Cell Therapy - MED - A

Registration to month 6

CENTRE IDENTIFICATION

EBMT Code (CIC): ....

Hospital: ..... Unit: .....

Contact person.....

e-mail: .....

PATIENT DATA

Date of this Report: ..... - ..... - .....
yyyy *mm* *dd*

EBMT Registry Unique Identification Code (UIC) .....
(if applicable)

Hospital Unique <u>Patient</u> Number or Code (UPN): .....
Compulsory, registrations will not be accepted without this item. *<u>All</u> treatments performed in the same patient <u>must</u> be registered with the <u>same</u> patient identification number or code as this belongs to the patient and <u>not</u> to the treatment.*

Other type of patient identification codes (AIEOP etc.):
……
(Optional: This item is to be used by the centre to register a patient code for internal use as necessary)

Initials: ....._..... (first name(s) _family name(s))

Date of Birth: ..... - ..... - .....
yyyy *mm* dd

Sex: ☐ Male ☐ Female
(at birth)

CIC: ..... Hospital UPN: ..... Date of the first cell therapy infusion..... .... - .... - .....
(Do not write here the date of any HSCT) *yyyy* *mm* *dd*

INDICATION FOR CELL THERAPY TREATMENT

SELECT ALL THAT APPLY

☐ **Treatment of a Primary disease, including Infections or Infection prevention**

Date of initial diagnosis: ..... - ..... - .....
yyyy mm dd

INDICATE THE PRIMARY DISEASE FOR WHICH THIS CELL THERAPY WAS GIVEN

☐ Primary Acute Leukaemia
- ☐ Acute myelogenous leukaemia (Page 14)
- ☐ Precursor lymphoid neoplasms (Page 16)
- ☐ Other Primary Acute Leukaemia (Page 17)

☐ Chronic Leukaemia
- ☐ Chronic Myeloid Leukaemia (CML) (Page 18)
- ☐ Chronic Lymphocytic Leukaemia (CLL) (Page 19)
- ☐ Prolymphocytic Leukaemia (PLL) (Page 20)

☐ Lymphoma (Page 21)
- ☐ Non Hodgkin
- ☐ Hodgkin's Disease

☐ Myelodysplastic syndrome and/or myeloproliferative neoplasm (Page 21)
- ☐ MDS
- ☐ MDS/MPN
- ☐ Myeloproliferative neoplasm

☐ Myeloma /Plasma cell disorder (Page 26)

☐ Solid Tumour (Page 28)

☐ Bone marrow failure and/or graft failure (Page 27)

☐ Inherited disorders (Page 29)
- ☐ Primary immune deficiencies
- ☐ Metabolic disorders
- ☐ Other

☐ Histiocytic disorders (Page 30)

☐ Haemoglobinopathy (Page 27)

☐ Autoimmune disease
- ☐ Connective (Page 31)
- ☐ Vasculitis (Page 31)
- ☐ Arthritis (Page 32)
- ☐ Neurological (MS, etc) (Page 32)
- ☐ Haematological (Page 32)
- ☐ Bowel disorder (Page 33)
- ☐ Other (Diabetes, etc.) (Page 33)

☐ Infections (Page 35)

Other primary diseases
- ☐ Cardiovascular disease (Page 34)
- ☐ Muscoskeletal disorder (Page 34)
- ☐ Neurologic disorder (Page 34)
- ☐ Ocular disease, specify ……
- ☐ Pulmonary disease, specify ……

Complete and attach the relevant DISEASE CLASSIFICATION SHEET as per the page numbers indicated above, including the date of Cell therapy and disease status at Cell therapy, then continue to Clinical setting in the next page.

☐ **Treatment or prevention of complications derived or expected from a previous treatment including HSCT**

Indicate the date of the last HSCT for this patient ..... - ..... - ..... ☐ Not applicable
yyyy *mm* *dd*

Date of first cell infusion for this treatment ..... - ..... - .....
yyyy *mm* *dd*

☐ **Other indication, specify**:_____

Please, contact the Registry helpdesk before proceeding: ***registryhelpdesk@ebmt.org***

THERAPY

Clinical setting: ☐ Clinical trial (CT)

Phase ☐ 1 ☐ 1/2 ☐ 2 ☐ 2/3 ☐ 3

Blind trial ☐ No ☐ Yes

Randomised trial ☐ No ☐ Yes

Eudract number…….. USA CT number…… UMIN CT number……
(Japan)

☐ Tick here if you want this registration hidden until ..... - ..... - .....
(indicate by which date the registration can be made available for research) yyyy mm dd

☐ Institutional guidelines / standard treatment
☐ Hospital exemption
☐ Compassionate use

Performance score of the patient at initiation of treatment

SYSTEM USED *(choose only one)***:**

☐ Karnofsky or ☐ Lansky: Score: ☐ 10 ☐ 20 ☐ 30 ☐ 40 ☐ 50 ☐ 60 ☐ 70 ☐ 80 ☐ 90 ☐ 100

☐ ECOG: Score: ☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4

Cell origin

☐ Autologous -> Go to CELL THERAPY INFUSION UNIT

☐ Allogeneic

This product is manufactured from:

☐ A known donor never used before to treat this patient -> Continue with DONOR section below
(eg. from a Donor registry or related)

☐ A donor that is already registered as part of a previous treatment -> Skip DONOR section and go to CELL THERAPY INFUSION UNIT

☐ An unknown donor with not available data -> Skip DONOR section and go to CELL THERAPY INFUSION UNIT
(eg. from a commercial product)

Donor

HLA match type

☐ HLA-identical sibling *(may include non-monozygotic twin)*
☐ Syngeneic *(monozygotic twin)*
☐ HLA-matched other relative
☐ HLA-mismatched relative: Degree of mismatch ☐ 1 HLA locus mismatch
☐ ≥ 2 HLA loci mismatch

Donor ID given by the centre .....

☐ Unrelated donor

ION code of the Donor Registry or Cord Blood Bank (*up to 4 characters)* ....

Name of donor registry or Cord Blood Bank ....

Donor centre name .....
(if applicable, optional)

Donor ID given by the Donor Registry or the Cord Blood Bank listed above .....

Patient ID given by the Donor Registry or the Cord Blood Bank listed above .....
(optional)

Donor information

Date of birth : .... - .... - .... **OR** Age at time of donation…… *years* …….. *months*
yyyy *mm* *dd* *(if date of birth not provided)*

Donor Sex ☐ Male ☐ Female
(at birth)

CELL THERAPY INFUSION UNIT(S)

Was there more than one cell infusion unit administered during this treatment

☐ No

☐ Yes: Number of different cell infusion units that form part of this treatment .....

Cell Therapy Infusion Unit – Description and collection

If more than one cell infusion unit, replicate this section for each one of them

IDENTIFICATION

Name of the manufacturing facility ....

Name of the package *(if applicable)* ....

Batch number *(if applicable)* .....

Identification of the Cell Infusion Unit given by the Centre ....
*This item is **mandatory** if more than one cell infusion unit has been used in the same treatment*

TISSUE SOURCE *(check all that apply)*

☐ Bone Marrow ☐ Peripheral Blood ☐ Umbilical cord Blood
☐ Umbilical cord tissue ☐ Adipose ☐ Tumour
☐ Other, specify .....

Cell types *(check all that apply)*

☐ Unselected lymphocytes ☐ CD4+ lymphocytes ☐ CD8+ lymphocytes
☐ Mesenchymal ☐ Dendritic cells ☐ CD34+
☐ NK cells ☐ Mononuclear cells
☐ Other, specify .....

