EBMT Centre Identification Code (CIC): _ _ _
Hospital Unique Patient Number (UPN): _ _ _ _ _ _ _ _ _ _ _ _
Patient Number in EBMT database: _ _ _ _ _ _ _ _ _

Treatment Type ☐ HSCT ☐ CT ☐ OTHER
Treatment Date _ _ _ _/ _ _/ _ _ *(YYYY/MM/DD)*

CELLULAR THERAPIES FORM
-- Pre-Infusion Registration --

INFORMED CONSENT

Was the patient asked to consent to data submission?	☐ **No**	☐ **Yes**	
Date of informed consent: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*			
Is your centre using the EBMT consent form?	☐ **No**	☐ **Yes**	
Did the patient consent to data sharing with health authorities and/or researchers?	☐ **No**	☐ **Yes**	☐ **Unknown**
Did the patient consent to data sharing with Health Technology Assessment bodies (HTA)?	☐ **No**	☐ **Yes**	☐ **Unknown**
Did the patient consent to data sharing with Market Authorisation Holders (MAH)?	☐ **No**	☐ **Yes**	☐ **Unknown**
Did the patient consent to their medical records being reviewed?	☐ **No**	☐ **Yes**	☐ **Unknown**

CENTRE IDENTIFICATION

EBMT Centre Identification Code (CIC): _____

Hospital: _____

Unit: _____

Type of unit or team responsible for this cellular therapy:
(Optional; this is a coded replication of the above unit field and can be used by centres that have more than one department/unit reporting to the EBMT)

- ☐ Adults
- ☐ Allograft
- ☐ Autograft
- ☐ BMT unit
- ☐ Dept. Medicine
- ☐ Haematology
- ☐ Oncology
- ☐ Paediatrics
- ☐ Paediatric haematology
- ☐ Paediatric oncology

Contact person: _____

PATIENT DATA

EBMT Unique Identification Code (UIC): _____
(Patient number in EBMT database; complete if patient had a previous treatment and is already registered in the database)

Date of this report: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*

Hospital Unique Patient Number or code (UPN): _____
(Compulsory; registrations will not be accepted without this item. All treatments (transplants and CAR T-cell) 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 code(s): _____
(Optional; to be used by the centre to register a patient code for internal use as necessary)

Date of birth: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*

Sex *(at birth)***:**
☐ Male
☐ Female

Initials: _____ / _____ *(first name(s) / family name(s))*

ABO group:
☐ A
☐ B
☐ AB
☐ O

Rh factor:
☐ Absent
☐ Present
☐ Not evaluated

If the patient had a previous cellular therapy or a stem cell transplant, please make sure that this previous treatment is registered and that the latest follow-up has been recorded using the appropriate follow-up form before proceeding; this is so relapse data and other events between transplants/advanced cellular therapies can be captured.

INDICATION FOR CELLULAR THERAPY

☐ **Treatment of a primary disease:**

Indicate below for which disease this cellular therapy has been received.

☐ Primary Acute Leukaemia	
Acute Myelogenous Leukaemia (AML)	*(page 8)*
Precursor Lymphoid Neoplasms (previously ALL)	*(page 12)*
Other Primary Acute Leukaemia	*(page 15)*
☐ Chronic Leukaemia	
Chronic Myeloid Leukaemia (CML)	*(page 16)*
Chronic Lymphocytic Leukaemia (CLL)	*(page 16)*
Prolymphocytic Leukaemias (PLL) and Other Chronic Leukaemias	*(page 17)*
☐ Lymphoma	
Non-Hodgkin Lymphoma (NHL)	*(page 19)*
Hodgkin's Lymphoma (HL)	*(page 23)*
Immunodeficiency-associated lymphoproliferative disorders (including PTLD)	*(page 23)*
☐ Myelodysplastic Syndromes (MDS) and/or Myeloproliferative Neoplasm (MPN)	
MDS	*(page 24)*
MDS/MPN	*(page 26)*
MPN	*(page 28)*
☐ Plasma Cell Disorders (PCD including Multiple Myeloma (MM)	*(page 31)*
☐ Bone Marrow Failure Syndromes including Aplastic Anaemia	*(page 33)*
☐ Haemoglobinopathy	*(page 34)*
☐ Solid Tumour	*(page 35)*
☐ Inherited Disorders	
Primary immune deficiencies (PID)	*(page 37)*
Metabolic disorders	*(page 38)*
Platelet and other inherited disorder	*(page 39)*
☐ Histiocytic disorders	*(page 40)*
☐ Autoimmune disease	
Connective tissue	*(page 41)*
Vasculitis	*(page 41)*
Arthritis	*(page 41)*
Neurological	*(page 42)*
Haematological	*(page 42)*
Bowel disorder	*(page 42)*
Other autoimmune disease (Diabetes, etc.)	*(page 42)*
☐ Infections	*(page 43)*
☐ Other primary disease; specify: _____	*(page 44)*

Complete and attach the relevant disease classification sheet as per page numbers indicated above.

Date of diagnosis: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*

INDICATION FOR CELLULAR THERAPY continued

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

Before continuing please make sure that the above mentioned transplant/ cellular therapy has been registered and that a MED-A annual follow-up form has been submitted; this is so relapse data and other events between transplants and/or cellular therapies can be captured.

☐ **Both, treatment of primary disease and complication**
Complete and attach the relevant disease classification sheet as per page numbers indicated above.

BASIC INFORMATION ON THE PLANNED CELLULAR THERAPY

Clinical setting:
(select only one)

☐ As per marketing approval / Standard of care / Institutional guidelines

☐ Hospital exemption

☐ Compassionate use / Accelerated access

☐ Investigational drug product (IDP)/ Clinical trial (CT)

Phase: ☐ 1 ☐ 1/2 ☐ 2 ☐ 2/3 ☐ 3
Blind trial: ☐ No ☐ Yes
Randomised trial: ☐ No ☐ Yes

Eudract number: _____

USA NCT number: _____

UMIN CT number: _____

☐ Unknown

Cell origin:

☐ Autologous *--> Continue with 'Planned Cellular Therapy Product' on page 5*

☐ Allogeneic

This product is manufactured from:

☐ A known donor never used to treat this patient *(e.g. from a donor registry or related)*
--> Complete 'Donor' section on page 5

☐ A donor that is already registered as part of a previous treatment
--> Skip 'Donor' section and continue with 'Planned Cellular Therapy Product' on page 5

☐ An unknown donor with no data available *(e.g. from a commercial product)*
--> Skip 'Donor' section and continue with 'Planned Cellular Therapy Product' on page 5

DONOR INFORMATION

Date of birth: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* *OR* **Age at time of donation :** _____ *(years)* _____ *(months)*
(only if date of birth not provided)

Sex *(at birth)***:**
☐ Male
☐ Female

Donor Identification:

Donor ID given by the treating centre *(mandatory)*: _____

Global registration identifier for donors: _____

Donor ID given by the Donor Registry or Cord Blood Bank: _____

ION code of the Donor Registry or Cord Blood Bank *(mandatory)*: _____

EuroCord code for the Cord Blood Bank *(if applicable)*: _____

Name of Donor Registry or Cord Blood Bank: _____

PLANNED CELLULAR THERAPY PRODUCT
Description

If more than one planned cellular therapy product please replicate this section for each one of them.

