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 <u>Patient</u> 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 <u>not</u> 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)*

- ☐ 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 LYMPHOMA

INITIAL DIAGNOSIS

Has the information requested in this section been submitted with a previous transplant registration for this patient?

- ☐ Yes: go to page 11, *Status at HSCT*
- ☐ No: proceed with this section

DIAGNOSIS
Lymphoma (main disease code 3)

☐ **NHL (B-cell)** → ***Go to page 3***

☐ **NHL (T-cell and NK cell)** → ***Go to page 4***

☐ **Hodgkins** → ***Go to page 5***

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

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

LYMPHOMAS (main disease code 3)
B-Cell Non Hodgkin Lymphomas (NHL)

Disease

Date of Initial Diagnosis ……..... - ..... - .....
yyyy mm dd

Mature B-cell Neoplasms	
☐ Splenic marginal zone lymphoma	
☐ Extranodal marginal zone lymphoma of mucosa associated lymphoid tissue (MALT)	
☐ Nodal marginal zone lymphoma	
☐ Lymphoplasmacytic lymphoma (LPL)	
☐ Waldenstrom macroglobulinaemia (LPL with monoclonal IgM)	**International Prognostic Scoring System for Waldenström's Macroglobulinemia (ISSWM)** ☐ Low risk (0-1 score points except age >65) ☐ Intermediate risk (score 2 or age >65 alone) ☐ High risk (3-5) ☐ Not evaluated
☐ Follicular lymphoma	**Grading** ☐ Grade I ☐ Grade II ☐ Grade III ☐ Not evaluated **Prognostic score (FLIPI)** ☐ Low risk ☐ Intermediate risk ☐ High risk ☐ Not evaluated
☐ Primary cutaneous follicle centre lymphoma	
☐ Mantle cell lymphoma	**Grading** ☐ indolent ☐ classical ☐ pleomorphic ☐ blastoid ☐ Not evaluated **Prognostic score (MIPI)** ☐ Low risk ☐ Intermediate risk ☐ High risk ☐ Not evaluated KI-67 (Proliferation index) __ __ % Positive ☐ Not evaluated
☐ Diffuse large B-cell lymphoma (DLBCL), (NOS)	**International Prognostic Index (IPI)** ☐ Low risk (0-1 score points) ☐ Low-Intermediate risk (2) ☐ High-intermediate risk (3) ☐ High risk (4 or 5) ☐ Not evaluated KI-67 (Proliferation index) __ __ % Positive ☐ Not evaluated
☐ T-cell/hystiocyte rich large B cell lymphoma	
☐ Primary DLBCL of the CNS	
☐ Primary cutaneous DLBCL, leg type	
☐ EBV positive DLBCL of the elderly	
☐ DLBCL associated with chronic inflammation	
☐ Lymphomatoid granulomatosis	
☐ Primary mediastinal (thymic) large B-cell lymphoma	
☐ Intravascular large B-cell lymphoma	
☐ ALK positive large B-cell lymphoma	
☐ Plasmablastic lymphoma	
☐ Large B-cell lymphoma arising in HHV8-associated multicentric Castleman disease	
☐ Primary effusion lymphoma (PEL)	
☐ Burkitt lymphoma (BL)	
☐ B-cell lymphoma, unclassifiable, with features intermediate between diffuse large B-cell lymphoma and Burkitt lymphoma (Intermediate DLBCL/BL)	
☐ B-cell lymphoma, unclassifiable, with features intermediate between diffuse large B-cell lymphoma and classical Hodgkin lymphoma (Intermediate DLBCL/HD)	
☐ Other B-cell, specify:_____	

Transformed from another type of lymphoma at the event leading to this HSCT
☐ No
☐ Yes: Date of original diagnosis .... - .... - ....
yyyy mm dd
Indicate the type of the original lymphoma ....
☐Unknown

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

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

LYMPHOMAS **(main disease code 3)**
T-Cell Non Hodgkin Lymphomas (NHL)

DISEASE

Date of Initial Diagnosis ……..... - ..... - .....
yyyy mm dd

Mature T-cell & NK-cell Neoplasms	
☐ T-cell large granular lymphocytic leukaemia	
☐ Aggressive NK-cell leukaemia	
☐ Systemic EBV positive T-cell lymphoproliferative disease of childhood	
☐ Hydroa vacciniforme-like lymphoma	
☐ Adult T-cell leukaemia/lymphoma	
☐ Extranodal NK/T-cell lymphoma, nasal type	
☐ Enteropathy-associated T-cell lymphoma	
☐ Hepatosplenic T-cell lymphoma	
☐ Subcutaneous panniculitis-like T-cell lymphoma	

