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 .... - .... - ....
yyyy mm dd

Sex: ☐ Male ☐ Female

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
- ☐ Myelogenous (AML)
- ☐ Lymphoblastic (ALL)

☐ Secondary Acute Leukaemia
(do not use if transformed from MDS/MPS)

☐ Chronic Leukaemia
- ☐ Chronic Myeloid Leukaemia (CML)
- ☐ Chronic Lymphocytic Leukaemia

☐ Lymphoma
- ☐ Non Hodgkin
- ☐ Hodgkin's Disease

☐ Myeloma /Plasma cell disorder

☐ Solid Tumour

☐ Myelodysplastic syndromes
- ☐ MDS
- ☐ MD/MPS

☐ Myeloproliferative syndrome

☐ Aplastic anaemia

☐ Inherited disorders
- ☐ Primary immune deficiencies
- ☐ Metabolic disorders

☐ Histiocytic disorders

☐ Autoimmune disease
- ☐ Juvenile Idiopathic Arthritis
- ☐ Multiple Sclerosis
- ☐ Systemic Lupus
- ☐ Systemic Sclerosis

☐ Haemoglobinopathy

☐ Other diagnosis, specify:___________________________________

SPECIFICATIONS OF THE DISEASE

AL AMYLOIDOSIS

INITIAL DIAGNOSIS

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

☐ Yes: go to page 4, *Pre-HSCT Treatment* ☐ No: proceed with this section

EVIDENCE OF UNDERLYING PLASMA CELL DISORDER

☐ No

☐ Yes

☐ Monoclonal Gammopathy

☐ Multiple Myeloma

☐ Other B-cell malignancy, specify ..……………......................

Select one as applicable

☐ IgG
☐ IgA
☐ IgD
☐ IgE
☐ IgM
☐ Absent
☐ Not evaluated

Select one as applicable

☐ Kappa
☐ Lambda
☐ Absent
☐ Not evaluated

If Multiple myeloma

Stage at diagnosis (Salmon and Durie)

	I	II	III
A	☐	☐	☐
B	☐	☐	☐

DIAGNOSIS OF AMYLOIDOSIS

Methods

Hereditary Amyloidosis	☐ Excluded	☐ Not evaluated
Immunohistochemistry	☐ Done	☐ Not evaluated

CLINICAL AND LABORATORY DATA

Hb *(g/dL)*	....	☐ Not evaluated
Serum creatinine	.... Units: ☐ *µmol/L* ☐ *mg/dL*	☐ Not evaluated
Creatinine clearance *(mL/min)*	....	☐ Not evaluated
Total urinary protein excretion *(mg/24 h)*	....	☐ Not evaluated
Total urinary albumin excretion *(mg/24 h)*	....	☐ Not evaluated
Serum calcium *(mmol/L)*	.... -	☐ Not evaluated
Serum albumin *(g/L)*	....	☐ Not evaluated
Serum alkaline phosphatase *(IU/L)*	....	☐ Not evaluated
Serum bilirubin	.... Units: ☐ *µmol/L* ☐ *mg/dL*	☐ Not evaluated
Serum NT-pro-BNP *(ng/L)*	....	☐ Not evaluated
Serum c-Troponin T *(µg/L)*	....	☐ Not evaluated

Bone marrow investigations

BM aspirate: % plasmacytosis	....	☐ Not evaluated
BM trephine: % plasmacytosis	....	☐ Not evaluated

Immunoglobulins

Monoclonal Ig in serum *(g/L)* ....

Immunofixation of serum ☐ Negative ☐ Positive ☐ Not evaluated ☐ Unknown

Free light chains in serum:

Kappa light chains *(mg/L)* .... ☐ Not evaluated.

Lambda light chains *(mg/L)* .... ☐ Not evaluated

Immunofixation of urine ☐ Negative ☐ Positive ☐ Not evaluated ☐ Unknown

Monoclonal light chains in urine *(g/24 h)* ....

Serum β2 microglobulin *(mg/L)* .... - ....