Is the planned cellular therapy product a commercial product?
☐ No
☐ Yes

Will the planned cellular therapy product consist of more than one cell infusion unit?
☐ No
☐ Yes: Number of different cell infusion units: _____

PLANNED CELLULAR THERAPY INFUSION PRODUCT
Description continued

If more than one planned cellular therapy product please replicate this section for each one of them.

Identification:

Name of manufacturer:

- ☐ Autolus
- ☐ Bluebird Bio
- ☐ Celgene/ Bristol Myer Squibb
- ☐ Celyad
- ☐ GlaxoSmithKline (GSK)
- ☐ Janssen (Johnson & Johnson)
- ☐ Kite Gilead
- ☐ Miltenyi
- ☐ Novartis
- ☐ Orchard
- ☐ Vertex
- ☐ Local hospital or university
- ☐ Other; specify: _____

Name of product *(if applicable)*:

- ☐ Abecma
- ☐ Breyanzi
- ☐ Cilta-cel
- ☐ Eli-cel
- ☐ Kymriah
- ☐ Tecartus
- ☐ Yescarta
- ☐ Other; specify: _____

Tissue source:

- ☐ Bone Marrow
- ☐ Peripheral Blood
- ☐ Umbilical Cord Blood
- ☐ Tumour
- ☐ Other; specify: _____

Collection procedure:

Date of collection: _ _ _ _ / _ _ /_ _ *(YYYY/MM/DD)*
(If more than one collection enter the date of the first collection.)

Number of collections: _____

END OF GENERAL PRE-INFUSION REGISTRATION

To complete PRE-INFUSION REGISTRATION please fill in the applicable disease classification.

ACUTE LEUKAEMIAS
Acute Myeloid Leukaemias (AML) - *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 (previously “Acute Leukaemia transformed from MDS or MDS/MPN”):
  Was there a previous diagnosis of MDS or MDS/MPN?
  - ☐ No *(continue with 'Predisposing Condition'* below)
  - ☐ Yes *(fill in the MDS (page 24) or MDS/MPN (page 26); then continue with 'Predisposing Condition' below)*
- ☐ 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)
- ☐ AML (megakaryoblastic) with t(1;22) (p13;q13); RBM15-MKL1
- ☐ 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 (previously “Secondary Acute Leukaemia”; related to prior treatment but NOT after a previous diagnosis of MDS or MDS/MPN .)

ACUTE LEUKAEMIAS
Acute Myeloid Leukaemias (AML) - *main disease code 1*

DISEASE continued

Did the patient have a predisposing condition prior to the diagnosis of leukaemia?

☐ No

☐ Yes:
- ☐ Aplastic Anaemia
- ☐ Bloom Syndrome
- ☐ Fanconi Anaemia
- ☐ Unknown

Is this a donor cell leukaemia?
(Only applicable if the patient has received an allograft prior to the diagnosis of acute leukaemia.)

☐ No

☐ Yes

☐ Not evaluated

CHROMOSOME ANALYSIS

Chromosome analysis at diagnosis *(all methods including FISH)***:**
(Include all analyses before treatment; describe results of the most recent complete analysis)

☐ Normal		
☐ Abnormal:	Complex karyotype: *(3 or more abnormalities)*	☐ No ☐ Yes ☐ Unknown
	Monosomal karyotype: *(≥2 autosomal monosomies or 1 autosomal monosomie + at least 1 structural abnormality)*	☐ No ☐ Yes ☐ Unknown
☐ Not done or failed		
☐ Unknown		

ACUTE LEUKAEMIAS
Acute Myeloid Leukaemias (AML) - *main disease code 1*

CHROMOSOME ANALYSIS continued

Transcribe the complete karyotype: ____

OR

Indicate below whether the abnormalities were absent, present or not evaluated.

t(15;17)	☐ Absent	☐ Present	☐ Not evaluated
t(8;21)	☐ Absent	☐ Present	☐ Not evaluated
inv(16)/ t(16;16)	☐ Absent	☐ Present	☐ Not evaluated
11q23 abnormality type *(fill in only if a 11q23 abnormality is present)*:	☐ Absent	☐ Present	☐ Not evaluated
t(9;11)	☐ Absent	☐ Present	☐ Not evaluated
t(11;19)	☐ Absent	☐ Present	☐ Not evaluated
t(10;11)	☐ Absent	☐ Present	☐ Not evaluated
t(6;11)	☐ Absent	☐ Present	☐ Not evaluated
Other abn(11q23); specify: ___________	☐ Absent	☐ Present	
3q26 (EVI1) abnormality type *(fill in only if a 3q26 abnormality is present)*:	☐ Absent	☐ Present	☐ Not evaluated
inv(3) / t(3;3)	☐ Absent	☐ Present	☐ Not evaluated
t(2;3)(p21;q26)	☐ Absent	☐ Present	☐ Not evaluated
Other (3q26)/EVI1 rearrangement; specify: ___________	☐ Absent	☐ Present	
t(6;9)	☐ Absent	☐ Present	☐ Not evaluated
abn 5 type *(fill in only if an abn 5 is present)*:	☐ Absent	☐ Present	☐ Not evaluated
del (5q)	☐ Absent	☐ Present	☐ Not evaluated
monosomy 5	☐ Absent	☐ Present	☐ Not evaluated
Add(5q)	☐ Absent	☐ Present	☐ Not evaluated
Other abn(5q); specify: ___________	☐ Absent	☐ Present	
abn 7 type *(fill in only if an abn 7 is present)*:	☐ Absent	☐ Present	☐ Not evaluated
del(7q)	☐ Absent	☐ Present	☐ Not evaluated
monosomy 7	☐ Absent	☐ Present	☐ Not evaluated
add(7q)	☐ Absent	☐ Present	☐ Not evaluated
Other abn(7q); specify: ___________	☐ Absent	☐ Present	
-17	☐ Absent	☐ Present	☐ Not evaluated
abn(17p)	☐ Absent	☐ Present	☐ Not evaluated
t(1;22)	☐ Absent	☐ Present	☐ Not evaluated
Trisomy 8	☐ Absent	☐ Present	☐ Not evaluated
Other; specify: ___________	☐ Absent	☐ Present	

ACUTE LEUKAEMIAS
Acute Myeloid Leukaemias (AML) - *main disease code 1*

MOLECULAR MARKER ANALYSIS

Molecular Marker analysis at diagnosis:

☐ Absent
☐ Present
☐ Not done or failed
☐ Unknown

Indicate below whether the markers were absent, present or not evaluated.

