

# Cell Therapy - MED - A

## REGISTRATION - DAY 0

### 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 Patient 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 not to the treatment.

Other type of patient identification codes: .....  
*(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)*

## 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	
<input type="checkbox"/> Primary Acute Leukaemia <input type="checkbox"/> Acute myelogenous leukaemia (Page 11) <input type="checkbox"/> Precursor lymphoid neoplasms (Page 13) <input type="checkbox"/> Other Primary Acute Leukaemia (Page 14)	<input type="checkbox"/> Inherited disorders (Page 26) <input type="checkbox"/> Primary immune deficiencies <input type="checkbox"/> Metabolic disorders <input type="checkbox"/> Other
<input type="checkbox"/> Chronic Leukaemia <input type="checkbox"/> Chronic Myeloid Leukaemia (CML) (Page 15) <input type="checkbox"/> Chronic Lymphocytic Leukaemia (CLL) (Page 16) <input type="checkbox"/> Prolymphocytic Leukaemia (PLL) (Page 17)	<input type="checkbox"/> Histiocytic disorders (Page 27) <input type="checkbox"/> Haemoglobinopathy (Page 24)
<input type="checkbox"/> Lymphoma (Page 18) <input type="checkbox"/> Non Hodgkin <input type="checkbox"/> Hodgkin's Disease	<input type="checkbox"/> Autoimmune disease <input type="checkbox"/> Connective (Page 28) <input type="checkbox"/> Vasculitis (Page 28) <input type="checkbox"/> Arthritis (Page 29) <input type="checkbox"/> Neurological (MS, etc) (Page 29)
<input type="checkbox"/> Myelodysplastic syndrome and/or myeloproliferative neoplasm (Page 18) <input type="checkbox"/> MDS <input type="checkbox"/> MDS/MPN <input type="checkbox"/> Myeloproliferative neoplasm	<input type="checkbox"/> Haematological (Page 29) <input type="checkbox"/> Bowel disorder (Page 30) <input type="checkbox"/> Other (Diabetes, etc.) (Page 30)
<input type="checkbox"/> Myeloma /Plasma cell disorder (Page 23)	<input type="checkbox"/> Infections (Page 32)
<input type="checkbox"/> Solid Tumour (Page 25)	Other primary diseases <input type="checkbox"/> Cardiovascular disease (Page 31) <input type="checkbox"/> Musculoskeletal disorder (Page 31) <input type="checkbox"/> Neurologic disorder (Page 31) <input type="checkbox"/> Ocular disease, specify ..... <input type="checkbox"/> Pulmonary disease, specify .....
<input type="checkbox"/> Bone marrow failure and/or graft failure (Page 24)	

**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 on 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](mailto: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  
  $\geq 2$  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 : ..... - ..... - .....  
*yyyy mm dd*

OR Age at time of donation..... years ..... months  
 (if date of birth not provided)

Donor Sex  Male  Female  
 (at birth)



## 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 ..... CTUCID

**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



**Patient preparative treatment**

No       Yes

**Specification and dose of the preparative regimen**

<b>TOTAL PRESCRIBED CUMULATIVE DOSE* as per protocol: Include any systemic drugs (chemo, growth factors, antibodies, etc.)</b>				
Name of drug (any given before day 0)	DOSE	UNITS		
.....		<input type="checkbox"/> mg/m <sup>2</sup>	<input type="checkbox"/> mg/Kg	<input type="checkbox"/> AUC **
.....		<input type="checkbox"/> mg/m <sup>2</sup>	<input type="checkbox"/> mg/Kg	<input type="checkbox"/> AUC **
.....		<input type="checkbox"/> mg/m <sup>2</sup>	<input type="checkbox"/> mg/Kg	<input type="checkbox"/> AUC **
.....		<input type="checkbox"/> mg/m <sup>2</sup>	<input type="checkbox"/> mg/Kg	<input type="checkbox"/> AUC **
.....		<input type="checkbox"/> mg/m <sup>2</sup>	<input type="checkbox"/> mg/Kg	<input type="checkbox"/> AUC **
.....		<input type="checkbox"/> mg/m <sup>2</sup>	<input type="checkbox"/> mg/Kg	<input type="checkbox"/> AUC **
.....		<input type="checkbox"/> mg/m <sup>2</sup>	<input type="checkbox"/> mg/Kg	<input type="checkbox"/> AUC **