Bone structure (X-ray) ☐ Normal ☐ Lytic lesion present ☐ Not evaluated ☐ Unknown

Typical clinical symptoms

Macroglossy	☐ Absent	☐ Present	☐ Not evaluated	☐ Unknown
Periorbital bleeding	☐ Absent	☐ Present	☐ Not evaluated	☐ Unknown
Shoulder pad sign	☐ Absent	☐ Present	☐ Not evaluated	☐ Unknown

ORGAN INVOLVEMENT AT DIAGNOSIS

	Dominant organ(s) involved	Additional organ involvement	Biopsy	No involvement
Soft Tissues	☐	☐	☐	☐
Gastrointestinal Tract	☐	☐	☐	☐
Heart	☐	☐	☐	☐
Liver	☐	☐	☐	☐
Kidney	☐	☐	☐	☐
Peripheral nerves	☐	☐	☐	☐
Autonomic nerves	☐	☐	☐	☐
Other	☐	☐	☐	☐

Specify ......……..... .... ……………………………….

ORGAN-SPECIFIC DATA AT DIAGNOSIS

Liver

Liver span in ultrasound or CT scan *(cm craniocaudal diameter)* .... ☐ Not evaluated

Heart

NYHA class ☐ I ☐ II ☐ III ☐ IV ☐ Unknown

Left ventricular ejection fraction *(%)* .... ☐ Not evaluated

Interventricular septal wall thickness *(mean # mm in echocardiogram)* .... ☐ Not evaluated

Gastrointestinal

Weight loss	☐ No	☐ Yes	☐ Not evaluated	☐ Unknown
Malabsorption	☐ No	☐ Yes	☐ Not evaluated	☐ Unknown
GI bleeding	☐ No	☐ Yes	☐ Not evaluated	☐ Unknown

Other evidence of gastrointestinal involvement: ………………………………………………..
……………………………………………………………………

Peripheral neuropathy

Neurological exam ☐ Normal ☐ Abnormal ☐ Not evaluated or failed ☐ Unknown

If abnormal:

Specify abnormality ……………………………………………………………………

PNP severity ☐ grade I ☐ grade II ☐ grade III ☐ grade IV

Autonomic neuropathy

Orthostatic hypotension ☐ Yes ☐ No ☐ Not evaluated ☐ Unknown
Intractable diarrhoea ☐ Yes ☐ No ☐ Not evaluated ☐ Unknown
Inflexible pulse rate ☐ Yes ☐ No ☐ Not evaluated ☐ Unknown

Other sites

Clinical evidence for involvement of other sites:………………………………………………..

PRE-HSCT TREATMENT

If this registration pertains to a second or subsequent HSCT whether the patient had therapy should be counted since last reported HSCT.

WAS THE PATIENT TREATED BEFORE THE HSCT PROCEDURE?

☐ No
☐ Yes:

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

Modality: Chemotherapy ☐ No ☐ Yes: Chemotherapy regimen ....
Number of cycles ....

Other ....

HSCT

DATE OF HSCT : .... - .... - .... (EVENT: "HSCT")
yyyy mm dd

HSCT TYPE

☐ Allogeneic: *proceed to "Status at Start of Conditioning" on page 5*

Autologous: Date of 1st collection or pheresis: .... - .... - ....
yyyy mm dd

STATUS OF DISEASE AT COLLECTION (AUTOGRAFTS ONLY)

IMMEDIATELY PRIOR TO MOBILISING CHEMOTHERAPY AND/OR GROWTH FACTOR IF USED

Haematological status

☐ At diagnosis ☐ CR1 ☐ CR2 ☐ >CR2
☐ PR1 ☐ PR2 ☐ >PR2 ☐ MR
☐ No change ☐ Progression ☐ Unknown