AML1-ETO (RUNX1/RUNXT1) *Molecular product of t(8;21)*	☐ Absent	☐ Present	☐ Not evaluated
CBFB-MYH11 *Molecular product of inv(16)(p13.1;q22) or (16;16)(p13.1;q22)*	☐ Absent	☐ Present	☐ Not evaluated
PML-RARα *Molecular product of t(15;17)*	☐ Absent	☐ Present	☐ Not evaluated
MLL-rearrangement/mutation *(fill in only if 11q23 abnormality is present)*:	☐ Absent	☐ Present	☐ Not evaluated
MLLT3(AF9)-MLL *Molecular product of t(9;11)(p22;q23)*	☐ Absent	☐ Present	☐ Not evaluated
MLL-PTD (partial tandem duplication)	☐ Absent	☐ Present	☐ Not evaluated
MLLT4(AF6)-MLL *Molecular product of t(6;11)(q27;q23)*	☐ Absent	☐ Present	☐ Not evaluated
ELL-MLL *Molecular product of t(11;19)(q23;p13.1)*	☐ Absent	☐ Present	☐ Not evaluated
MLLT1(ENL)-MLL *Molecular product of t(11;19)(q23;p13.3)*	☐ Absent	☐ Present	☐ Not evaluated
MLLT10(AF10)-MLL *Molecular product of t(10;11)(p12;q23)*	☐ Absent	☐ Present	☐ Not evaluated
Other MLL-rearrangement; specify: _____	☐ Absent	☐ Present	☐ Not evaluated
DEK-NUP214(CAN) *Molecular product of translocation t(6;9)(p23;q34)*	☐ Absent	☐ Present	☐ Not evaluated
RPN1-EVI1 *Molecular product of inv(3)(q21q26.2) or t(3;3)(q21q26.2)*	☐ Absent	☐ Present	☐ Not evaluated
RBM15-MKL1 *Molecular product of translocation t(1;22)(p13;q13)*	☐ Absent	☐ Present	☐ Not evaluated
NPM1 mutation	☐ Absent	☐ Present	☐ Not evaluated
CEBPA mutation	☐ Absent	☐ Present	☐ Not evaluated
FLT3-ITD (internal tandem duplication)	☐ Absent	☐ Present	☐ Not evaluated
DNMT3A	☐ Absent	☐ Present	☐ Not evaluated
ASXL1	☐ Absent	☐ Present	☐ Not evaluated
TP53	☐ Absent	☐ Present	☐ Not evaluated
RUNX1	☐ Absent	☐ Present	☐ Not evaluated
c-KIT	☐ Absent	☐ Present	☐ Not evaluated
Other; specify: _____	☐ Absent	☐ Present	☐ Not evaluated

ACUTE LEUKAEMIAS
Acute Myeloid Leukaemias (AML) - *main disease code 1*

INVOLVEMENT AT DIAGNOSIS

Involvement at diagnosis:

Bone Marrow:	☐ No	☐ Yes	☐ Not evaluated
CNS:	☐ No	☐ Yes	☐ Not evaluated
Testes/Ovary:	☐ No	☐ Yes	☐ Not evaluated
Other:	☐ No	☐ Yes; specify: _____	

ACUTE LEUKAEMIAS
Precursor Lymphoid Neoplasms (previously ALL) - *main disease code 1*

DISEASE

Classification:

- ☐ B lymphoblastic leukaemia/lymphoma *(previously Precursor B-cell ALL)*
  - ☐ with t(9;22)(q34;q11.2); BCR-ABL1
  - ☐ with t(v;11q23); MLL rearranged
  - ☐ with t(1;19)(q23;p13.3); E2A-PBX1
  - ☐ with t(12;21)(p13;q22); TEL-AML1 (ETV-RUNX1)
  - ☐ with hyperdiploidy
  - ☐ with hypodiploidy
  - ☐ with t(5;14)(q31;q32); IL3-IGH
  - ☐ Not otherwise specified (NOS)
  - ☐ Other; specify: _____
- ☐ T Lymphoblastic Leukaemia/Lymphoma *(previously Precursor T-cell ALL)*

Secondary origin: Is this PLN related to prior exposure of therapeutic drugs or radiation?

☐ No
☐ Yes
☐ Unknown

Is this a donor cell leukaemia?
(Only applicable if the patient has received an allograft prior to the diagnosis of acute leukaemia.)

☐ No
☐ Yes
☐ Not evaluated

CHROMOSOME ANALYSIS

Chromosome analysis at diagnosis *(all methods including FISH)*:
(Include all analyses before treatment; describe results of the most recent complete analysis)

- ☐ Normal
- ☐ Abnormal: Complex karyotype: *(3 or more abnormalities)*
  - ☐ No
  - ☐ Yes
  - ☐ Unknown
- ☐ Not done or failed
- ☐ Unknown

ACUTE LEUKAEMIAS
Precursor Lymphoid Neoplasms (previously ALL) - *main disease code 1*

CHROMOSOME ANALYSIS continued

Transcribe the complete karyotype: ____

OR

Indicate below whether the abnormalities were absent, present or not evaluated.

t(9;22)	☐ Absent	☐ Present	☐ Not evaluated
11q23 abnormalities *(fill in only if 11q23 abnormalities is present)*	☐ Absent	☐ Present	☐ Not evaluated
t(4;11)	☐ Absent	☐ Present	☐ Not evaluated
Other abn(11q23); specify: ____________________	☐ Absent	☐ Present	
t(12;21)	☐ Absent	☐ Present	☐ Not evaluated
Hyperdiploidy (>46 chromosomes) *(fill in only if hyperdiploidy is present)*:	☐ Absent	☐ Present	☐ Not evaluated
50 – 66 chromosomes	☐ Absent	☐ Present	☐ Not evaluated
Trisomy; specify extra chromosome: _____	☐ Absent	☐ Present	☐ Not evaluated
Other hyperdiploid karyotype; number of chromosomes: _____	☐ Absent	☐ Present	
Hypodiploidy (<46 chromosomes): *(fill in only if hypodiploidy is present)*:	☐ Absent	☐ Present	☐ Not evaluated
Low hypodiploid; 32 - 39 chromosomes;	☐ Absent	☐ Present	☐ Not evaluated
Near haploid, 24-31 chromosomes;	☐ Absent	☐ Present	☐ Not evaluated
Monosomy; specify: ____________________	☐ Absent	☐ Present	☐ Not evaluated
Other; number of chromosomes: _____	☐ Absent	☐ Present	
t(5;14)(q31;q32)	☐ Absent	☐ Present	☐ Not evaluated
t(1;19)	☐ Absent	☐ Present	☐ Not evaluated
Trisomy 8	☐ Absent	☐ Present	☐ Not evaluated
Other; specify: ____________________	☐ Absent	☐ Present	

MOLECULAR MARKER ANALYSIS

Molecular Marker analysis at diagnosis:

☐ Absent
☐ Present
☐ Not done or failed
☐ Unknown

ACUTE LEUKAEMIAS
Precursor Lymphoid Neoplasms (previously ALL) - *main disease code 1*

MOLECULAR MARKER ANALYSIS continued

Indicate below whether the abnormalities were absent, present or not evaluated.