\* Report the total prescribed cumulative dose as per protocol. **Multiply daily dose in mg/kg or mg/m<sup>2</sup> 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 <sup>6</sup> /kg      10 <sup>6</sup>	
<b>Lymphocytes</b> <small>CI EUNSLYMPH</small>	<small>UNSLYMUUNIT</small>	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> <input type="checkbox"/>
<b>CD4+ lymphocytes</b>		<input type="checkbox"/> Not evaluated	<input type="checkbox"/> <input type="checkbox"/>
<b>CD8+ lymphocytes</b> <small>CI ECD4LYMP</small>	<small>CI ECD8UNIT</small>	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> <input type="checkbox"/>
<b>CD3+ lymphocytes</b>		<input type="checkbox"/> Not evaluated	<input type="checkbox"/> <input type="checkbox"/>
<b>Pathogen specific lymphocytes, specify.....</b> <small>CI ESPTCNUM CI ETCSPCFY</small>	<small>CSPTCUNIT</small>	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> <input type="checkbox"/>
<b>Tumour specific lymphocytes, specify.....</b>		<input type="checkbox"/> Not evaluated	<input type="checkbox"/> <input type="checkbox"/>
<b>Regulatory T-cells</b> <small>CI ETCELREG</small>	<small>CI TCELUNIT</small>	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> <input type="checkbox"/>
<b>Mesenchymal</b>		<input type="checkbox"/> Not evaluated	<input type="checkbox"/> <input type="checkbox"/>
<b>Dendritic cells</b> <small>CI EDNDRCEL</small>	<small>CI DNDRUNIT</small>	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> <input type="checkbox"/>
<b>CD34+ cells</b>		<input type="checkbox"/> Not evaluated	<input type="checkbox"/> <input type="checkbox"/>
<b>NK cells</b> <small>CI ENKCELLS</small>	<small>CI ENKUNIT</small>	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> <input type="checkbox"/>
<b>Mononuclear cells</b>		<input type="checkbox"/> Not evaluated	<input type="checkbox"/> <input type="checkbox"/>
<b>Endothelial cell progenitor</b> <small>CI ENDOTHEL</small>	<small>CI ENDOUNIT</small>	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> <input type="checkbox"/>
<b>Other, specify .....</b>		<input type="checkbox"/> Not evaluated	<input type="checkbox"/> <input type="checkbox"/>

**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

# Survival Status

- Alive       Dead

**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:.....

## 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 with 11q23 (MLL) abnormalities
- AML with BCR-ABL1
- AML with mutated NPM1
- AML with biallelic mutation of CEBPA
- AML with mutated RUNX1

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	
<input type="checkbox"/> Primary induction failure			
<input type="checkbox"/> Complete haematological remission (CR)	<input type="checkbox"/> 1 <sup>st</sup> <input type="checkbox"/> 2 <sup>nd</sup> <input type="checkbox"/> 3 <sup>rd</sup> or higher	<b>CYTOGENETIC REMISSION</b> <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Not evaluated <input type="checkbox"/> Not applicable* <input type="checkbox"/> Unknown	<b>MOLECULAR REMISSION</b> <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Not evaluated <input type="checkbox"/> Not applicable* <input type="checkbox"/> Unknown
<input type="checkbox"/> Relapse	<input type="checkbox"/> 1 <sup>st</sup> <input type="checkbox"/> 2 <sup>nd</sup> <input type="checkbox"/> 3 <sup>rd</sup> 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		
<input type="checkbox"/> Chronic phase (CP)	<input type="checkbox"/> 1 <sup>st</sup>	<b>HAEMATOLOGICAL</b> <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not evaluated <input type="checkbox"/> Unknown	<b>CYTOGENETIC</b> <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not evaluated <input type="checkbox"/> Not applicable* <input type="checkbox"/> Unknown	<b>MOLECULAR</b> <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not evaluated <input type="checkbox"/> Not applicable* <input type="checkbox"/> Unknown
	<input type="checkbox"/> 2 <sup>nd</sup>			
	<input type="checkbox"/> 3 <sup>rd</sup> or higher			
<input type="checkbox"/> Accelerated phase	<input type="checkbox"/> 1 <sup>st</sup> <input type="checkbox"/> 2 <sup>nd</sup> <input type="checkbox"/> 3 <sup>rd</sup> or higher			
<input type="checkbox"/> Blast crisis	<input type="checkbox"/> 1 <sup>st</sup> <input type="checkbox"/> 2 <sup>nd</sup> <input type="checkbox"/> 3 <sup>rd</sup> or higher			