Organ status ☐ At diagnosis ☐ Response ☐ No change ☐ Progression ☐ Unknown

STATUS OF DISEASE AT START OF CONDITIONING FOR BMT

Haematological status

☐ At diagnosis ☐ CR1 ☐ CR2 ☐ >CR2
☐ PR1 ☐ PR2 ☐ >PR2 ☐ MR
☐ No change ☐ Progression ☐ Unknown

Organ status ☐ At diagnosis ☐ Response ☐ No change ☐ Progression ☐ Unknown

CLINICAL AND LABORATORY DATA

Hb *(g/dL)*	....	☐ Not evaluated
Serum creatinine	.... Units: ☐ *μmol/L* ☐ *mg/dL*	☐ Not evaluated
Creatinine clearance *(mL/min)*	....	☐ Not evaluated
Total urinary protein excretion *(mg/24 h)*	....	☐ Not evaluated
Total urinary albumin excretion *(mg/24 h)*	....	☐ Not evaluated
Serum calcium *(mmol/L)*	.... -	☐ Not evaluated
Serum albumin *(g/L)*	....	☐ Not evaluated
Serum alkaline phosphatase *(IU/L)*	....	☐ Not evaluated
Serum bilirubin	.... Units: ☐ *μmol/L* ☐ *mg/dL*	☐ Not evaluated
Serum NT-pro-BNP *(ng/L)*	....	☐ Not evaluated
Serum c-Troponin T *(μg/L)*	....	☐ Not evaluated

Bone marrow investigations

BM aspirate: % plasmacytosis .... ☐ Not evaluated
BM trephine: % plasmacytosis .... ☐ Not evaluated

Immunoglobulins

Monoclonal Ig in serum *(g/L)* ....
Immunofixation of serum ☐ Negative ☐ Positive ☐ Not evaluated ☐ Unknown
Free light chains in serum:
Kappa light chains *(mg/L)* .... ☐ Not evaluated.
Lambda light chains *(mg/L)* .... ☐ Not evaluated
Immunofixation of urine ☐ Negative ☐ Positive ☐ Not evaluated ☐ Unknown
Monoclonal light chains in urine *(g/24 h)* ....
Serum β2 microglobulin *(mg/L)* .... - ....

ORGAN INVOLVEMENT AT HSCT

	Dominant organ(s) involved	Additional organ involvement	Biopsy	No involvement
Soft Tissues	☐	☐	☐	☐
Gastrointestinal Tract	☐	☐	☐	☐
Heart	☐	☐	☐	☐
Liver	☐	☐	☐	☐
Kidney	☐	☐	☐	☐
Peripheral nerves	☐	☐	☐	☐
Autonomic nerves	☐	☐	☐	☐
Other	☐	☐	☐	☐

Specify ....

ORGAN-SPECIFIC DATA AT HSCT

Liver

Liver span in ultrasound or CT scan *(cm craniocaudal diameter)* .... ☐ Not evaluated

Heart

NYHA class ☐ I ☐ II ☐ III ☐ IV ☐ Unknown

Left ventricular ejection fraction *(%)* .... ☐ Not evaluated

Interventricular septal wall thickness .... ☐ Not evaluated
(mean # mm in echocardiogram)

Gastrointestinal

Weight loss ☐ No ☐ Yes ☐ Not evaluated ☐ Unknown

Malabsorption ☐ No ☐ Yes ☐ Not evaluated ☐ Unknown

GI bleeding ☐ No ☐ Yes ☐ Not evaluated ☐ Unknown

Other evidence of gastrointestinal involvement: ………………………………………………..
…………………………………………………………………

Peripheral neuropathy

Neurological exam ☐ Normal ☐ Abnormal ☐ Not evaluated or failed ☐ Unknown

If abnormal:
Specify abnormality …..………….................…………………………………………

PNP severity ☐ grade I ☐ grade II ☐ grade III ☐ grade IV ☐ Unknown

Autonomic neuropathy

Orthostatic hypotension ☐ Yes ☐ No ☐ Not evaluated ☐ Unknown

Intractable diarrhoea ☐ Yes ☐ No ☐ Not evaluated ☐ Unknown

Inflexible pulse rate ☐ Yes ☐ No ☐ Not evaluated ☐ Unknown

Other sites

Clinical evidence for involvement of other sites:………………………………………………..