☐ Mycosis fungoides (MF) ☐ Sézary syndrome	**ISCL/EORTC** ☐ IA ☐ IB ☐ IIA ☐ IIB ☐ IIIA ☐ IIIB ☐ IVA_1 ☐ IVA_2 ☐ IVB ☐ Not evaluated

☐ Lymphomatoid papulosis	
☐ Primary cutaneous anaplastic large cell lymphoma	
☐ Primary cutaneous gamma-delta T-cell lymphoma	
☐ Primary cutaneous CD8 positive aggressive epidermotropic cytotoxic T-cell lymphoma	
☐ Primary cutaneous CD4 positive small/medium T-cell lymphoma	

☐ Peripheral T-cell lymphoma, NOS (PTCL) ☐ Angioimmunoblastic T-cell lymphoma ☐ Anaplastic large-cell lymphoma (ALCL), ALK-positive ☐ Anaplastic large-cell lymphoma (ALCL), ALK-negative ☐ Other T-cell, specify:_____	**International Prognostic Index (IPI)** ☐ Low risk (0-1 score points) ☐ Low-Intermediate risk (2) ☐ High-intermediate risk (3) ☐ High risk (4 or 5) ☐ Not evaluated

LYMPHOMAS **(main disease code 3)**
Hodgkin Lymphomas

Disease

Date of Initial Diagnosis ……..... - ..... - .....
yyyy *mm* *dd*

Classification:

- ☐ Nodular lymphocyte predominant
- ☐ Classical predominant
- ☐ Other, specify:_____

ALL LYMPHOMAS

Assessments at Diagnosis

STAGE AT DIAGNOSIS

ANN ARBOR STAGING FOR ADULT NON-BURKITT'S PATIENTS
MURPHY STAGE FOR BURKITT'S DISEASE AND PAEDIATRIC PATIENTS.

Stage	**Systemic symptoms**
☐ I	☐ Absent (A)
☐ II	☐ Present (B)
☐ III	☐ Not evaluated
☐ IV	☐ Unknown
☐ Not evaluated	
☐ Unknown	

DISEASE INVOLVEMENT AT DIAGNOSIS

Size of largest mass

☐ < 5 cm ☐ 5-10 cm ☐ > 10 cm ☐ No mass ☐ Unknown

LDH LEVELS

☐ Normal ☐ Elevated ☐ Not evaluated ☐ Unknown

Specific sites of involvement

☐ Nodes below the diaphragm	☐ Bone marrow	☐ Extranodal (CNS)
☐ Mediastinum	☐ Extranodal (testis /ovary)	☐ Nodes above the diaphragm
☐ Lung	☐ Liver	☐ Spleen

☐ Other : .....

TREATMENT GIVEN BEFORE THE 1ST TRANSPLANT

Has the information requested in this section been submitted with a previous transplant registration for this patient?

☐ Yes: go to page 10, *"Disease History before HSCT"*

☐ No: proceed with this section

IF THE NUMBER OF TREATMENTS GIVEN BEFORE THE 1ST TRANSPLANT IS HIGHER THAN 3, PLEASE PHOTOCOPY THIS PAGE AS MANY TIMES AS NECESSARY TO PROVIDE INFORMATION ON ALL TREATMENTS

WAS THE PATIENT TREATED BEFORE THE 1ST TRANSPLANT PROCEDURE?

☐ No – *Proceed to page 10, "Disease History before HSCT"*

☐ Yes **Date started** .... - ....
yyyy mm dd

Sequential number of this treatment: .....
(counted from diagnosis)