COLLECTION PROCEDURE *(check all that apply)*

Method ☐ Bone Marrow aspirate ☐ Leukapheresis or lymphapheresis
☐ Byoptic sample ☐ Other, specify……..

Date of the collection ..... - ..... - .....
If more than one collection use the date of the first collecition yyyy mm dd

Number of collections ……

Mobilising agent(s) used

☐ No

☐ Yes, specify the agents used ……..……..
(G-CSF, Plerixafor, etc.)

Cell Therapy Infusion Unit – Manipulation

If more than one cell infusion unit, replicate this section for each one of them:

Identification of the Cell Infusion Unit given by the Centre .... CTIUCID

***EX-VIVO* MANIPULATION OF THE PRODUCTS CONTAINED IN THE CELL THERAPY INFUSION UNIT**

☐ No -> Skip MANIPULATION section and go straight to CELL INFUSION PRODUCT FROZEN two pages below
☐ Yes -> Continue with MANIPULATION section below
☐ Unknown

IF YES:

Manipulation laboratory

Onsite, by local cell processing facility	☐ No	☐ Yes
Offsite, by a non commercial facility	☐ No	☐ Yes
Offsite, by a commercial facility	☐ No	☐ Yes

Gene manipulation

☐ No
☐ Yes: **TYPE**

Gene transfer ☐ No ☐ Yes: ☐ Retroviral vector, specify .....
☐ Lentiviral vector, specify .....
☐ Other vector specify .....

Number of gene transfer cycles …..

Transgene ☐ CAR, specify target .....
☐ Suicide gene, specify .....
☐ TCR, specify target ..... / specify HLA element .....
☐ Other, specify .....

Gene editing ☐ No ☐ Yes: Manipulated gene ☐ CCR5
☐ Factor IX
☐ Factor VIII
☐ Other gene, specify .....

Other ☐ No ☐ Yes, specify ……

Recognition of a specific target / antigen

☐ No
☐ Yes: **TYPE** *(check all that apply)*

☐ Viral ☐ Adenovirus ☐ BK virus ☐ Cytomegalovirus (CMV)
☐ Epstein-Barr virus ☐ Human herpes virus 6 ☐ Human immunodeficiency virus (HIV)
☐ Other virus, specify ……..……..

☐ Fungal ☐ Candida ☐ Aspergillus ☐ Fusarium ☐ Zygomycetes
☐ Other fungal, specify ……..

☐ Tumour / cancer antigen, specify ……..……..

☐ Other target, specify ……..……..

Cell Therapy Infusion Unit – Manipulation (continued)

If more than one cell infusion unit, replicate this section for each one of them:

Identification of the Cell Infusion Unit given by the Centre .... CTIUCID

Selection

☐ No

☐ Yes: Positive ☐ No ☐ Yes

Negative ☐ No ☐ Yes

Expansion

☐ No

☐ Yes: Number of days in culture……. or Expansion passage ……..

Expansion fold (ratio initial/final no. of cells)…….....

Induced differentiation

☐ No

☐ Yes

Was the cell infusion product frozen

☐ No

☐ Yes

THERAPY and CELL INFUSION(s)

Chronological number of cell therapy treatment for this patient …..

If number of cell therapy treatment >1:

Same package/product as for the previous cell therapy treatment? ☐ No ☐ Yes ☐ Not applicable

If >1, date of last cell therapy treatment before this one: ..... - .....-.....
yyyy *mm* *dd*

If >1, type of last cell therapy treatment before this one: ☐ Allo ☐ Auto

If >1 and Allograft, Was the same donor used for all prior and current cell therapy treatments?

☐ No ☐ Yes

If >1, was last cell therapy treatment performed at another institution?

☐ No ☐ Yes: CIC if known .....

Name of the institution …….

City …….

⇨ If >1, please submit an Annual follow up form before proceeding, **giving the date of the subsequent cell therapy as the date of last contact**. (This is so we can capture relapse data and other events between cell therapies).

Primary aim of the cell therapy treatment *(tick all that apply)*

*IF INDICATION IS THE TREATMENT OF A **PRIMARY DISEASE INCLUDING INFECTIOUS DISEASES***

☐ Main disease treatment ☐ Prevention of disease relapse or progression

☐ Disease relapse or progression ☐ Other, specify ....

*IF INDICATION IS THE **TREATMENT OR PREVENTION OF A COMPLICATIONS DERIVED FROM A PREVIOUS TRANSPLANT***

GvHD
☐ Unrelated to GvHD
☐ Prevention / prophylaxis of GvHD
☐ Treatment of GvHD

Graft function
☐ Unrelated to graft function
☐ Prevention of rejection / promotion of cell engraftment
☐ Graft enhancement
☐ Graft failure treatment

Immune reconstitution
☐ Unrelated to Immune reconstitution
☐ Immune reconstitution

Patient preparative treatment

☐ No ☐ Yes

Specification and dose of the preparative regimen

TOTAL PRESCRIBED CUMULATIVE DOSE* as per protocol: Include any systemic drugs (chemo, growth factors, antibodies, etc.)				
Name of drug (any given before day 0)	**DOSE**	**UNITS**		
.....		☐ mg/m^2	☐ mg/Kg	☐ AUC**
.....		☐ mg/m^2	☐ mg/Kg	☐ AUC**
.....		☐ mg/m^2	☐ mg/Kg	☐ AUC**
.....		☐ mg/m^2	☐ mg/Kg	☐ AUC**
.....		☐ mg/m^2	☐ mg/Kg	☐ AUC**
.....		☐ mg/m^2	☐ mg/Kg	☐ AUC**
.....		☐ mg/m^2	☐ mg/Kg	☐ AUC**

* Report the total prescribed cumulative dose as per protocol. **Multiply daily dose in mg/kg or mg/m² by the number of days**;
eg. for Busulfan given 4mg/kg daily for 4 days, total dose to report is 16mg/kg

** AUC = Area under the curve

Other type of treatment ☐ No ☐ Yes, specify ....

CELL INFUSION EPISODES

Were there more than one cell infusion episode during this treatment or procedure?

☐ No

☐ Yes: Number of cell infusion episodes during this procedure .....

Cell infusion episode

If more than one cell infusion episode, replicate this section for each one of them

Date of cell infusion episode .....

If more than one Unit was used, indicate the name of the Unit as described in the Cell Infusion Unit section

……. ***This item is mandatory if more than one unit was used***

Route of infusion *(check all that apply)*

☐ Systemic including Intravenous

☐ Local, specify: ☐ Intra-arterial ☐ Intramuscular

☐ Other route .....

Cells infused

Cell type		**Number of cells** *(Not adjusted for cell viability)*	**Units** *(tick one)* 10^6/kg	10^6
Lymphocytes CIEUNSLYMPH	UNSLYMUNIT	☐ Not evaluated	☐	☐
CD4+ lymphocytes		☐ Not evaluated	☐	☐
CD8+ lymphocytes CIECD4LYMP	CIECD8UNIT	☐ Not evaluated	☐	☐
CD3+ lymphocytes		☐ Not evaluated	☐	☐
Pathogen specific lymphocytes, specify…... CIESPTCNUM CIETCSPCFY	CSPTCUNIT	☐ Not evaluated	☐	☐
Tumour specific lymphocytes, specify……		☐ Not evaluated	☐	☐
Regulatory T-cells CIETCELREG	CITCELUNIT	☐ Not evaluated	☐	☐
Mesenchymal		☐ Not evaluated	☐	☐
Dendritic cells CIEDNDRCEL	CIDNDRUNIT	☐ Not evaluated	☐	☐
CD34+ cells		☐ Not evaluated	☐	☐
NK cells CIENKCELLS	CIENKUNIT	☐ Not evaluated	☐	☐
Mononuclear cells		☐ Not evaluated	☐	☐
Endothelial cell progenitor CIENDOTHEL	CIENDOUNIT	☐ Not evaluated	☐	☐
Other, specify		☐ Not evaluated	☐	☐

Did the treatment that includes this cell therapy episode also include other type of treatment?