BCR-ABL *Molecular product of t(9;22)(q34;q11.2)*	☐ Absent	☐ Present	☐ Not evaluated
MLL-rearrangement/mutation *(fill in only if a MLL-rearrangement abnormality is present)*:	☐ Absent	☐ Present	☐ Not evaluated
AFF1(AF4)-MLL *Molecular product of t(4;11)(q21;q23)*	☐ Absent	☐ Present	☐ Not evaluated
MLLT1(ENL)-MLL *Molecular product of t(11;19)(q23;p13.3)*	☐ Absent	☐ Present	☐ Not evaluated
MLLT3(AF9)-MLL *Molecular product of t(9;11)(p22;q23)*	☐ Absent	☐ Present	☐ Not evaluated
Other MLL-rearrangement; specify: _____	☐ Absent	☐ Present	
TEL(ETV6)-AML1(RUNX1) *Molecular product of t(12;21)(p13;q22)*	☐ Absent	☐ Present	☐ Not evaluated
IL3-IGH *Molecular product of translocation t(5;14)(q31;q32)*	☐ Absent	☐ Present	☐ Not evaluated
TCF3-PBX1 *Molecular product of translocation (1;19)(q23;p13.3)*	☐ Absent	☐ Present	☐ Not evaluated
IKZF1 (IKAROS)	☐ Absent	☐ Present	☐ Not evaluated
NOTCH1 & FBWX7	☐ Absent	☐ Present	☐ Not evaluated
Other; specify: _____	☐ Absent	☐ Present	

White blood cell count at diagnosis: _____ 10^9 cells/L ☐ Not available/Unknown

ACUTE LEUKAEMIAS
Other Acute Leukaemias - *main disease code 1*

DISEASE

Classification:

Acute leukaemia 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: Is this other acute leukaemia related to prior exposure of therapeutic drugs or radiation?

☐ No
☐ Yes
☐ Unknown

Is this a donor cell leukaemia?
(Only applicable if the patient has received an allograft prior to the diagnosis of acute leukaemia.)

☐ No
☐ Yes
☐ Not evaluated

CHRONIC LEUKAEMIAS
Chronic Myelogenous Leukaemias (CML) - *main disease code 2*

DISEASE

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

t(9;22) *(Chromosome analysis)*	☐ Absent	☐ Present	☐ Not evaluated
bcr-abl *(Molecular marker analysis)*	☐ Absent	☐ Present	☐ Not evaluated

CHRONIC LEUKAEMIAS
Chronic Lymphocytic Leukaemias (CLL) - *main disease code 2*

DISEASE

Classification:

☐ Chronic lymphocytic leukaemia (CLL) / small lymphocytic lymphoma

☐ Richter's syndrom:

Transformed from a previous known CLL? ☐ Yes: Date of original CLL diagnosis: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*
☐ No: Primary Richter *(without previously known diagnosis of CLL)*

CHROMOSOME ANALYSIS

Chromosome analysis at diagnosis *(all methods including FISH)***:**
(Include all analyses before treatment; describe results of the most recent complete analysis)

☐ Normal
☐ Abnormal
☐ Not done or failed
☐ Unknown

Transcribe the complete karyotype: ____

OR

Indicate below whether the abnormalities were absent, present or not evaluated.

Trisomy 12	☐ Absent	☐ Present	☐ Not evaluated
del(13q14)	☐ Absent	☐ Present	☐ Not evaluated
del(11q22-23)	☐ Absent	☐ Present	☐ Not evaluated
del(17p)	☐ Absent	☐ Present	☐ Not evaluated
Other; specify: _______________	☐ Absent	☐ Present	

CHRONIC LEUKAEMIAS
Chronic Lymphocytic Leukaemias (CLL) - *main disease code 2*

MOLECULAR MARKER ANALYSIS

Molecular Marker analysis at diagnosis:

☐ Absent
☐ Present
☐ Not done of failed
☐ Unknown

Indicate below whether the markers were absent, present or not evaluated.

TP53 mutations	☐ Absent	☐ Present	☐ Not evaluated
Other; specify: _____	☐ Absent	☐ Present	

CHRONIC LEUKAEMIAS
Prolymphocytic Leukaemias (PLL) and Others - *main disease code 2*

DISEASE

Classification:

- ☐ Prolymphocytic Leukaemia (PLL)
  - ☐ PLL; B-cell
  - ☐ PLL; T-cell
- ☐ Hairy Cell Leukaemia
- ☐ Other chronic leukaemia; specify: _____

CHROMOSOME ANALYSIS
only applicable for PLL

Chromosome analysis at diagnosis *(all methods including FISH)*:
(Include all analyses before treatment; describe results of the most recent complete analysis)

☐ Normal
☐ Abnormal
☐ Not done or failed
☐ Unknown

CHRONIC LEUKAEMIAS
Prolymphocytic Leukaemias (PLL) and Others - *main disease code 2*

CHROMOSOME ANALYSIS continued

only applicable for PLL

Transcribe the complete karyotype: ____

OR

Indicate below whether the abnormalities were absent, present or not evaluated.

inv(14)/ t(14;14)(q11;q32)	☐ Absent ☐ Present ☐ Not evaluated
del(14)(q12)	☐ Absent ☐ Present ☐ Not evaluated
t(11;14)(q23;q11)	☐ Absent ☐ Present ☐ Not evaluated
t(7;14)(q35;q32.1)	☐ Absent ☐ Present ☐ Not evaluated
t(X;14)(q35;q11)	☐ Absent ☐ Present ☐ Not evaluated
idic(8)(p11)	☐ Absent ☐ Present ☐ Not evaluated
Other; specify: _______________	☐ Absent ☐ Present

IMMUNOPHENOTYPING

only applicable for T-cell PLL

Immunophenotype of T-cells at diagnosis:
Note: Terminal desoxynucleotidyl transferase (TdT) must be negative.

Indicate below whether the phenotypes were absent, present or not evaluated.