☐ Unknown

Drugs given

Antibodies:	☐ Alemtuzumab (MabCampath) (CD52)			
	☐ Brentuximab (Adcetris) (CD30)			
	☐ Obinutuzumab (Gyzeva) (CD20)			
	☐ Ofatumumab (Azerra) (CD20)			
	☐ Rituximab (Mabthera) (CD20)			
	☐ other antibody, specify_____			
Radioimmunotherapy:	☐ Bexxar (CD20) *(radiolabelled MoAB)*			
	☐ Zevalin (CD20) *(radiolabelled MoAB)*			
		Relapse/progression under this drug		
Specific inhibitors:	☐ ABT-199 (BCL2-Inhibitor)	☐ Yes	☐ No	☐ Unknown
	☐ Crizotinib (ALK-Inhibitor)	☐ Yes	☐ No	☐ Unknown
	☐ CC-292 (B cell receptor kinase inhibitor)	☐ Yes	☐ No	☐ Unknown
	☐ Ibrutinib (B cell receptor kinase inhibitor)	☐ Yes	☐ No	☐ Unknown
	☐ Idelalisib (B cell receptor kinase inhibitor)	☐ Yes	☐ No	☐ Unknown
	☐ other inhibitor, specify_____	☐ Yes	☐ No	☐ Unknown
Other:	☐ Bortezomib (Velcade)			
	☐ Revlimid (Lenalidomide)			
	☐ Other, specify _____			

Radiotherapy ☐ No ☐ Yes

Response to this line of therapy

☐ Complete remission ☐ Partial remission (> 50 %) ☐ No response (< 50 %) ☐ Relapse/progression

ADDITIONAL TREATMENT GIVEN BEFORE THE 1ST TRANSPLANT?

☐ No – *Proceed to page 10, "Disease History before HSCT"*

☐ Yes **Date started** .... - ....
yyyy mm dd

Sequential number of this treatment: .....
(counted from diagnosis)

☐ Unknown

Drugs given

Antibodies:	☐ Alemtuzumab (MabCampath) (CD52)			
	☐ Brentuximab (Adcetris) (CD30)			
	☐ Obinutuzumab (Gyzeva) (CD20)			
	☐ Ofatumumab (Azerra) (CD20)			
	☐ Rituximab (Mabthera) (CD20)			
	☐ other antibody, specify_____			
Radioimmunotherapy:	☐ Bexxar (CD20) *(radiolabelled MoAB)*			
	☐ Zevalin (CD20) *(radiolabelled MoAB)*			
		Relapse/progression under this drug		
Specific inhibitors:	☐ ABT-199 (BCL2-Inhibitor)	☐ Yes	☐ No	☐ Unknown
	☐ Crizotinib (ALK-Inhibitor)	☐ Yes	☐ No	☐ Unknown
	☐ CC-292 (B cell receptor kinase inhibitor)	☐ Yes	☐ No	☐ Unknown
	☐ Ibrutinib (B cell receptor kinase inhibitor)	☐ Yes	☐ No	☐ Unknown
	☐ Idelalisib (B cell receptor kinase inhibitor)	☐ Yes	☐ No	☐ Unknown
	☐ other inhibitor, specify_____	☐ Yes	☐ No	☐ Unknown
Other:	☐ Bortezomib (Velcade)			
	☐ Revlimid (Lenalidomide)			
	☐ Other, specify _____			

Radiotherapy ☐ No ☐ Yes

Response to this line of therapy

☐ Complete remission ☐ Partial remission (> 50 %) ☐ No response (< 50 %) ☐ Relapse/progression

ADDITIONAL TREATMENT GIVEN BEFORE THE 1ST TRANSPLANT?

☐ No – *Proceed to page 10, "Disease History before HSCT"*

☐ Yes **Date started** .... - ....
yyyy mm dd

Sequential number of this treatment: .....
(counted from diagnosis)

☐ Unknown

Drugs given

Antibodies:	☐ Alemtuzumab (MabCampath) (CD52)			
	☐ Brentuximab (Adcetris) (CD30)			
	☐ Obinutuzumab (Gyzeva) (CD20)			
	☐ Ofatumumab (Azerra) (CD20)			
	☐ Rituximab (Mabthera) (CD20)			
	☐ other antibody, specify_____			
Radioimmunotherapy:	☐ Bexxar (CD20) *(radiolabelled MoAB)*			
	☐ Zevalin (CD20) *(radiolabelled MoAB)*			
		Relapse/progression under this drug		
Specific inhibitors:	☐ ABT-199 (BCL2-Inhibitor)	☐ Yes	☐ No	☐ Unknown
	☐ Crizotinib (ALK-Inhibitor)	☐ Yes	☐ No	☐ Unknown
	☐ CC-292 (B cell receptor kinase inhibitor)	☐ Yes	☐ No	☐ Unknown
	☐ Ibrutinib (B cell receptor kinase inhibitor)	☐ Yes	☐ No	☐ Unknown
	☐ Idelalisib (B cell receptor kinase inhibitor)	☐ Yes	☐ No	☐ Unknown
	☐ other inhibitor, specify_____	☐ Yes	☐ No	☐ Unknown
Other:	☐ Bortezomib (Velcade)			
	☐ Revlimid (Lenalidomide)			
	☐ Other, specify _____			