☐ No ☐ Yes, specify……..

Was this other type of treatment given: ☐ No ☐ Yes ☐ Simultaneously to the cell therapy
☐ After the cell therapy episode was finished
☐ Unknown

RESPONSE

TO BE ANSWERED ONLY WHEN THE INDICATION WAS THE TREATMENT OF A PRIMARY DISEASE INCLUDING INFECTIONS

Best clinical/biological response after the entire cell therapy treatment

- ☐ Complete remission / Normalisation of organ function / No infection present
- ☐ Partial remission / Partial or non normalisation of organ function
- ☐ No response
- ☐ Disease progression or worsening of organ function
- ☐ Not evaluated

Date response evaluated: ..... - ..... - ..... …..
yyyy mm dd

TO BE ANSWERED ONLY WHEN THE INDICATION WAS THE TREATMENT OF COMPLICATIONS DERIVED FROM A PREVIOUS TRANSPLANT

Complication	**Response**				
GvHD	☐ Resolved	☐ Improved	☐ No response	☐ Progressed	☐ Not evaluated
Graft failure	☐ Resolved	☐ Improved	☐ No response	☐ Progressed	☐ Not evaluated
Immune reconstitution	☐ Resolved	☐ Improved	☐ No response	☐ Progressed	☐ Not evaluated

Date response evaluated: ..... - ..... - ..... …..
yyyy mm dd

LAST CONTACT DATE FOR 6 MONTH ASSESSMENT

*If patient died **before** the 6 months had elapsed, enter the date of death, otherwise enter Date of Cell therapy + 6 MONTHS approximately.*

Six month assessment : ..... - ..... - ..... ☐ Not applicable
yyyy mm dd

Date of death: ..... - ..... - ..... ☐ Not applicable
yyyy mm dd

Toxicity during the first 6 months after the cell therapy was initiated

DO NOT INCLUDE INFORMATION ON COMPLICATIONS THAT WERE RESOLVED BEFORE THE CELL THERAPY THIS FORM REFERS TO

Acute Graft Versus Host Disease *(Cells of allogeneic origin only)*
Maximum Grade:
☐ 0 (none) ☐ I ☐ II ☐ III ☐ IV ☐ Present but grade unknown ☐ Not evaluated

Date of onset .... - .... - ....
yyyy *mm* *dd*

Stage:

Skin	☐ 0 (none)	☐ 1	☐ 2	☐ 3	☐ 4
Liver	☐ 0 (none)	☐ 1	☐ 2	☐ 3	☐ 4
Lower GI tract	☐ 0 (none)	☐ 1	☐ 2	☐ 3	☐ 4
Upper GI tract	☐ 0 (none)	☐ 1			
Other site affected	☐ No	☐ Yes			

Related to Cell Therapy ☐ No ☐ Yes
Resolved? ☐ No ☐ Yes

Chronic Graft Versus Host Disease present
(allogeneic treatment only)

☐ No *(never)*
☐ Yes: Date of diagnosis of cGvHD ..... - ..... -.....
yyyy *mm* *dd*

Maximum extent during this period
☐ Limited ☐ Extensive ☐ Unknown

Maximum NIH score during this period
☐ Mild ☐ Moderate ☐ Severe ☐ Not calculated

Other complications or toxicities during this period
☐ No -> Skip TOXICITIES table below and go straight to SECONDARY MALIGNANCIES on the next page
☐ Yes -> Continue with the TOXICITIES table below
☐ Unknown

Toxicities

	No	Yes	Grade	Date of diagnosis	Related to cell therapy	Ongoing at last assessment	Date of resolution
Cytokine storm	☐	☐		.....-..... -	☐ No ☐ Yes	☐ Yes ☐ No:	..... -..... - .....
Neurotoxicity	☐	☐		.....-..... -	☐ No ☐ Yes	☐ Yes ☐ No:	..... -..... - .....
Grade IV Organ toxicity as per WHO							
Liver	☐	☐		.....-..... -	☐ No ☐ Yes	☐ Yes ☐ No:	..... -..... - .....
Lungs	☐	☐		.....-..... -	☐ No ☐ Yes	☐ Yes ☐ No:	..... -..... - .....
Heart	☐	☐		.....-..... -	☐ No ☐ Yes	☐ Yes ☐ No:	..... -..... - .....
Kidney	☐	☐		.....-..... -	☐ No ☐ Yes	☐ Yes ☐ No:	..... -..... - .....
Other, specify	☐	☐		.....-..... -	☐ No ☐ Yes	☐ Yes ☐ No:	..... -..... - .....
Bone marrow aplasia/failure	☐	☐		.....-..... -	☐ No ☐ Yes	☐ Yes ☐ No:	..... -..... - .....
Other, specify ……..	☐	☐		.....-..... -	☐ No ☐ Yes	☐ Yes ☐ No:	..... -..... - .....
				yyyy mm dd			*yyyy mm dd*

Secondary Malignancy

Did a secondary malignancy, lymphoproliferative or myeloproliferative disorder occur?

☐ No ☐ Yes:

Date of diagnosis: ..... - ..... - .....
yyyy *mm* *dd*

Diagnosis: .....

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 or a malignancy of the cellular product**?**

☐ No ☐ Yes ☐ Not applicable

Graft assessment

ONLY FOR PATIENTS THAT HAVE RECEIVED A PREVIOUS TRANSPLANT

Graft loss

☐ No ☐ Yes ☐ Not evaluated

First Relapse/Progression or Significant worsening after Cell therapy

TO BE ANSWERED ONLY WHEN THE INDICATION WAS THE TREATMENT OF A PRIMARY DISEASE INCLUDING INFECTIONS

First Relapse or Progression or Significant worsening of organ function of the primary disease
(detected by any method)

☐ No

☐ Yes: Date first seen ..... - ..... - .....
yyyy *mm* *dd*

☐ Continuous progression since cell therapy

Last Disease Status

TO BE ANSWERED ONLY WHEN THE INDICATION WAS THE TREATMENT OF A PRIMARY DISEASE INCLUDING INFECTIONS

Last disease status

☐ Complete remission / Normalisation of organ function / No infection present

☐ Partial remission / Partial or non normalisation of organ funcition

☐ No response

☐ Disease progression or worsening of organ function

☐ Not evaluated

Date of evaluation: ..... - ..... - .....
yyyy *mm* *dd*

Survival Status

☐ Alive ☐ Dead ☐ Check here if patient lost to follow up

Main Cause of Death *(check only one main cause)*:
☐ Relapse or Progression/Persistent disease
☐ Cell Therapy related: .....
☐ HSCT Related Cause
☐ Unknown
☐ Other: .....