CD4+	☐ Absent ☐ Present ☐ Not evaluated
CD8+	☐ Absent ☐ Present ☐ Not evaluated

Lymphocyte count at diagnosis: _______________ 10^9 cells/L

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

DISEASE

Classification: Mature B-cell Neoplasms

☐ Splenic marginal zone lymphoma	
☐ Extranodal marginal zone lymphoma of mucosa associated lymphoid tissue (MALT)	
☐ Nodal marginal zone lymphoma	
☐ Lymphoplasmacytic lymphoma (LPL)	
☐ Waldenstrom macroglobulinaemia (LPL with monoclonal IgM)	**International Prognostic Scoring System for Waldenström's Macroglobulinemia (ISSWM):** ☐ Low risk *(0-1 score points except age >65)* ☐ Intermediate risk *(2 score points or age >65 alone)* ☐ High risk *(3-5 score points)* ☐ Not evaluated
☐ Follicular lymphoma	**Grading:** ☐ Grade I ☐ Grade II ☐ Grade III ☐ Not evaluated **Prognostic score (FLIPI):** ☐ Low risk ☐ Intermediate risk ☐ High risk ☐ Not evaluated
☐ Primary cutaneous follicle centre lymphoma	
☐ Mantle cell lymphoma	**Grading:** ☐ Indolent ☐ Classical ☐ Pleomorphic ☐ Blastoid ☐ Not evaluated **Prognostic score (MIPI):** ☐ Low risk ☐ Intermediate risk ☐ High risk ☐ Not evaluated **KI-67 *(proliferation index)*: _ _ % positive** ☐ Not evaluated
☐ Diffuse large B-cell lymphoma (DLBCL), (NOS)	**International prognostic score (IPI):** ☐ Low risk *(0-1 score points)* ☐ Low-intermediate risk *(2 score points)* ☐ High-intermediate risk *(3 score points)* ☐ High risk *(4-5 score points)* ☐ Not evaluated **KI-67: _ _ % positive *(proliferation index)*** ☐ Not evaluated
☐ T-cell/histiocyte rich large B cell lymphoma	
☐ Primary DLBCL of the CNS	
☐ Primary cutaneous DLBCL, leg type	
☐ EBV positive DLBCL of the elderly	
☐ Germinal centre B-cell type (GCB) DLBCL	
☐ Activated B-cell type (ABC or non-GCB) DLBCL	
☐ 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	
☐ HHV8-positive DLBCL,NOS	
☐ Primary effusion lymphoma (PEL)	
☐ Burkitt lymphoma (BL)	
☐ High-grade B-cell lymphoma with MYC and BCL2 and/or BCL6 rearrangements	
☐ 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 (Gray zone lymphoma)	
☐ Other B-cell lymphoma; specify: _____	

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

DISEASE continued

Transformed from another type of lymphoma at the event leading to this cellular therapy?

☐ No

☐ Yes: Date of original diagnosis: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*

Indicate the type of the original lymphoma: _____

☐ Unknown

Please complete Chromosome Analysis, Molecular Marker Analysis and Immunophenotyping sections only for patients receiving cellular therapy for the followin types of B-cell NHL:

- *Mantle cell lymphoma*
- *Waldenstrom macroglobulinaemia*
- *Burkitt lymphoma or Intermediate DLBCL/ Burkitt lymphoma*

CHROMOSOME ANALYSIS

Chromosome analysis at diagnosis *(all methods including FISH)*:
(Include all analyses before treatment; describe results of the most recent complete analysis)

☐ Normal

☐ Abnormal

☐ Not done or failed

☐ Unknown

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

Mantle cell lymphoma or Waldenstrom macro- globulinaemia	**del(17p)** FISH used:	☐ Absent ☐ Present ☐ Not evaluated ☐ No ☐ Yes
Burkitt lymphoma or Intermediate DLBCL/ Burkitt lymphoma	**t(2;8)**	☐ Absent ☐ Present ☐ Not evaluated
	t(8;14)	☐ Absent ☐ Present ☐ Not evaluated
	t(8;22)	☐ Absent ☐ Present ☐ Not evaluated
	t(14;18)	☐ Absent ☐ Present ☐ Not evaluated
	myc rearrangement	☐ Absent ☐ Present ☐ Not evaluated
	BCL2 rearrangement	☐ Absent ☐ Present ☐ Not evaluated
	BCL6 rearrangement	☐ Absent ☐ Present ☐ Not evaluated

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

Please complete Chromosome Analysis, Molecular Marker Analysis and Immunophenotyping sections only for patients receiving cellular therapy for the followin types of B-cell NHL:

- *Mantle cell lymphoma*
- *Waldenstrom macroglobulinaemia*
- *Burkitt lymphoma or Intermediate DLBCL/ Burkitt lymphoma*

MOLECULAR MARKER ANALYSIS

Molecular Marker analysis at diagnosis:

☐ Absent
☐ Present
☐ Not done of failed
☐ Unknown

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

Mantle cell lymphoma	**TP53 mutation**	☐ Absent ☐ Present ☐ Not evaluated
Burkitt lymphoma or Intermediate DLBCL/ Burkitt lymphoma	**myc rearrangment**	☐ Absent ☐ Present ☐ Not evaluated
Intermediate DLBCL/ Burkitt lymphoma	**BCL2 rearrangement**	☐ Absent ☐ Present ☐ Not evaluated
	BCL6 rearrangement	☐ Absent ☐ Present ☐ Not evaluated

IMMUNOPHENOTYPING

Immunophenotyping at diagnosis:

☐ Absent
☐ Present
☐ Not done of failed
☐ Unknown

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

Mantle cell lymphoma	**SOX 11**	☐ Absent ☐ Present ☐ Not evaluated
Burkitt lymphoma or Intermediate DLBCL/ Burkitt lymphoma	**MYC**	☐ Absent ☐ Present ☐ Not evaluated
Intermediate DLBCL/ Burkitt lymphoma	**BCL2/IgH**	☐ Absent ☐ Present ☐ Not evaluated
	BCL6	☐ Absent ☐ Present ☐ Not evaluated

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

DISEASE

Classification: 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	
☐ Monomorphic epitheliotropic intestinal T-cell lymphoma	
☐ Hepatosplenic T-cell lymphoma	
☐ Subcutaneous panniculitis-like T-cell lymphoma	
☐ Mycosis fungoides (MF)	**ISCL/EORT staging:** ☐ IA ☐ IB ☐ IIA ☐ IIB ☐ IIIA ☐ IIIB ☐ IVA1 ☐ IVA2 ☐ IVB ☐ Not evaluated
☐ 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)	**International prognostic score (IPI):** ☐ Low risk *(0-1 score points)* ☐ Low-intermediate risk *(2 score points)* ☐ High-intermediate risk *(3 score points)* ☐ High risk *(4-5 score points)* ☐ Not evaluated
☐ Angioimmunoblastic T-cell lymphoma	
☐ Anaplastic large-cell lymphoma (ALCL), ALK-positive	
☐ Anaplastic large-cell lymphoma (ALCL), ALK-negative	
☐ Other T-cell: specify: _____	

LYMPHOMAS
Hodgkin Lymphomas - *main disease code 3*

DISEASE

Classification:

- ☐ Nodular lymphocyte predominant
- ☐ Classical predominant; lymphocyte-rich
- ☐ Classical predominant; nodular sclerosis
- ☐ Classical predominant; mixed cellularity
- ☐ Classical predominant; lymphocyte-depleted
- ☐ Classical predominant; NOS
- ☐ Other; specify: _____

LYMPHOMAS
Immunodeficiency-associated lymphoproliferative disorders (incl. PTLD) - *main disease code 3*

DISEASE

Classification:

- ☐ Lymphoproliferative disease associated with primary immune disorder
- ☐ Lymphoma associated with HIV infection
- ☐ Post-transplant lymphoproliferative disorder (PTLD)
  - ☐ Non-destructive PTLD
    - ☐ Plasmacytic hyperplasia PTLD
    - ☐ Infectious mononucleosis PTLD
    - ☐ Florid follicular hyperplasia PTLD
  - ☐ Polymorphic PTLD
  - ☐ Monomorphic PTLD
    - ☐ B-cell type
    - ☐ T-/NK-cell type
  - ☐ Classical Hodgkin lymphoma PTLD
- ☐ Other iatrogenic immunodeficiency-associated lymphoproliferative disorder

Did the disease result from a previous solid organ transplant?