Radiotherapy ☐ No ☐ Yes

Response to this line of therapy

☐ Complete remission ☐ Partial remission (> 50 %) ☐ No response (< 50 %) ☐ Relapse/progression

Selected B-Cell Non Hodgkin Lymphomas (NHL)

⇨ **Please complete this section for patients given HSCT for the following types of B-cell NHL:**

- **Mantle cell lymphoma**
- **Waldenstrom macroglobulinaemia**
- **Burkitt lymphoma OR "Intermediate DLBCL/Burkitt Lymphoma"**

Date of this HSCT: ..... - ..... - .....
yyyy mm dd

Chromosome Analysis at any time before HSCT

☐ Normal ☐ Abnormal ☐ Not done or failed ☐ Unknown

If abnormal, please complete this table according to the type of lymphoma diagnosed

	Abnormality	**Absent**	**Present**	**FISH used**	**Not evaluated**
Mantle cell lymphoma *or* Waldenstrom macroglobulinaemia	del 17p	☐	☐	☐ No ☐ Yes	☐
Burkitt Lymphoma *or* "Intermediate DLBCL/ Burkitt Lymphoma"	t(2;8)	☐	☐		☐
	t(8;14)	☐	☐		☐
	t(8;22)	☐	☐		☐
	t(14;18)	☐	☐		☐
	myc rearrangement	☐	☐		☐
	BCL-2 rearrangement	☐	☐		☐
	BCL-6 rearrangement	☐	☐		☐

Immunophenotyping / immunohistochemistry at any time before HSCT

Immunophenotyping tested ☐ Yes ☐ No ☐ Unknown

Provide answers according to the type of lymphoma diagnosed

	Phenotype	**Present**	**Absent**	**Not evaluated**
Mantle cell lymphoma	SOX11	☐	☐	☐
Burkitt Lymphoma *or* "Intermediate DLBCL/ Burkitt Lymphoma"	MYC	☐	☐	☐
"Intermediate DLBCL/ Burkitt Lymphoma"	BCL-2/IgH	☐	☐	☐
	BCL-6	☐	☐	☐

Molecular Markers at any time before HSCT

☐ Not evaluated ☐ Present ☐ Absent ☐ Unknown

Provide answers according to the type of lymphoma diagnosed

	Marker	**Present**	**Absent**	**Not evaluated**
Mantle cell lymphoma	TP53 mutation	☐	☐	☐
Burkitt Lymphoma *or* "Intermediate DLBCL/ Burkitt Lymphoma"	*myc* rearrangement	☐	☐	☐
"Intermediate DLBCL/ Burkitt Lymphoma"	*BCL-2* rearrangement	☐	☐	☐
	BCL-6 rearrangement	☐	☐	☐

DISEASE HISTORY BEFORE HSCT

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

TREATMENT SUMMARY

Number of prior lines of treatment ☐ 1 ☐ 2 ☐ 3 or more ☐ None ☐ unknown
(since diagnosis if 1st transplant, or since last reported transplant)

Modality used at least once:	Chemotherapy	☐ No	☐ Yes	☐ Unknown
	MoAB *(Immunotherapy*)	☐ No	☐ Yes	☐ Unknown
	Radiotherapy	☐ No	☐ Yes	☐ Unknown

Splenectomy ☐ No ☐ Yes, Date : .... - .... - ....
yyyy mm dd

COMPLETE REMISSION AND RELAPSE HISTORY BEFORE THE 1ST HSCT

If patient did not have treatment before the 1st HSCT or the information requested in this section has been submitted with a previous registration for this patient go to page 11, *Status of disease at HSCT*

CR achieved before the 1st transplant:

☐ Yes: Date of first CR: .... - .... - ....
☐ No *yyyy mm dd*

Number of treatment lines necessary to reach this first remission: .....