Contributory Cause of Death *(check as many as appropriate)*:
☐ GVHD
☐ Cytokine release syndrome
☐ Interstitial pneumonitis
☐ Pulmonary toxicity
☐ Infection:
- ☐ bacterial
- ☐ viral
- ☐ fungal
- ☐ parasitic
- ☐ unknown

☐ Rejection/Poor graft function
☐ History of severe Veno occlusive disorder (VOD)
☐ Haemorrhage
☐ Cardiac toxicity
☐ Central nervous system (CNS) toxicity
☐ Gastrointestinal (GI) toxicity
☐ Skin toxicity
☐ Renal failure
☐ Multiple organ failure

☐ Other:.....

Persistence of the Infused Cells

Were tests performed to detect the persistence of the cellular products druing this period?

☐ No ☐ Yes: Date of the last test ..... - ..... - .....
yyyy *mm* *dd*

Technique used ***/***

☐ Molecular (PCR) ☐ Flow cytometry ☐ Chimaerism ☐ Imaging ☐ Immunohistochemistry

☐ Other, specify ……..……..

Were cells detected?

☐ No

☐ Yes

ACUTE LEUKAEMIAS

Primary Acute Myeloid Leukaemia (AML) (1 of 2) (main disease code 1)

Disease

Classification:

AML with recurrent genetic abnormalities

- ☐ AML with t(8;21)(q22;q22); *RUNX1-RUNX1T1*
- ☐ AML with inv(16)(p13.1;q22) or t(16;16)(p13.1;q22); *CBFB-MYH11*
- ☐ Acute promyelocytic leukaemia with t(15;17)(q22;q12); *PML/RARA*
- ☐ AML with t(9;11) (p22;q23); MLLT3-MLL
- ☐ AML with t(6;9) (p23;q24); DEK-NUP214
- ☐ AML with inv(3) (q21;q26.2) or t(3;3) (q21;q26.2); RPN1-EVI1
- ☐ AML (megakaryoblastic) with t(1;22) (p13;q13); RBM15-MKL1
- ☐ AML with myelodysplasia related changes

AML not otherwise categorised (NOS)

- ☐ AML with minimal differentiation (FAB M0)
- ☐ AML without maturation (FAB M1)
- ☐ AML with maturation (FAB M2)
- ☐ Acute myelomonocytic leukaemia (FAB M4)
- ☐ Acute monoblastic and monocytic leukaemia (FAB M5)
- ☐ Acute erythroid leukaemia (FAB M6)
- ☐ Acute megakaryoblastic leukaemia (FAB M7)
- ☐ Acute basophilic leukaemia
- ☐ Acute panmyelosis with myelofibrosis

- ☐ Myeloid sarcoma

- ☐ Myeloid proliferations related to Down syndrome

- ☐ Blastic plasmacytoid dendritic cell neoplasm (BPDCN)

- ☐ Therapy related myeloid neoplasia *(old "Secondary Acute Leukaemia")*
  Related to prior treatment but NOT after a previous diagnosis of MDS or MPN

Donor cell leukaemia?

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

Is this a donor cell leukaemia ☐ No ☐ Yes ☐ Not evaluated

ACUTE LEUKAEMIAS
Primary Acute Myeloid Leukaemia (AML) (2 of 2)

Status at Cell therapy

Date of first cell infusion ..... - ..... - .....
yyyy mm dd

STATUS	NUMBER	TYPE OF REMISSION	
☐ Primary induction failure			
☐ Complete haematological remission (CR)	☐ 1st ☐ 2nd ☐ 3rd or higher	CYTOGENETIC REMISSION ☐ No ☐ Yes ☐ Not evaluated ☐ Not applicable* ☐ Unknown	MOLECULAR REMISSION ☐ No ☐ Yes ☐ Not evaluated ☐ Not applicable* ☐ Unknown
☐ Relapse	☐ 1st ☐ 2nd ☐ 3rd or higher		

* *No abnormalities detected prior to this time point*

ACUTE LEUKAEMIAS
Precursor lymphoid neoplasms *(old ALL)* (main disease code 1)

Disease

Classification:

☐ B lymphoblastic leukaemia/lymphoma NOS *(old Precursor B-cell ALL)*
- ☐ with t(9;22)(q34;q11.2); *BCR-ABL1*
- ☐ with t(v;11q23); *MLL* rearranged
- ☐ with t(12;21)(p13;q22); *TEL-AML1 (ETV-RUNX1)*
- ☐ with hyperdiploidy
- ☐ with hypodiploidy
- ☐ with t(5;14)(q31;q32); *IL3-IGH*
- ☐ with t(1;19)(q23;p13.3); *E2A-PBX1*

☐ T lymphoblastic leukaemia/lymphoma *(old Precursor T-cell ALL)*

Secondary Origin?

Secondary origin

Related to prior exposure to therapeutic drugs or radiation ☐ No ☐ Yes ☐ Unknown

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

Is this a donor cell leukaemia ☐ No ☐ Yes ☐ Not evaluated

Status at Cell therapy

Date of first cell infusion ..... - ..... - .....
yyyy *mm* *dd*

STATUS	NUMBER	TYPE OF REMISSION	
☐ Primary induction failure	VNUMSTM		
☐ Complete haematological remission (CR)	☐ 1st ☐ 2nd ☐ 3rd or higher	CYTOGENETIC REMISSION ☐ No ☐ Yes ☐ Not evaluated ☐ Not applicable* ☐ Unknown	MOLECULAR REMISSION ☐ No ☐ Yes ☐ Not evaluated ☐ Not applicable* ☐ Unknown
☐ Relapse	☐ 1st ☐ 2nd ☐ 3rd or higher		

* *No abnormalities detected prior to this time point*

ACUTE LEUKAEMIAS

Other Acute Leukaemias (main disease code 1)

Disease

Classification:

Acute Leukaemias of ambiguous lineage

- ☐ Acute undifferentiated leukaemia
- ☐ Mixed phenotype NOS
  - ☐ Mixed phenotype B/myeloid, NOS
  - ☐ Mixed phenotype T/myeloid, NOS
- ☐ Natural killer (NK)- cell lymphoblastic leukaemia/lymphoma
- ☐ Other, specify.....

Secondary Origin?

Secondary origin

Related to prior exposure to therapeutic drugs or radiation ☐ No ☐ Yes ☐ Unknown

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

Is this a donor cell leukaemia ☐ No ☐ Yes ☐ Not evaluated

Status at Cell therapy

Date of first cell infusion ..... - ..... - .....
yyyy *mm* *dd*

STATUS	NUMBER	TYPE OF REMISSION	
☐ Primary induction failure			
☐ Complete haematological remission (CR)	☐ 1st ☐ 2nd ☐ 3rd or higher	CYTOGENETIC REMISSION ☐ No ☐ Yes ☐ Not evaluated ☐ Not applicable* ☐ Unknown	MOLECULAR REMISSION ☐ No ☐ Yes ☐ Not evaluated ☐ Not applicable* ☐ Unknown
☐ Relapse	☐ 1st ☐ 2nd ☐ 3rd or higher		

* *No abnormalities detected prior to this time point*

CHRONIC LEUKAEMIAS

Chronic Myelogenous Leukaemias (CML) (main disease code 2)

Disease

Classification: ***(****CMML is not a CML but MDS/MPN)*
At least one investigation must be positive

Translocation (9;22)	☐ Absent	☐ Present	☐ Not evaluated
bcr-abl	☐ Absent	☐ Present	☐ Not evaluated