STATUS OF DISEASE AT 100 DAYS AFTER HSCT

If patient died before 100 days, please check 'Not evaluable' and proceed to FORMS TO BE FILLED IN on page 8.

BEST HAEMATOLOGICAL RESPONSE TO HSCT AT 100 DAYS

☐ CR1 ☐ CR2 ☐ >CR2_

☐ PR1 ☐ PR2 ☐ >PR2 ☐ MR

☐ No change ☐ Progression ☐ Not evaluable ☐ Unknown

DATE RESPONSE ACHIEVED OR ASSESSED :....... .... - .... - ....
yyyy mm dd

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

CLINICAL AND LABORATORY DATA

Hb *(g/dL)*	....	☐ Not evaluated
Serum creatinine	.... Units: ☐ *µmol/L* ☐ *mg/dL*	☐ Not evaluated
Creatinine clearance *(mL/min)*	....	☐ Not evaluated
Total urinary protein excretion *(mg/24 h)*	....	☐ Not evaluated
Total urinary albumin excretion *(mg/24 h)*	....	☐ Not evaluated
Serum calcium *(mmol/L)*	.... -	☐ Not evaluated
Serum albumin *(g/L)*	....	☐ Not evaluated
Serum alkaline phosphatase *(IU/L)*	....	☐ Not evaluated
Serum bilirubin	.... Units: ☐ *µmol/L* ☐ *mg/dL*	☐ Not evaluated
Serum NT-pro-BNP *(ng/L)*	....	☐ Not evaluated
Serum c-Troponin T *(µg/L)*	....	☐ Not evaluated

Bone marrow investigations

BM aspirate: % plasmacytosis .... ☐ Not evaluated

BM trephine: % plasmacytosis .... ☐ Not evaluated

Immunoglobulins

Monoclonal Ig in serum *(g/L)* ....

Immunofixation of serum ☐ Negative ☐ Positive ☐ Not evaluated ☐ Unknown

Free light chains in serum:

Kappa light chains *(mg/L)* .... ☐ Not evaluated.

Lambda light chains *(mg/L)* .... ☐ Not evaluated

Immunofixation of urine ☐ Negative ☐ Positive ☐ Not evaluated ☐ Unknown

Monoclonal light chains in urine *(g/24 h)* ....

Serum β2 microglobulin *(mg/L)* .... - ....

ORGAN-SPECIFIC RESPONSES AT 100 DAYS AFTER HSCT

Kidney

Renal response ☐ Response ☐ No response/stable disease ☐ Progressive disease
☐ Not evaluable ☐ Not evaluated/not applicable ☐ Unknown

Liver

Liver span in ultrasound or CT scan *(cm craniocaudal diameter)* .... ☐ Not evaluated

Hepatic response ☐ Response ☐ No response/stable disease ☐ Progressive disease
☐ Not evaluable ☐ Not evaluated/not applicable ☐ Unknown

Heart

NYHA class ☐ I ☐ II ☐ III ☐ IV ☐ Unknown

Left ventricular ejection fraction *(%)* .... ☐ Not evaluated

Interventricular septal wall thickness .... ☐ Not evaluated
(mean # mm in echocardiogram)

Cardiac response ☐ Response ☐ No response/stable disease ☐ Progressive disease
☐ Not evaluable ☐ Not evaluated/not applicable ☐ Unknown

Gastrointestinal

Weight loss	☐ No	☐ Yes	☐ Not evaluated	☐ Unknown
Malabsorption	☐ No	☐ Yes	☐ Not evaluated	☐ Unknown
GI bleeding	☐ No	☐ Yes	☐ Not evaluated	☐ Unknown

GI response	☐ Response	☐ No response/stable disease	☐ Progressive disease
	☐ Not evaluable	☐ Not evaluated/not applicable	☐ Unknown