TO BE COMPLETED ONLY IF PATIENT HAD A CR BEFORE THE 1ST TRANSPLANT

Relapse before the 1st transplant:

☐ Yes: Date of first relapse: .. .. - .... - ....
☐ No *yyyy mm dd*

STATUS OF DISEASE AT HSCT

Date of this HSCT: ..... - ..... - .....
yyyy mm dd

Technique used for disease assessment:

CT scan done ☐ No ☐ Yes
PET ☐ Negative ☐ Positive ☐ Not evaluated

STATUS

☐ Never treated
☐ Complete remission (CR)
☐ Unconfirmed (CRU*) ☐ Confirmed
*CRU – complete response with persistent scan abnormalities of unknown significance
☐ Partial response (PR) – (with or without a prior CR)
☐ Stable disease
☐ Untreated relapse (from a previous CR) / untreated progression (from a previous PR)
☐ Chemorefractory relapse or progression, including primary refractory disease
☐ Disease status unknown

Was this patient **refractory** to any line of chemotherapy before this HSCT? ☐ No ☐ Yes

Number of Complete remissions (CR, CRu) achieved by the patient prior to this HSCT: ……..
Count <u>all</u> CR including this one if applicable

Number of Partial remissions (PR) achieved by the patient prior to this HSCT: ……..
Count <u>all</u> PR including this one if applicable

DISEASE INVOLVEMENT AT TRANSPLANT

☐ Yes ☐ No ☐ Not evaluated ☐ Unknown

Size of largest mass *(if patient in CR at HSCT, indicate "No mass")*

☐ < 5 cm ☐ 5-10 cm ☐ > 10 cm ☐ No mass ☐ Not evaluated

Specific sites of disease *(to be completed ONLY if patient NOT in CR at transplant)*

☐ Nodes below the diaphragm ☐ Bone marrow ☐ Extranodal (CNS)
☐ Mediastinum ☐ Extranodal (testis /ovary) ☐ Nodes above the diaphragm
☐ Lung ☐ Liver ☐ Spleen
☐ Other : .....

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

DAY 100 LYMPHOMA

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 RESPONSE AT 100 DAYS AFTER TRANSPLANTATION

☐ Complete remission *(maintained or achieved)*
- ☐ Unconfirmed
- ☐ Confirmed: ☐ By CT scan ☐ By PET

☐ Partial remission (> 50 %)
- ☐ Progression

☐ No response (< 50 %)
- ☐ Early death/Not evaluable

If Complete remission: Date of CR ..... - ..... - .....
yyyy mm dd

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 Unique Patient Number (UPN): ..... HSCT Date..... .... - .... - ....
yyyy mm dd

FOLLOW UP | LYMPHOMA

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

Complications after Transplant (Allografts)

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 (none)	☐ I	☐ II	☐ III	☐ IV
Liver	☐ 0 (none)	☐ I	☐ II	☐ III	☐ IV
Lower GI tract	☐ 0 (none)	☐ I	☐ II	☐ III	☐ IV
Upper GI tract	☐ 0 (none)	☐ I			
Other site affected	☐ No	☐ Yes			

Resolution

☐ No ☐ Yes: Date of resolution: ....- .... - ....
yyyy mm dd

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

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

SECONDARY MALIGNANCY, LYMPHOPROLIFERATIVE OR MYELOPROLIFRATIVE DISORDER DIAGNOSED

☐ Previously reported

☐ Yes, date of diagnosis: .... - .... - ....
yyyy mm dd

Diagnosis: ☐ AML ☐ MDS ☐ Lymphoproliferative disorder ☐ Other .....

IF THE PATIENT HAS RECEIVED AN ALLOGRAFT PRIOR TO THE DIAGNOSIS OF ACUTE LEUKAEMIA, ANSWER THE FOLLOWING QUESTION

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

☐ No

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
An allo boost is an infusion of cells from the same donor without conditioning, with no evidence of graft rejection.

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**

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 DLI only	
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 any non DLI infusion	
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

-Chemo / radiotherapy

Additional DISEASE treatment given excluding cell infusion?

☐ No
☐ Yes: ☐ Preemptive / preventive *(planned before the transplant took place)*
☐ For relapse / progression or persistent disease *(not planned)*

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

Chemo/drug/agent ..... ☐ Unknown
(including MoAB, vaccination, etc.)
Radiotherapy ☐ No ☐ Yes ☐ Unknown

Other treatment ☐ No ☐ Yes, specify: .... ☐ Unknown
☐ 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 HSCT
☐ Unknown

DISEASE AND PATIENT STATUS ON DATE LAST SEEN

LAST DISEASE STATUS

☐ Complete Remission
☐ Relapse / progression

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 Unique Patient Number (UPN): ..... HSCT Date..... .... - .... - ....
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

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

.....