Status at cell therapy

Date of this cell therapy: ..... - ..... - .....
yyyy *mm* *dd*

PHASE	NUMBER	TYPE OF REMISSION		
		HAEMATOLOGICAL	CYTOGENETIC	MOLECULAR
☐ Chronic phase (CP)	☐ 1st ☐ 2nd ☐ 3rd or higher	☐ Yes ☐ No ☐ Not evaluated ☐ Unknown	☐ Yes ☐ No ☐ Not evaluated ☐ Not applicable* ☐ Unknown	☐ Yes ☐ No ☐ Not evaluated ☐ Not applicable* ☐ Unknown
☐ Accelerated phase	☐ 1st ☐ 2nd ☐ 3rd or higher			
☐ Blast crisis	☐ 1st ☐ 2nd ☐ 3rd or higher			

* *No abnormality detected prior to this time point*

CHRONIC LEUKAEMIAS
Chronic Lymphocytic leukaemias (CLL) (main disease code 2)

Disease

Classification:

☐ Chronic lymphocytic leukaemia (CLL)/small lymphocytic lymphoma

☐ Richter's syndrome

Transformed from a previously known CLL

☐ Yes: Date of original CLL diagnosis .... - .... - ....
yyyy *mm* *dd*

☐ No: Primary Richter *(without previous known diagnosis of CLL)*

Status at cell therapy

Date of this cell therapy: ..... - ..... - .....
yyyy *mm* *dd*

STATUS	**MINIMAL RESIDUAL DISEASE (MRD)** *(by FACS or PCR)*
☐ Complete remission (CR) ☐ Partial response (PR)	☐ Negative ☐ Positive ☐ Not evaluated
☐ Stable disease (SD) ☐ Relapse *(untreated)* ☐ Progression (PD) ☐ Never treated	

CHRONIC LEUKAEMIAS

Prolymphocytic and Other leukaemias (PLL & Other) (main disease code 2)

Disease

☐ Prolymphocytic Leukaemia (PLL)
- ☐ PLL, B-cell
- ☐ PLL, T-cell

☐ Hairy Cell Leukaemia

☐ Other leukaemia, specify:_____

Status at cell therapy

Date of this cell therapy: ..... - ..... - .....
yyyy *mm* *dd*

STATUS

☐ Complete remission (CR):
☐ Partial remission (PR)
☐ Stable disease (SD)
☐ Relapse *(untreated)*
☐ Progression (PD)
☐ Never treated

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

Disease

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)
- ☐ Follicular lymphoma
- ☐ Primary cutaneous follicle centre lymphoma
- ☐ Mantle cell lymphoma
- ☐ Diffuse large B-cell lymphoma (DLBCL), (NOS)
  - ☐ 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 DLCBL/BL)
- ☐ B-cell lymphoma, unclassifiable, with features intermediate between diffuse large B-cell lymphoma and classical Hodgkin lymphoma (Intermediate DLCBL/HD)
- ☐ Other B-cell, specify:_____

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
- ☐ 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:_____

FOR B-CELL LYMPHOMAS:

Transformed from another type of lymphoma before this cell therapy treatment

- ☐ No
- ☐ Yes

Hodgkin Lymphomas

Classification:

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

LYMPHOMAS

Status at cell therapy

Date of this cell therapy: ..... - ..... - .....
yyyy *mm* *dd*

Number of prior lines of treatment ☐ 1 ☐ 2 ☐ 3 or more ☐ None ☐ unknown

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

MYELODYSPLASTIC SYNDROME (MDS) (main disease code 6)

Disease

Select only one

WHO Classification at diagnosis:

- ☐ Refractory anaemia (RA) *(without ring sideroblasts)*
- ☐ RA with ring sideroblasts (RARS)
- ☐ MDS associated with isolated del(5q)
- ☐ Refractory cytopenia with multilineage dysplasia (RCMD)
- ☐ RCMD with ringed sideroblasts (RCMD-RS)
- ☐ RA with excess of blasts-1 (RAEB-1)
- ☐ RA with excess of blasts-2 (RAEB-2)
- ☐ Childhood myelodysplastic syndrome (*Refractory cytopenia of childhood (RCC)*)
- ☐ MDS Unclassifiable (MDS-U)

Secondary Origin?

Therapy related MDS: *(Secondary origin)*

- ☐ Yes: Disease related to prior exposure to therapeutic drugs or radiation
- ☐ No
- ☐ Unknown

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

Is this a donor cell leukaemia ☐ No ☐ Yes ☐ Not evaluated

Status at cell therapy

Date of this cell therapy: ..... - ..... - .....
yyyy *mm* *dd*

Select only one

WHO Classification at HSCT:

- ☐ Refractory anaemia (without ring sideroblasts) RA
- ☐ RA with ring sideroblasts (RARS)
- ☐ MDS associated with isolated del(5q)
- ☐ Refractory cytopenia with multilineage dysplasia (RCMD)
- ☐ RCMD with ringed sideroblasts (RCMD-RS)
- ☐ RA with excess of blasts-1 (RAEB-1)
- ☐ RA with excess of blasts-2 (RAEB-2)
- ☐ Childhood myelodysplastic syndrome (*Refractory cytopenia of childhood (RCC)*)
- ☐ MDS Unclassifiable (MDS-U)

STATUS	NUMBER
Treated with chemotherapy: ☐ Primary refractory phase (no change)	
☐ Complete remission (CR)	☐ 1st ☐ 2nd ☐ 3rd or higher
☐ Improvement but no CR	
☐ Relapse (after CR)	☐ 1st ☐ 2nd ☐ 3rd or higher
☐ Progression/worse ☐ Never treated (Supportive care or treatment without chemotherapy)	

COMBINED MYELODYSPLASTIC SYNDROME/MYELOPROLIFERATIVE NEOPLASM (MDS/MPN) (main disease code 6)

Disease

☐ Chronic myelomonocytic leukaemia (CMMoL, CMML)
☐ Juvenile myelomonocytic leukaemia (JCMMoL, JMML, JCML, JCMML)
☐ Atypical CML ((t(9;22) negative and BCR-ABL1 negative)

Therapy related MDS/MPN: *(Secondary origin)*
☐ Yes: Disease related to prior exposure to therapeutic drugs or radiation
☐ No
☐ Unknown

Status at cell therapy

Date of this cell therapy: ..... - ..... - .....
yyyy *mm* *dd*

STATUS
CMML / Atypical CML

STATUS	NUMBER
Treated with chemotherapy: ☐ Primary refractory phase (no change)	
☐ Complete remission (CR)	☐ 1st ☐ 2nd ☐ 3rd or higher
☐ Improvement but no CR	
☐ Relapse (after CR)	☐ 1st ☐ 2nd ☐ 3rd or higher
☐ Progression/worse ☐ Never treated (Supportive care or treatment without chemotherapy)	

MYELOPROLIFERATIVE NEOPLASMS (MPN) (main disease code 6)

Disease

- ☐ Primary myelofibrosis *(Chronic idiopathic myelofibrosis; fibrosis with myeloid metaplasia)*
- ☐ Polycythaemia vera
- ☐ Essential or primary thrombocythaemia
- ☐ Hyper eosinophilic syndrome (HES)
- ☐ Chronic eosinophilic leukaemia (CEL)
- ☐ Chronic neutrophilic leukaemia
- ☐ Systemic mastocytosis
- ☐ Mast cell leukaemia
- ☐ Mast cell sarcoma
- ☐ MPN not otherwise specified
- ☐ Other, specify:_____

☐ Myeloid and lymphoid neoplasms with FGFR1 abnormalities *(Stem cell leukaemia-lymphoma syndrome, 8p11 syndrome)*

Secondary Origin?