Peripheral neuropathy
(Compare current situation to situation before HSCT)

Neurological exam	☐ Improved	☐ Worsened	☐ Unchanged	☐ Unknown
PNP severity	☐ grade I	☐ grade II	☐ grade III	☐ grade IV

PN response	☐ Response	☐ No response/stable disease	☐ Progressive disease
	☐ Not evaluable	☐ Not evaluated/not applicable	☐ Unknown

Autonomic neuropathy

AN response	☐ Response	☐ No response/stable disease	☐ Progressive disease
	☐ Not evaluable	☐ Not evaluated/not applicable	☐ Unknown

Evidence of new organ involvement
Clinical evidence for involvement of new sites:………………………………………………..

KARNOFSKY : ....

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 Office for instructions

FOLLOW UP — AL AMYLOIDOSIS

Unique Identification Code (UIC) .... - .... - .... *(if known)*
Hospital Unique Patient Number ....
Initials ....
Date of birth .... - .... - .... Date of HSCT : .... - .... - ....
yyyy mm dd *yyyy mm dd*

PATIENT LAST SEEN

DATE OF LAST CONTACT OR DEATH: ....…..... - .... - ....
yyyy mm dd

Complete haematological remission obtained after the HSCT in the absence of additional disease treatment

- ☐ Previously reported
- ☐ Yes, date ....…..... .... - .... - ....
- ☐ No *yyyy mm dd*
- ☐ Unknown

COMPLICATIONS AFTER 100 DAYS

PLEASE USE THE DOCUMENT "DEFINITIONS OF INFECTIOUS DISEASES AND COMPLICATIONS AFTER STEM CELL 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 *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.*
Bacteraemia / fungemia / viremia / parasites		
SYSTEMIC SYMPTOMS OF INFECTION		
Septic shock		
ARDS		
Multiorgan failure due to infection		
ENDORGAN DISEASES		
Pneumonia		
Hepatitis		

CNS infection		
Gut infection		
Skin infection		
Cystitis		
Retinitis		
Other:		
		dd mm yyyy

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)*	**CTC grade** 0 1 2 3 4	**Date**	**Comments**
Cardiovascular	☐ ☐ ☐ ☐ ☐		
Dermatologic	☐ ☐ ☐ ☐ ☐		
Gastrointestinal	☐ ☐ ☐ ☐ ☐		
Haemorrhage	☐ ☐ ☐ ☐ ☐		
Hepatic	☐ ☐ ☐ ☐ ☐		
Neurologic	☐ ☐ ☐ ☐ ☐		
Pulmonary	☐ ☐ ☐ ☐ ☐		
Renal	☐ ☐ ☐ ☐ ☐		
Secondary malignancy	☐ ☐ ☐ ☐ ☐		
Other:	☐ ☐ ☐ ☐ ☐		
		dd mm yyyy	

ADDITIONAL COMMENTS ....
....

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 THERAPIES SINCE LAST 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 10^8 ☐ 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

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

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)*

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

☐ Unknown

LAST DISEASE AND PATIENT STATUS

HAEMATOLOGICAL DISEASE STATUS

☐ Complete remission

☐ Partial remission

☐ Stable disease

☐ Progression

☐ Not evaluable

☐ Unknown

KARNOFSKY:...........

ORGAN RESPONSE

☐ Response

☐ Non Response

☐ Progression

☐ Not evaluable

☐ Unknown

CLINICAL AND LABORATORY DATA

Hb *(g/dL)*	....		☐ Not evaluated
Serum creatinine	....	Units: ☐ *µmol/L* ☐ *mg/dL*	☐ Not evaluated
Creatinine clearance *(mL/min)*	....		☐ Not evaluated
Total urinary protein excretion *(mg/24 h)*	....		☐ Not evaluated
Total urinary albumin excretion *(mg/24 h)*	....		☐ Not evaluated
Serum calcium *(mmol/L)*	.... -		☐ Not evaluated
Serum albumin *(g/L)*	....		☐ Not evaluated
Serum alkaline phosphatase *(IU/L)*	....		☐ Not evaluated
Serum bilirubin	....	Units: ☐ *µmol/L* ☐ *mg/dL*	☐ Not evaluated
Serum NT-pro-BNP *(ng/L)*	....		☐ Not evaluated
Serum c-Troponin T *(µg/L)*	....		☐ Not evaluated

