed.

Ethnicity: ☐ Hispanic or Latino ☐ Not Hispanic or Latino

Race *(check all that apply)*

☐ White ☐ Black ☐ Asian

☐ American Indian/Alaska Native ☐ Native Hawaiian/Other Pacific Islander

COMORBID CONDITIONS

Compulsory for CIBMTR Research centres / Optional for other centres wishing to include these items in their own studies

Were there any ***clinically significant*** co-existing disease or organ impairment at time of patient assessment prior to preparative *(conditioning)* regimen?

☐ No

☐ Yes:

Comorbidity		Definitions	No	Yes	Not evaluated
Solid tumor, previously present		Treated at any time point in the patient's past history, excluding nonmelanoma skin cancer	☐	☐	☐
Inflammatory bowel disease		Crohn's disease or ulcerative colitis	☐	☐	☐
Rheumatologic		SLE, RA, polymyositis, mixed CTD, or polymyalgia rheumatica	☐	☐	☐
Infection		Requiring continuation of antimicrobial treatment after day 0	☐	☐	☐
Diabetes		Requiring treatment with insulin or oral hypoglycemics but not diet alone	☐	☐	☐
Renal:	moderate/severe	Serum creatinine > 2 mg/dL or >177 µmol/L, on dialysis, or prior renal transplantation	☐	☐	☐
Hepatic:	mild	Chronic hepatitis, bilirubin > ULN to 1.5 × ULN, or AST/ALT > ULN to 2.5 × ULN	☐	☐	☐
	moderate/severe	Liver cirrhosis, bilirubin > 1.5 × ULN, or AST/ALT > 2.5 × ULN	☐	☐	☐
Arrhythmia		Atrial fibrillation or fl utter, sick sinus syndrome, or ventricular arrhythmias	☐	☐	☐
Cardiac		Coronary artery disease, congestive heart failure, myocardial infarction, or EF ≤ 50%	☐	☐	☐
Cerebrovascular disease		Transient ischemic attack or cerebrovascular accident	☐	☐	☐
Heart valve disease		Except mitral valve prolapse	☐	☐	☐
Pulmonary:	moderate	DLco and/or FEV1 66-80% or dyspnea on slight activity	☐	☐	☐
	severe	DLco and/or FEV1 ≤ 65% or dyspnea at rest or requiring oxygen	☐	☐	☐
Obesity		Patients with a body mass index > 35 kg/m2	☐	☐	☐
Peptic ulcer		Requiring treatment	☐	☐	☐
Psychiatric disturbance		Depression or anxiety requiring psychiatric consult or treatment	☐	☐	☐
Other Specify..			☐	☐	☐