Secondary origin:

- ☐ Yes: Disease related to prior exposure to therapeutic drugs or radiation
- ☐ No
- ☐ Unknown

Status at cell therapy

Date of this cell therapy: ..... - ..... - .....
yyyy *mm* *dd*

Classification at HSCT:

- ☐ Primary myelofibrosis *(Chronic idiopathic myelofibrosis; fibrosis with myeloid metaplasia)*
- ☐ Polycythaemia vera
- ☐ Essential or primary thrombocythaemia
- ☐ Hyper eosinophilic syndrome (HES)
- ☐ Chronic eosinophilic leukaemia (CEL)
- ☐ Chronic neutrophilic leukaemia
- ☐ Systemic mastocytosis
- ☐ Mast cell leukaemia
- ☐ Mast cell sarcoma

☐ Myeloid and lymphoid neoplasms with FGFR1 abnormalities *(Stem cell leukaemia-lymphoma syndrome, 8p11 syndrome)*

☐ Transformed to myelofibrosis from PV/ET: Date of transformation ..... - ..... - .....
yyyy *mm* *dd*

☐ MPN not otherwise specified

STATUS	NUMBER
Treated with chemotherapy: ☐ Primary refractory phase (no change)	
☐ Complete remission (CR)	☐ 1st ☐ 2nd ☐ 3rd or higher
☐ Improvement but no CR	
☐ Relapse (after CR)	☐ 1st ☐ 2nd ☐ 3rd or higher
☐ Progression/worse ☐ Never treated (Supportive care or treatment without chemotherapy)	

PLASMA CELL DISORDERS (PCD) including MULTIPLE MYELOMA (MM) (main disease code 4)

Disease

Classification

- ☐ Multiple myeloma (MM)
  - ☐ MM –heavy chain and light chain *Check light and heavy chain types →*
  - ☐ MM -light chain *Check light chain type only →*
  - ☐ MM -non-secretory

HEAVY CHAIN TYPE
- ☐ IgG
- ☐ IgA
- ☐ IgD
- ☐ IgE
- ☐ IgM *(not Waldenstrom)*

LIGHT CHAIN TYPE
- ☐ Kappa
- ☐ Lambda

- ☐ Plasma cell leukaemia
- ☐ Solitary plasmacytoma of bone
- ☐ Primary amyloidosis
- ☐ POEMS
- ☐ Monoclonal light and heavy chain deposition disease (LCDD/HCDD)
- ☐ Other, specify:_____

Status at cell therapy

Date of this cell therapy: ..... - ..... - .....
yyyy *mm* *dd*

STATUS	NUMBER
☐ Never treated	
☐ Stringent complete remission (sCR) ☐ Complete remission (CR) ☐ Very good partial remission (VGPR) ☐ Partial remission (PR) ☐ Relapse from CR (untreated)	☐ 1st ☐ 2nd ☐ 3rd or higher
☐ Progression ☐ No change / stable disease	

BONE MARROW FAILURE SYNDROMES including APLASTIC ANAEMIA (BMF) (main disease code 7)

Disease

Classification:

Acquired:

- ☐ Severe Aplastic Anaemia (SAA),
- ☐ Amegakaryocytosis, acquired (not congenital)
- ☐ Acquired Pure Red Cell Aplasia (PRCA) (not congenital)
- ☐ Paroxysmal nocturnal haemoglobinuria (PNH)
- ☐ Acquired Pure White Cell Aplasia
- ☐ Other acquired cytopenic syndrome, specify: _____

Etiology:
- ☐ Secondary to hepatitis
- ☐ Secondary to toxin/other drug
- ☐ Idiopathic
- ☐ Other, specify: _____

Congenital:

- ☐ Amegakaryocytosis / thrombocytopenia
- ☐ Fanconi anaemia
- ☐ Diamond-Blackfan anaemia (congenital PRCA)
- ☐ Shwachman-Diamond Syndrome
- ☐ Dyserythropoietic anaemia
- ☐ Dyskeratoris congenita
- ☐ Other congenital anaemia, specify: _____

Cell Therapy

Date of this cell therapy: ..... - ..... - .....
yyyy *mm* *dd*

HAEMOGLOBINOPATHY (main disease code 11)

Disease

Classification:

- ☐ Thalassaemia
- ☐ Sickle cell disease
- ☐ Other haemoglobinopathy, specify: _____

Cell Therapy

Date of this cell therapy: ..... - ..... - .....
yyyy *mm* *dd*

SOLID TUMOURS (main disease code 5)

Disease

Classification:

- ☐ Bone sarcoma (excluding Ewing sarcoma/PNET)
- ☐ Breast
- ☐ Central nervous system tumours (include CNS PNET)
- ☐ Colorectal
- ☐ Ewing sarcoma (ES)/PNET, extra-skeletal
- ☐ Ewing sarcoma(ES)/PNET, skeletal
- ☐ Germ cell tumour, extragonadal only
- ☐ Head and neck
- ☐ Hepatobiliary
- ☐ Kidney cancer excluding Wilm's tumour
- ☐ Lung cancer, non-small cell
- ☐ Lung cancer, small cell
- ☐ Medulloblastoma
- ☐ Melanoma
- ☐ Other, specify .....
- ☐ Neuroblastoma
- ☐ Ovarian (carcinoma)
- ☐ Pancreatic
- ☐ Prostate
- ☐ Renal cell
- ☐ Retinoblastoma
- ☐ Rhabdomyosarcoma
- ☐ Soft tissue sarcoma (excluding Rhabdo. and extra-skeletal ES)
- ☐ Germ cell tumour, gonadal
- ☐ Thymoma
- ☐ Wilm's tumour

Status at cell therapy

Date of this cell therapy: ..... - ..... - .....
yyyy *mm* *dd*

STATUS

- ☐ Adjuvant
- ☐ Never treated (upfront)
- ☐ Stable disease/no response

☐ Complete remission (CR)
- ☐ Confirmed
- ☐ Unconfirmed (CRU*)

*CRU – complete response with persistent scan abnormalities of unknown significance

NUMBER
- ☐ 1st
- ☐ 2nd
- ☐ 3rd or higher

☐ 1st Partial response (PR1)

☐ Relapse

NUMBER
- ☐ 1st
- ☐ 2nd
- ☐ 3rd or higher

SENSITIVITY TO CHEMOTHERAPY
- ☐ Sensitive
- ☐ Resistant
- ☐ Untreated

☐ Progressive disease (PD)

PRIMARY IMMUNE DEFICIENCIES (PID) (main disease code 8)

Disease

Classification:

- ☐ Absence of T and B cells SCID
- ☐ Absence of T, normal B cell SCID
- ☐ ADA deficiency (Adenosine deaminase deficiency)
- ☐ Ataxia telangiectasia
- ☐ Bare lymphocyte syndrome
- ☐ Cartilage hair hypoplasia
- ☐ CD 40 Ligand deficiency
- ☐ Chediak-Higashi syndrome
- ☐ Chronic granulomatous disease
- ☐ Common variable immunodeficiency
- ☐ DiGeorge anomaly
- ☐ IPEX syndrome
- ☐ Kostmann syndrome-congenital neutropenia
- ☐ Leukocyte adhesion deficiencies
- ☐ Neutrophil actin deficiency
- ☐ Omenn syndrome
- ☐ PNP deficiency *(Purine nucleoside phosphorylase)*
- ☐ Reticular dysgenesis
- ☐ SCID other, specify: .....
- ☐ SCID, unspecified
- ☐ Wiskott Aldrich syndrome
- ☐ X-linked lymphoproliferative syndrome
- ☐ Other, specify: .....
- ☐ Immune deficiencies, not otherwise specified