\* No abnormality detected prior to this time point







## LYMPHOMAS

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

#### Disease

<p><b>B-cell Neoplasms</b></p> <p><input type="checkbox"/> Splenic marginal zone lymphoma</p> <p><input type="checkbox"/> Extranodal marginal zone lymphoma of mucosa associated lymphoid tissue (MALT)</p> <p><input type="checkbox"/> Nodal marginal zone lymphoma</p> <p><input type="checkbox"/> Lymphoplasmacytic lymphoma (LPL)</p> <p style="padding-left: 20px;"><input type="checkbox"/> Waldenstrom macroglobulinaemia (LPL with monoclonal IgM)</p> <p><input type="checkbox"/> Follicular lymphoma</p> <p><input type="checkbox"/> Primary cutaneous follicle centre lymphoma</p> <p><input type="checkbox"/> Mantle cell lymphoma</p> <p><input type="checkbox"/> Diffuse large B-cell lymphoma (DLBCL), (NOS)</p> <hr/> <p><input type="checkbox"/> T-cell/histiocyte rich large B cell lymphoma</p> <p><input type="checkbox"/> Primary DLBCL of the CNS</p> <p><input type="checkbox"/> Primary cutaneous DLBCL, leg type</p> <p><input type="checkbox"/> EBV positive DLBCL of the elderly</p> <p><input type="checkbox"/> DLBCL associated with chronic inflammation</p> <p><input type="checkbox"/> Lymphomatoid granulomatosis</p> <p><input type="checkbox"/> Primary mediastinal (thymic) large B-cell lymphoma</p> <p><input type="checkbox"/> Intravascular large B-cell lymphoma</p> <p><input type="checkbox"/> ALK positive large B-cell lymphoma</p> <p><input type="checkbox"/> Plasmablastic lymphoma</p> <p><input type="checkbox"/> Large B-cell lymphoma arising in HHV8-associated multicentric Castlemans disease</p> <p><input type="checkbox"/> Primary effusion lymphoma (PEL)</p> <p><input type="checkbox"/> Burkitt lymphoma (BL)</p> <p><input type="checkbox"/> B-cell lymphoma, unclassifiable, with features intermediate between diffuse large B-cell lymphoma and Burkitt lymphoma (Intermediate DLCBL/BL)</p> <p><input type="checkbox"/> B-cell lymphoma, unclassifiable, with features intermediate between diffuse large B-cell lymphoma and classical Hodgkin lymphoma (Intermediate DLCBL/HD)</p> <p><input type="checkbox"/> Other B-cell, specify: _____</p>	<p><b>Mature T-cell &amp; NK-cell Neoplasms</b></p> <p><input type="checkbox"/> T-cell large granular lymphocytic leukaemia</p> <p><input type="checkbox"/> Aggressive NK-cell leukaemia</p> <p><input type="checkbox"/> Systemic EBV positive T-cell lymphoproliferative disease of childhood</p> <p><input type="checkbox"/> Hydroa vacciniforme-like lymphoma</p> <p><input type="checkbox"/> Adult T-cell leukaemia/lymphoma</p> <p><input type="checkbox"/> Extranodal NK/T-cell lymphoma, nasal type</p> <p><input type="checkbox"/> Enteropathy-associated T-cell lymphoma</p> <p><input type="checkbox"/> Hepatosplenic T-cell lymphoma</p> <p><input type="checkbox"/> Subcutaneous panniculitis-like T-cell lymphoma</p> <p><input type="checkbox"/> Mycosis fungoides (MF)</p> <p><input type="checkbox"/> Sézary syndrome</p> <p><input type="checkbox"/> Lymphomatoid papulosis</p> <p><input type="checkbox"/> Primary cutaneous anaplastic large cell lymphoma</p> <p><input type="checkbox"/> Primary cutaneous gamma-delta T-cell lymphoma</p> <p><input type="checkbox"/> Primary cutaneous CD8 positive aggressive epidermotropic cytotoxic T-cell lymphoma</p> <p><input type="checkbox"/> Primary cutaneous CD4 positive small/medium T-cell lymphoma</p> <p><input type="checkbox"/> Peripheral T-cell lymphoma, NOS (PTCL)</p> <p><input type="checkbox"/> Angioimmunoblastic T-cell lymphoma</p> <p><input type="checkbox"/> Anaplastic large-cell lymphoma (ALCL), ALK-positive</p> <p><input type="checkbox"/> Anaplastic large-cell lymphoma (ALCL), ALK-negative</p> <p><input type="checkbox"/> Other T-cell, specify: _____</p>
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*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: \_\_\_\_\_