☐ No

☐ Yes: Date of transplant: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*

Type of transplant:
- ☐ Renal
- ☐ Cardiac
- ☐ Pulmonary
- ☐ Other; specify: _____

☐ Unknown

MYELODYSPLASTIC SYNDROMES (MDS)
main disease code 6

DISEASE

Classification:

- ☐ Refractory anaemia without ring sideroblasts (RA)
- ☐ Refractory anaemia with ring sideroblasts (RARS)
- ☐ Myelodysplastic syndrome with isolated del(5q) chromosomal abnormality
- ☐ Refractory cytopenia with multi-lineage dysplasia (RCMD)
- ☐ Refractory cytopenia with multi-lineage dysplasia with ringed sideroblasts (RCMD-RS)
- ☐ Refractory anaemia with excess of blasts-1 (RAEB-1)
- ☐ Refractory anaemia with excess of blasts-2 (RAEB-2)
- ☐ Childhood myelodysplastic syndrome (Refractory cytopenia of childhood; RCC)
- ☐ Myelodysplastic syndrome, unclassifiable (MDS-U)

Therapy-related MDS?
(Secondary origin)

- ☐ No
- ☐ Yes, disease related to prior exposure to therapeutic drugs or radiation
- ☐ Unknown

Is this a donor cell leukaemia?
(Only applicable if the patient has received an allograft prior to the diagnosis of MDS.)

- ☐ No
- ☐ Yes
- ☐ Not evaluated

CHROMOSOME ANALYSIS

Chromosome analysis at diagnosis *(all methods including FISH)***:**
(Include all analyses before treatment; describe results of the most recent complete analysis)

- ☐ Normal
- ☐ Abnormal: Complex karyotype: *(3 or more abnormalities)* ☐ No ☐ Yes ☐ Unknown
- ☐ Not done or failed
- ☐ Unknown

MYELODYSPLASTIC SYNDROMES (MDS)

main disease code 6

CHROMOSOME ANALYSIS continued

Transcribe the complete karyotype: ____

OR

Indicate below whether the abnormalities were absent, present or not evaluated.

del(Y)	☐ Absent	☐ Present	☐ Not evaluated
abn 5 type *(fill in only if an abn 5 is present)*:	☐ Absent	☐ Present	☐ Not evaluated
del(5q)	☐ Absent	☐ Present	☐ Not evaluated
Other abn(5q); specify: ___________	☐ Absent	☐ Present	
del(20q)	☐ Absent	☐ Present	☐ Not evaluated
abn 7 type *(Ffll in only if an abn 7 is present)*:	☐ Absent	☐ Present	☐ Not evaluated
del(7q)	☐ Absent	☐ Present	☐ Not evaluated
Other abn(7q); specify: ___________	☐ Absent	☐ Present	
abn 3 type *(Ffll in only if an abn 3 is present)*:	☐ Absent	☐ Present	☐ Not evaluated
inv(3)	☐ Absent	☐ Present	☐ Not evaluated
t(3q;3q)	☐ Absent	☐ Present	☐ Not evaluated
del(3q)	☐ Absent	☐ Present	☐ Not evaluated
Other abn(3q); specify: __________	☐ Absent	☐ Present	
del(11q)	☐ Absent	☐ Present	☐ Not evaluated
Trisomy 8	☐ Absent	☐ Present	☐ Not evaluated
Trisomy 19	☐ Absent	☐ Present	☐ Not evaluated
i(17q)	☐ Absent	☐ Present	☐ Not evaluated
Other; specify: ____________	☐ Absent	☐ Present	

MOLECULAR MARKER ANALYSIS

Molecular Marker analysis at diagnosis:

☐ Absent

☐ Present

☐ Not done or fialed

☐ Unknown

If an AML with myelodysplasia-related changes is entered, return to Acute Leukaemias on page 8 to continue.

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

DISEASE

Classification:

☐ 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/MPD?
(Secondary origin)

☐ No

☐ Yes, disease related to prior exposure to therapeutic drugs or radiation

☐ Unknown

CHROMOSOME ANALYSIS

Chromosome analysis at diagnosis *(all methods including FISH)*:
(Include all analyses before treatment; describe results of the most recent complete analysis)

☐ Normal		
☐ Abnormal:	Complex karyotype: *(3 or more abnormalities)*	☐ No ☐ Yes ☐ Unknown
☐ Not done or failed		
☐ Unknown		

Transcribe the complete karyotype: ____

OR

Indicate below whether the abnormalities were absent, present or not evaluated.

abn 1 type; specify: _______________	☐ Absent	☐ Present	☐ Not evaluated
abn 5 type; specify: _______________	☐ Absent	☐ Present	☐ Not evaluated
abn 7 type; specify: _______________	☐ Absent	☐ Present	☐ Not evaluated
Trisomy 8	☐ Absent	☐ Present	☐ Not evaluated
Trisomy 9	☐ Absent	☐ Present	☐ Not evaluated
del(20q)	☐ Absent	☐ Present	☐ Not evaluated
del(13q)	☐ Absent	☐ Present	☐ Not evaluated
Other; specify: _______________	☐ Absent	☐ Present	

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

MOLECULAR MARKER ANALYSIS

Molecular Marker analysis at diagnosis:

☐ Absent
☐ Present
☐ Not done or failed
☐ Unknown

Indicate below whether the markers were absent, present or not evaluated.