Cell Therapy

Date of this cell therapy: ..... - ..... - .....
yyyy *mm* *dd*

INHERITED DISORDERS OF METABOLISM (main disease code 8)

Disease

Classification:

- ☐ Adrenoleukodystrophy
- ☐ Aspartyl glucosaminuria
- ☐ B-glucuronidase deficiency (VII)
- ☐ Fucosidosis
- ☐ Gaucher disease
- ☐ Glucose storage disease
- ☐ Hunter syndrome (II)
- ☐ Hurler syndrome (IH)
- ☐ I-cell disease
- ☐ Krabbe disease (globoid leukodystrophy)
- ☐ Lesch-Nyhan (HGPRT deficiency)
- ☐ Mannosidosis
- ☐ Maroteaux-Lamy (VI)
- ☐ Metachromatic leukodystrophy
- ☐ Morquio (IV)
- ☐ Mucolipidoses, unspecified
- ☐ Mucopolysaccharidosis (V)
- ☐ Mucopolysaccharidosis, unspecified
- ☐ Niemann-Pick disease (Type A,B)
- ☐ Niemann-Pick disease (Type C,D,E)
- ☐ Neuronal ceroid – lipofuscinosis (Batten disease)
- ☐ Polysaccharide hydrolase abnormalities, unspecified
- ☐ Sanfilippo (III)
- ☐ Scheie syndrome (IS)
- ☐ Wolman disease
- ☐ Other, specify: .....
- ☐ Inherited disorders of metabolism, not otherwise specified

Cell Therapy

Date of this cell therapy: ..... - ..... - .....
yyyy *mm* *dd*

PLATELET and OTHER INHERITED DISORDERS (main disease code 8)

Disease

Classification:

- ☐ Glanzmann thrombasthenia
- ☐ Other inherited platelet abnormalities, specify: _____

- ☐ Osteopetrosis (malignant infantile osteopetrosis)
- ☐ Other osteoclast defects, specify: _____

Cell Therapy

Date of this cell therapy: ..... - ..... - .....
yyyy *mm* *dd*

HISTIOCYTIC DISORDERS (main disease code 9)

Disease

Classification:

- ☐ Histiocytic disorders, not otherwise specified (FELH)
- ☐ Langerhans Cell Histiocytosis *(Histiocytosis-X)*
- ☐ Histiocytic sarcoma *(malignant histiocytosis*)
- ☐ Familial erythro/haemophagocytic lymphohistiocytosis
- ☐ Haemophagocytosis (reactive or viral associated)
- ☐ Other, specify:_____

Cell Therapy

Date of this cell therapy: ..... - ..... - .....
yyyy *mm* *dd*

AUTOIMMUNE DISORDERS (main disease code 10)

CONNECTIVE TISSUE

DISEASE

Classification:

☐ Systemic sclerosis (SS)

Involvement/Clinical problem

- ☐ diffuse cutaneous
- ☐ limited cutaneous
- ☐ SSc sine scleroderma
- ☐ Other (MCTD: Mixed Connective Tissue Disease)
- ☐ other, specify:_____

Date of this cell therapy: ..... - ..... - .....
yyyy *mm* *dd*

☐ Systemic lupus erythematosus (SLE)

Date of this cell therapy: ..... - ..... - .....
yyyy *mm* *dd*

SLEDAI score …….

☐ Polymyositis- dermatomyositis
☐ Sjögren syndrome
☐ Antiphospholipid syndrome
☐ Other type of connective tisue disease, specify:_____

Date of this cell therapy: ..... - ..... - .....
yyyy *mm* *dd*

VASCULITIS

DISEASE

Classification:

☐ Wegener granulomatosis
☐ Polyarteritis nodosa
- ☐ Classical
- ☐ Microscopic

☐ Churg-Strauss
☐ Giant cell arteritis
☐ Takayasu
☐ Behçet's syndrome
☐ Overlap necrotising arteritis
☐ Other, specify:_____

Date of this cell therapy: ..... - ..... - .....
yyyy *mm* *dd*

AUTOIMMUNE DISORDERS (main disease code 10)

ARTHRITIS

DISEASE

Classification:
☐ Rheumatoid arthritis
☐ Psoriatic arthritis/psoriasis
☐ Juvenile idiopathic arthritis (JIA), systemic (Stills disease)
☐ Juvenile idiopathic arthritis (JIA), articular: Onset ☐ Oligoarticular
☐ Polyarticular
☐ Juvenile idiopathic arthritis: other, specify:_____
☐ Other arthritis: .....

Date of this cell therapy: ..... - ..... - .....
yyyy *mm* *dd*

NEUROLOGICAL

DISEASE

Classification:
☐ **MULTIPLE SCLEROSIS**

Date of this cell therapy: ..... - ..... - .....
yyyy *mm* *dd*

Disease status ☐ primary progressive
☐ secondary progressive
☐ relapsing/remitting
☐ other:_____

☐ Myasthenia gravis
☐ Amyotrophic lateral sclerosis (ALS)
☐ Chronic inflammatory demyelinating polyneuropathy (CIDP)
☐ Other autoimmune neurological disorder, specify:_____

Date of this cell therapy: ..... - ..... - .....
yyyy *mm* *dd*

HAEMATOLOGICAL

DISEASE

Classification:
☐ Idiopathic thrombocytopenic purpura (ITP)
☐ Haemolytic anaemia
☐ Evan syndrome
☐ Autoimmune lymphoproliferative syndrome (primary diagnosis, not subsequent to transplant)
☐ Other haematological autoimmune disease, specify:_____

Date of this cell therapy: ..... - ..... - .....
yyyy *mm* *dd*

AUTOIMMUNE DISORDERS (main disease code 10)

BOWEL

DISEASE

Classification:
☐ Crohn's disease
☐ Ulcerative colitis
☐ Other autoimmune bowel disease, specify:_____

Date of this cell therapy: ..... - ..... - .....
yyyy *mm* *dd*

OTHER AUTOIMMUNE DISORDER

DISEASE

Classification:
☐ Graves' disease
☐ Diabetes type 1
☐ Other autoimmune, specify:_____

Date of this cell therapy: ..... - ..... - .....
yyyy *mm* *dd*

OTHER PRIMARY DISEASE

NEUROLOGIC DISORDES (main disease code 12)

Classification:

- ☐ Duchenne Muscular Distrophy
- ☐ Acute cerebral vascular ischemia
- ☐ ALS, amiotrophic lateral sclerosis
- ☐ Parkinson disease
- ☐ Spinal cord injury
- ☐ Cerebral palsy
- ☐ Congenital hydrocephalus
- ☐ Other, specify:_____

Date of this cell therapy: ..... - ..... - .....
yyyy *mm* *dd*

CARDIOVASCULAR DISEASE (main disease code 13)

Classification:

- ☐ AMI, acute myocardial infarction
- ☐ Chronic coronary artery disease (ischemic, cardiomyopathy)
- ☐ Heart failure (non-ischemic etiology)
- ☐ Other cardiovascular disease
- ☐ Limb ischemia
- ☐ Thromboangitis obliterans
- ☐ Other peripheral vascular disease
- ☐ Other, specify:_____

Date of this cell therapy: ..... - ..... - .....
yyyy *mm* *dd*

MUSCULOSKELETAL (main disease code 15)

Classification:

- ☐ Avascular necrosis of femoral head
- ☐ Osteoarthritis
- ☐ Osteogenesis imperfecta
- ☐ Traumatic joint injury
- ☐ Other, specify:_____

Date of this cell therapy: ..... - ..... - .....
yyyy *mm* *dd*

INFECTION (main disease code 14)

☐ Prevention / prophylaxis
☐ Treatment

Pathogen involved:
☐ Adenovirus ☐ BK virus ☐ Cytomegalovius (CMV)
☐ Epstein-Barr virus ☐ Human herpex virus ☐ Human immunodeficiency virus (HIV)
☐ Other virus, specify ……..