**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:**       Yes: Disease related to prior exposure to therapeutic drugs or radiation  
 (Secondary origin)       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 Cellular Therapy:**

- 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: <input type="checkbox"/> Primary refractory phase (no change)	
<input type="checkbox"/> Complete remission (CR)	<input type="checkbox"/> 1 <sup>st</sup> <input type="checkbox"/> 2 <sup>nd</sup> <input type="checkbox"/> 3 <sup>rd</sup> or higher
<input type="checkbox"/> Improvement but no CR	
<input type="checkbox"/> Relapse (after CR)	<input type="checkbox"/> 1 <sup>st</sup> <input type="checkbox"/> 2 <sup>nd</sup> <input type="checkbox"/> 3 <sup>rd</sup> or higher
<input type="checkbox"/> Progression/worse <input type="checkbox"/> 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 Cellular Therapy:**

- 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: <input type="checkbox"/> Primary refractory phase (no change)	
<input type="checkbox"/> Complete remission (CR)	<input type="checkbox"/> 1 <sup>st</sup> <input type="checkbox"/> 2 <sup>nd</sup> <input type="checkbox"/> 3 <sup>rd</sup> or higher
<input type="checkbox"/> Improvement but no CR	
<input type="checkbox"/> Relapse (after CR)	<input type="checkbox"/> 1 <sup>st</sup> <input type="checkbox"/> 2 <sup>nd</sup> <input type="checkbox"/> 3 <sup>rd</sup> or higher
<input type="checkbox"/> Progression/worse <input type="checkbox"/> Never treated (Supportive care or treatment without chemotherapy)	









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

Disease

**Classification:**

- |  |  |
|--|--|
| <input type="checkbox"/> Absence of T and B cells SCID                   | <input type="checkbox"/> Kostmann syndrome-congenital neutropenia                  |
| <input type="checkbox"/> Absence of T, normal B cell SCID                | <input type="checkbox"/> Leukocyte adhesion deficiencies                           |
| <input type="checkbox"/> ADA deficiency (Adenosine deaminase deficiency) | <input type="checkbox"/> Neutrophil actin deficiency                               |
| <input type="checkbox"/> Ataxia telangiectasia                           | <input type="checkbox"/> Omenn syndrome  |
| <input type="checkbox"/> Bare lymphocyte syndrome                        | <input type="checkbox"/> PNP deficiency ( <i>Purine nucleoside phosphorylase</i> ) |
| <input type="checkbox"/> Cartilage hair hypoplasia                       | <input type="checkbox"/> Reticular dysgenesis                                      |
| <input type="checkbox"/> CD 40 Ligand deficiency                         | <input type="checkbox"/> SCID other, specify: .....                                |
| <input type="checkbox"/> Chediak-Higashi syndrome                        | <input type="checkbox"/> SCID, unspecified   |
| <input type="checkbox"/> Chronic granulomatous disease                   | <input type="checkbox"/> Wiskott Aldrich syndrome                                  |
| <input type="checkbox"/> Common variable immunodeficiency                | <input type="checkbox"/> X-linked lymphoproliferative syndrome                     |
| <input type="checkbox"/> DiGeorge anomaly                                | <input type="checkbox"/> Other, specify: .....                                     |
| <input type="checkbox"/> IPEX syndrome                                   | <input type="checkbox"/> 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:**

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

Cell Therapy

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