BCR-ABL; *Molecular product of t(9;22)(q34;q11.2)*	☐ Absent	☐ Present	☐ Not evaluated
JAK2 mutation	☐ Absent	☐ Present	☐ Not evaluated
FIP1L1-PDGFR	☐ Absent	☐ Present	☐ Not evaluated
PTPN-11	☐ Absent	☐ Present	☐ Not evaluated
K-RAS	☐ Absent	☐ Present	☐ Not evaluated
N-RAS	☐ Absent	☐ Present	☐ Not evaluated
CBL	☐ Absent	☐ Present	☐ Not evaluated
Other; specify: _____	☐ Absent	☐ Present	

MYELOPROLIFERATIVE NEOPLASM (MPN)

main disease code 6

DISEASE

Classification:

☐ 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
☐ Myeloid and lymphoid neoplasms with FGFR1 abnormalities (Stem cell leukaemia-lymphoma syndrome, 8p11 syndrome)
☐ Other; specify: _____

Therapy-related MDS/MPD?
(Secondary origin)

☐ No

☐ Yes, disease related to prior exposure to therapeutic drugs or radiation

☐ Unknown

IPPS risk score for myelofibrosis:

☐ Low risk

☐ Intermediate-1

☐ Intermediate-2

☐ High risk

☐ Not evaluated

MYELOPROLIFERATIVE NEOPLASM (MPN)
main disease code 6

CHROMOSOME ANALYSIS

Chromosome analysis at diagnosis *(all methods including FISH)***:**
(Include all analyses before treatment; describe results of the most recent complete analysis)

☐ Normal		
☐ Abnormal:	Complex karyotype: *(3 or more abnormalities)*	☐ No ☐ Yes ☐ Unknown
☐ Not done or failed		
☐ Unknown		

Transcribe the complete karyotype: ____

OR

Indicate below whether the abnormalities were absent, present or not evaluated.

abn 1 type; specify: ________________	☐ Absent	☐ Present	☐ Not evaluated
abn 5 type; specify: ________________	☐ Absent	☐ Present	☐ Not evaluated
abn 7 type; specify: ________________	☐ Absent	☐ Present	☐ Not evaluated
Trisomy 8	☐ Absent	☐ Present	☐ Not evaluated
Trisomy 9	☐ Absent	☐ Present	☐ Not evaluated
del(20q)	☐ Absent	☐ Present	☐ Not evaluated
del(13q)	☐ Absent	☐ Present	☐ Not evaluated
Other; specify: ________________	☐ Absent	☐ Present	

MOLECULAR MARKER ANALYSIS

Molecular Marker analysis at diagnosis:

☐ Absent
☐ Present
☐ Not done or failed
☐ Unknown

MYELOPROLIFERATIVE NEOPLASM (MPN)
main disease code 6

MOLECULAR MARKER ANALYSIS continued

Indicate below whether the markers were absent, present or not evaluated.

BCR-ABL; *Molecular product of t(9;22)(q34;q11.2)*	☐ Absent	☐ Present	☐ Not evaluated
JAK2 mutation	☐ Absent	☐ Present	☐ Not evaluated
	If present: allele burden _____ %		
cMPL mutation	☐ Absent	☐ Present	☐ Not evaluated
Calreticulin (CALR) mutation	☐ Absent	☐ Present	☐ Not evaluated
FIP1L1-PDGFR	☐ Absent	☐ Present	☐ Not evaluated
Other; specify: _____	☐ Absent	☐ Present	

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

DISEASE

Classification:

☐ Multiple myeloma (MM)	Heavy chain type:	Light chain type:
☐ MM; heavy chain and light chain → *Check light and/or heavy chain types as applicable*	☐ IgG ☐ IgA ☐ IgD ☐ IgE ☐ IgM (not Waldenstrom)	☐ Kappa ☐ Lambda
☐ MM; light chain → *Check light and/or heavy chain types as applicable*		
☐ MM; non-secretory		
☐ Plasma cell leukaemia		
☐ Solitary plasmacytoma of bone		
☐ Primary amyloidosis		
☐ POEMS		
☐ Monoclonal light and heavy chain deposition disease (LCDD/HCDD)		
☐ Other; specify: _____		

Staging at diagnosis:

Salmon & Durie staging for multiple myeloma:
(Please tick both columns.)

Stage	Symptoms
☐ I	☐ A
☐ II	☐ B
☐ II	

Revised ISS:

Stage
☐ I: ISSI I without high risk FISH and normal LDH
☐ II: not R-ISS I or III
☐ III: any ISS with high risk FISH and/or high LDH

OR

ISS STAGE:

Stage	β2-µglob (mg/L)	Albumin (g/L)
☐ I	< 3.5	> 35
☐ II	< 3.5	< 35
	OR	
	3.5 ≤ 5.5	any
☐ III	> 5.5	any

PLASMA CELL DISORDERS (PCD) incl. MULTIPLE MYELOMA (MM)

main disease code 4

CHROMOSOME ANALYSIS

Not applicable for Primary amyloidosis.

Chromosome analysis at diagnosis *(all methods including FISH)***:**
(Include all analyses before treatment; describe results of the most recent complete analysis)

☐ Normal		
☐ Abnormal:	Complex karyotype: *(3 or more abnormalities)*	☐ No ☐ Yes ☐ Unknown
☐ Not done or failed		
☐ Unknown		

Transcribe the complete karyotype: ____

OR

Indicate below whether the abnormalities were absent, present or not evaluated.

del(13q14)	☐ Absent	☐ Present	☐ Not evaluated
t(11;14)	☐ Absent	☐ Present	☐ Not evaluated
abn(17q)	☐ Absent	☐ Present	☐ Not evaluated
del(17p)	☐ Absent	☐ Present	☐ Not evaluated
t(4:14)	☐ Absent	☐ Present	☐ Not evaluated
t(14:16)	☐ Absent	☐ Present	☐ Not evaluated
1q amplification	☐ Absent	☐ Present	☐ Not evaluated
myc rearrangement	☐ Absent	☐ Present	☐ Not evaluated
Other; specify: _______________	☐ Absent	☐ Present	

MOLECULAR MARKER ANALYSIS

Not applicable for Primary amyloidosis.

Molecular Marker analysis at diagnosis:

☐ Absent
☐ Present
☐ Not done or failed
☐ Unknown

BONE MARROW FAILURE SYNDROMES (BMF) incl. APLASTIC ANAEMIA (AA)

main disease code 7

DISEASE

Classification:

Aquired:

☐ Severe Aplastic Anaemia (SAA)	Etiology:
☐ Amegakaryocytosis, acquired (not congenital)	☐ Secondary to hepatitis
☐ Acquired Pure Red Cell Aplasia (PRCA) (not congenital)	☐ Secondary to toxin/other drug
☐ Paroxysmal nocturnal haemoglobinuria (PNH)	☐ Idiopathic
☐ Acquired Pure White Cell Aplasia	☐ Other; specify: _____
☐ Other acquired cytopenic syndrome; specify: _____	

Congenital:

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

HAEMOGLOBINOPATHY
main disease code 1

DISEASE

Classification:

☐ Thalassaemia
- ☐ Beta 0
- ☐ Beta+
- ☐ Beta E
- ☐ Beta S (sickle cell + thalassaemia): **Percentage sickle cell:** _____ %