☐ Candida ☐ Aspergillus ☐ Fusarium ☐ Zygomycetes
☐ Other fungal, specify ……..

☐ Other, specify ……..

Date of this cell therapy: ..... - ..... - .....
yyyy *mm* *dd*

Cell Therapy - MED - A

Annual Follow Up

CENTRE IDENTIFICATION

EBMT Code (CIC): .... Hospital: ..... Unit: .....

Contact person..... e-mail: .....

PATIENT DATA

Date of this Report: ..... - ..... - .....
yyyy *mm* *dd*

EBMT Registry Unique Identification Code (UIC) .....

Hospital Unique <u>Patient</u> Number or Code (UPN): .....
Compulsory, registrations will not be accepted without this item. ***All treatments 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 treatment.***

Other type of patient identification codes (AIEOP etc.): ……
(Optional: This item is to be used by the centre to register a patient code for internal use as necessary)

Initials: ....._..... (first name(s) _family name(s))

Date of Birth: ..... - ..... - .....
yyyy *mm* dd

Date of last follow up or death: ..... - ..... - .....
yyyy *mm* *dd*

TOXICITY DURING THIS PERIOD

DO NOT INCLUDE INFORMATION ON TOXICITIES OR COMPLICATIONS THAT WERE RESOLVED <u>BEFORE</u> THE CELL THERAPY THIS FORM REFERS TO OR THAT HAVE ALREADY BEEN SUBMITTED WITH PREVIOUS FOLLOW UP FORMS

Acute Graft Versus Host Disease *(Cells of allogeneic origin only)*
Maximum Grade:
☐ 0 (none) ☐ I ☐ II ☐ III ☐ IV ☐ Present but grade unknown ☐ Not evaluated

Date of onset .... - .... - ....
yyyy *mm* *dd*

Stage:

Skin	☐ 0 (none)	☐ 1	☐ 2	☐ 3	☐ 4
Liver	☐ 0 (none)	☐ 1	☐ 2	☐ 3	☐ 4
Lower GI tract	☐ 0 (none)	☐ 1	☐ 2	☐ 3	☐ 4
Upper GI tract	☐ 0 (none)	☐ 1			
Other site affected	☐ No	☐ Yes			

Related to Cell Therapy ☐ No ☐ Yes
Resolved? ☐ No ☐ Yes

Chronic Graft Versus Host Disease present during this period

☐ No *(never)*

Yes: ☐ First episode since last HSCT

Date of diagnosis of cGvHD:
..... - ..... -.....
yyyy *mm* *dd*

☐ Recurrence

Date first evidence of cGVHD during this period:
..... - ..... -.....
yyyy *mm* *dd*

☐ Continuous since last reported episode

Maximum extent during this period
☐ Limited ☐ Extensive ☐ Unknown

Maximum NIH score during this period
☐ Mild ☐ Moderate ☐ Severe ☐ Not evaluated

☐ Resolved since last report *(currently absent)*

Other complications or toxicities during this period

☐ No -> Skip TOXICITIES table below and go straight to SECONDARY MALIGNANCIES on the next page
☐ Yes -> Continue with the TOXICITIES table below
☐ Unknown

Toxicities

	No	**Yes**	**Grade**	**Date of diagnosis**	**Related to cell therapy**	**Ongoing at last assessment**	**Date of resolution**
Cytokine storm	☐	☐		.....-..... -	☐ No ☐ Yes	☐ Yes ☐ No:	..... -..... - .....
Neurotoxicity	☐	☐		.....-..... -	☐ No ☐ Yes	☐ Yes ☐ No:	..... -..... - .....
Grade IV Organ toxicity							
Liver	☐	☐		.....-..... -	☐ No ☐ Yes	☐ Yes ☐ No:	..... -..... - .....
Lungs	☐	☐		.....-..... -	☐ No ☐ Yes	☐ Yes ☐ No:	..... -..... - .....
Heart	☐	☐		.....-..... -	☐ No ☐ Yes	☐ Yes ☐ No:	..... -..... - .....
Kidney	☐	☐		.....-..... -	☐ No ☐ Yes	☐ Yes ☐ No:	..... -..... - .....
Other, specify	☐	☐		.....-..... -	☐ No ☐ Yes	☐ Yes ☐ No:	..... -..... - .....
Bone marrow aplasia/failure	☐	☐		.....-..... -	☐ No ☐ Yes	☐ Yes ☐ No:	..... -..... - .....
Other, specify ……..	☐	☐		.....-..... -	☐ No ☐ Yes	☐ Yes ☐ No:	..... -..... - .....
				yyyy mm dd			*yyyy mm dd*

Secondary Malignancy

Did a secondary malignancy, lymphoproliferative or myeloproliferative disorder occur?

☐ No ☐ Yes:

Date of diagnosis: ..... - ..... - .....
yyyy *mm* *dd*

Diagnosis: .....

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 or a malignancy of the cellular product?

☐ No ☐ Yes ☐ Not applicable

First Relapse/Progression or Significant worsening after Cell therapy

TO BE ANSWERED ONLY WHEN THE INDICATION WAS THE TREATMENT OF A PRIMARY DISEASE INCLUDING INFECTIONS

☐ No

☐ Yes: Date first seen ..... - ..... - .....
yyyy *mm* *dd*

☐ Continuous progression since cell therapy

Last Disease Status

TO BE ANSWERED ONLY WHEN THE INDICATION WAS THE TREATMENT OF A PRIMARY DISEASE INCLUDING INFECTIONS

Last disease status

☐ Complete remission / Normalisation of organ function / No infection present

☐ Partial remission / Partial or non normalisation of organ funcition

☐ No response

☐ Disease progression or worsening of organ function

☐ Not evaluated

Survival Status

☐ Alive ☐ Dead ☐ Check here if patient lost to follow up

Main Cause of Death *(check only one main cause)*:
☐ Relapse or Progression/Persistent disease
☐ Cell Therapy related: .....
☐ HSCT Related Cause
☐ Unknown
☐ Other: .....

Contributory Cause of Death *(check as many as appropriate)*:
☐ GVHD
☐ Interstitial pneumonitis
☐ Pulmonary toxicity
☐ Infection:
- ☐ bacterial
- ☐ viral
- ☐ fungal
- ☐ parasitic
- ☐ unknown

☐ Rejection/Poor graft function
☐ History of severe Veno occlusive disorder (VOD)
☐ Haemorrhage
☐ Cardiac toxicity
☐ Central nervous system (CNS) toxicity
☐ Gastrointestinal (GI) toxicity
☐ Skin toxicity
☐ Renal failure
☐ Multiple organ failure

☐ Other:.....

Persistence of the infused cells

Were tests performed to detect the persistence of the cellular products during this period?

☐ No ☐ Yes: Date of the test ..... - ..... - .....
yyyy *mm* *dd*

Technique used

☐ Molecular (PCR) ☐ Flow cytometry ☐ Chimaerism ☐ Imaging ☐ Immunohistochemistry

☐ Other, specify ……..……..

Were cells detected?

☐ No

☐ Yes