Bone marrow investigations

BM aspirate: % plasmacytosis .... ☐ Not evaluated

BM trephine: % plasmacytosis .... ☐ Not evaluated

Immunoglobulins

Monoclonal Ig in serum *(g/L)* ....

Immunofixation of serum ☐ Negative ☐ Positive ☐ Not evaluated ☐ Unknown

Free light chains in serum:

Kappa light chains *(mg/L)* .... ☐ Not evaluated.

Lambda light chains *(mg/L)* .... ☐ Not evaluated

Immunofixation of urine ☐ Negative ☐ Positive ☐ Not evaluated ☐ Unknown

Monoclonal light chains in urine *(g/24 h)* ....

Serum β2 microglobulin *(mg/L)* .... - ....

ORGAN-SPECIFIC RESPONSES AT THIS FOLLOW UP

Renal response ☐ Response ☐ No response/stable disease ☐ Progressive disease
☐ Not evaluable ☐ Not evaluated/not applicable ☐ Unknown

Liver

Liver span in ultrasound or CT scan *(cm craniocaudal diameter)* .... ☐ Not evaluated

Hepatic response ☐ Response ☐ No response/stable disease ☐ Progressive disease
☐ Not evaluable ☐ Not evaluated/not applicable ☐ Unknown

Heart

NYHA class ☐ I ☐ II ☐ III ☐ IV ☐ Unknown

Left ventricular ejection fraction *(%)* .... ☐ Not evaluated

Interventricular septal wall thickness .... ☐ Not evaluated
(mean # mm in echocardiogram)

Cardiac response ☐ Response ☐ No response/stable disease ☐ Progressive disease
☐ Not evaluable ☐ Not evaluated/not applicable ☐ Unknown

Gastrointestinal

Weight loss ☐ No ☐ Yes ☐ Not evaluated ☐ Unknown

Malabsorption ☐ No ☐ Yes ☐ Not evaluated ☐ Unknown

GI bleeding ☐ No ☐ Yes ☐ Not evaluated ☐ Unknown

GI response ☐ Response ☐ No response/stable disease ☐ Progressive disease
☐ Not evaluable ☐ Not evaluated/not applicable ☐ Unknown

Peripheral neuropathy

(Compare current situation to situation before HSCT)

Neurological exam ☐ Improved ☐ Worsened ☐ Unchanged ☐ Unknown

PNP severity ☐ grade I ☐ grade II ☐ grade III ☐ grade IV

PN response ☐ Response ☐ No response/stable disease ☐ Progressive disease
☐ Not evaluable ☐ Not evaluated/not applicable ☐ Unknown

Autonomic neuropathy

AN response ☐ Response ☐ No response/stable disease ☐ Progressive disease
☐ Not evaluable ☐ Not evaluated/not applicable ☐ Unknown

Evidence of new organ involvement

Clinical evidence for involvement of new sites:……………………………………………………..

CONCEPTION

Has patient or partner become pregnant after this HSCT?

☐ Yes ☐ No ☐ Unknown

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

CAUSE OF DEATH *(check only one main cause)*

☐ Due to amyloidosis *(progression of disease)*

☐ Secondary malignancy

☐ HSCT related cause :

(check as many as appropriate)

Cause	Yes	No	Unknown
cGvHD	☐	☐	☐
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	☐	☐	☐
EBV lymphoproliferative disease	☐	☐	☐
Other:	☐		

☐ Unknown

☐ Other : ....

....

ADDITIONAL NOTES IF APPLICABLE

COMMENTS ....

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IDENTIFICATION & SIGNATURE

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