☐ Sickle Cell Disease

☐ Other haemoglobinopathy; specify: _____

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
- ☐ Germ cell tumour, gonadal
- ☐ Head and neck
- ☐ Hepatobiliary
- ☐ Kidney cancer excluding Wilm's tumour
- ☐ Lung cancer, non-small cell
- ☐ Lung cancer, small cell
- ☐ Medulloblastoma
- ☐ Melanoma
- ☐ Neuroblastoma
- ☐ Ovarian (carcinoma)
- ☐ Pancreatic
- ☐ Prostate
- ☐ Renal cell
- ☐ Retinoblastoma
- ☐ Rhabdomyosarcoma
- ☐ Soft tissue sarcoma (excluding Rhabdo. and extra-skeletal ES)
- ☐ Thymoma
- ☐ Wilm's tumour
- ☐ Other; specify: _____

TNM classification:

Type:
- ☐ Clinical
- ☐ Pathological

Tumour:
- ☐ TX
- ☐ T0
- ☐ T1
- ☐ T2
- ☐ T3
- ☐ T4
- ☐ Not evaluated
- ☐ Unknown

Nodes:
- ☐ NX
- ☐ N0
- ☐ N1
- ☐ N2
- ☐ N3
- ☐ Not evaluated
- ☐ Unknown

Metastases:
- ☐ MX
- ☐ M0
- ☐ M1
- ☐ Not evaluated
- ☐ Unknown

SOLID TUMOURS
main disease code 5

DISEASE continued

Disease-specific staging:

☐ I
☐ II
☐ III
☐ IV
☐ Not evaluated
☐ Unknown

Breast carcinoma risk factors and staging at diagnosis *(Breast carcinoma only)*:

Receptor status:

Estrogen (ER): ☐ Negative ☐ Positive: ER values: _____ ☐ Not evaluated
Progesteron (PgR): ☐ Negative ☐ Positive: PgR values: _____ ☐ Not evaluated
HER2/neu (c-erb-B2): ☐ Negative ☐ Positive ☐ Not evaluated

Defined by: ☐ ICH 3+ ☐ IHC 1/2+ and FISH+

Axillary lymph nodes at surgery: Nº positive / Nº examined = _____ / _____ ☐ Not evaluated

Sentinel Node: ☐ Negative ☐ Positive ☐ Not evaluated

Carcinoma type *(tick only one)*: ☐ Ductal carcinoma ☐ Lobular carcinoma

Proliferation index (activity by Ki67 or MiB1 immunostaining): _____ % of positive cells

Germ cell tumour risk factors and staging at diagnosis *(Germ cell tumours only)*:

Histological classification: ☐ Seminoma ☐ Non-seminoma

Site of origin: ☐ Gonadal
☐ Extra-gonadal: ☐ retroperitoneal ☐ mediastinal ☐ Other sites; specify: _____

INHERITED DISORDERS
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
☐ Immune deficiencies, not otherwise specified
☐ Kostmann syndrome-congenital neutropenia
☐ Leukocyte adhesion deficiencies
☐ Neutrophil actin deficiency
☐ Omenn syndrome
☐ PNP deficiency (Purine nucleoside phosphorylase deficiency)
☐ Reticular dysgenesis
☐ SCID, other; specify: _____
☐ SCID, unspecified
☐ Wiskott Aldrich syndrome
☐ X-linked lymphoproliferative syndrome
☐ Other; specify: _____

INHERITED DISORDERS
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)
☐ Inherited disorders of metabolism, not otherwise specified
☐ 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
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: _____

HISTIOCYTIC DISORDERS
main disease code 9

DISEASE

Classification:

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

AUTOIMMUNE DISORDERS
main disease code 10

DISEASE

Classification:

Connective tissue:

☐ Systemic sclerosis (SS)

Involvement/clinical problem:
- ☐ diffuse cutaneous
- ☐ limited cutaneous
- ☐ SSc sine scleroderma
- ☐ Mixed Connective Tissue Disease (MCTD)
- ☐ Other; specify: _____

☐ Systemic lupus erythematosus (SLE)
☐ Polymyositis dermatomyositis
☐ Sjögren syndrome
☐ Antiphospholipid syndrome
☐ Other type of connective tissue disease; specify: _____

Vasculitis:

☐ Wegener granulomatosis
☐ Classical polyarteritis nodosa
☐ Microscopic polyarteritis nodosa
☐ Churg-Strauss
☐ Giant cell arteritis
☐ Takayasu
☐ Behçet syndrome
☐ Overlap necrotising arteritis
☐ Other; specify: _____

Arthritis:

☐ Rheumatoid arthritis
☐ Psoriatic arthritis/psoriasis
☐ Juvenile idiopathic arthritis (JIA), systemic (Still's disease)
☐ Juvenile idiopathic arthritis (JIA), articular
- ☐ oligoarticular onset
- ☐ polyarticular onset

☐ Other Juvenile idiopathic arthritis; specify: _____
☐ Other arthritis; specify: _____

AUTOIMMUNE DISORDERS
main disease code 10

DISEASE continued

Classification:

Neurological diseases:

- ☐ Multiple Sclerosis
- ☐ Myasthenia gravis
- ☐ Amyotrophic lateral sclerosis (ALS)
- ☐ Chronic inflammatory demyelinating polyneuropathy (CIDP)
- ☐ Neuromyelitis Optica (NMO)
- ☐ Other autoimmune neurological disorder; specify: _____

Haematological diseases:

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

Bowel diseases:

- ☐ Crohn's disease
- ☐ Ulcerative colitis
- ☐ Other autoimmune bowel disease; specify: _____

Other autoimmune diseases:

- ☐ Grave's disease
- ☐ Insuline-dependent diabetes (IDD)
- ☐ Other autoimmune disease; specify: _____

OTHER PRIMARY DISEASES
Infections - *main disease code 14*

DISEASE

Classification:

☐ Prevention/Prophylaxis

☐ Treatment:

Pathogen involved:

- ☐ Adenovirus
- ☐ BK virus
- ☐ Cytomegalovirus (CMV)
- ☐ Epstein-Barr virus
- ☐ Human herpes virus
- ☐ Human immunodeficiency virus (HIV)
- ☐ Other virus; specify: _____
- ☐ Candida
- ☐ Aspergillus
- ☐ Other fungus; specify: _____
- ☐ Other infection; specify: _____

OTHER PRIMARY DISEASES
Neurological Disorders - *main disease code 12*

DISEASE

Classification:

- ☐ Duchenne muscular dystrophy
- ☐ Acute cerebral vascular ischemia
- ☐ Amyotrophic lateral sclerosis (ALS)
- ☐ Parkinson's disease
- ☐ Spinal cord injury
- ☐ Cerebral palsy
- ☐ Congenital hydrocephalus
- ☐ Other; specify: _____

OTHER PRIMARY DISEASES
Cardiovascular (Heart) Diseases - *main disease code 13*

DISEASE

Classification:

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

OTHER PRIMARY DISEASES
Musculoskeletal Disorders - *main disease code 15*

DISEASE

Classification:

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

END OF PRE-INFUSION REGISTRATION & DISEASE CLASSIFICATION SHEETS

Change history:

Version	Date	Description
v1.0	9-Feb-2022	First final version