CELLULAR THERAPIES FORM
-- Day 0 --

CENTRE IDENTIFICATION

EBMT Centre Identification Code (CIC): _____

Hospital: _____

Unit: _____

Contact person: _____

Centre in which the treatment is given (CIC): _____

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 or 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.)

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

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

Sex *(at birth)*:

☐ Male

☐ Female

PREVIOUS THERAPIES incl. BRIDGING THERAPIES
(given before transplant/cellular therapy)

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

☐ No (*continue with this section)*

☐ Yes (*proceed to 'Patient Status at Cellular Therapy' on* *page 5*)

Was the patient treated before this cellular therapy procedure?

☐ No (*proceed to 'Patient Status at Cellular Therapy' on* *page 5*)

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

Copy and repeat the whole 'Previous Therapies' section for each line of treatment. Do not include preparative/lymphodepleting regimen.

Sequential number of this treatment *(counted from diagnosis)*: __________

☐ Unknown

Chemotherapy/Drugs given?

☐ No *(proceed to "Radiotherapy' on* *page 3*)

☐ Yes *(report below)*

☐ Unknown

List all chemotherapy/drugs given during one line of treatment:

Drug/ Regimen:	**Nº of cycles:**	**Date started:** *(YYYY/MM/DD)*	**Date ended:** *(YYYY/MM/DD)*
		_ _ _ _/ _ _/ _ _	_ _ _ _/ _ _/ _ _
		_ _ _ _/ _ _/ _ _	_ _ _ _/ _ _/ _ _
		_ _ _ _/ _ _/ _ _	_ _ _ _/ _ _/ _ _
		_ _ _ _/ _ _/ _ _	_ _ _ _/ _ _/ _ _
		_ _ _ _/ _ _/ _ _	_ _ _ _/ _ _/ _ _
		_ _ _ _/ _ _/ _ _	_ _ _ _/ _ _/ _ _
		_ _ _ _/ _ _/ _ _	_ _ _ _/ _ _/ _ _
		_ _ _ _/ _ _/ _ _	_ _ _ _/ _ _/ _ _

PREVIOUS THERAPIES GIVEN BEFORE TRANSPLANT/CELLULAR THERAPY (inlcuding bridging therapies) continued

Copy and repeat the whole 'Previous Therapies' section for each line of treatment. Do not include preparative/lymphodepleting regimen.

List all chemotherapy/drugs given during one line of treatment:

Drug/ Regimen:	**Nº of cycles:**	**Date started:** *(YYYY/MM/DD)*	**Date ended:** *(YYYY/MM/DD)*
		_ _ _ _/ _ _/ _ _	_ _ _ _/ _ _/ _ _
		_ _ _ _/ _ _/ _ _	_ _ _ _/ _ _/ _ _
		_ _ _ _/ _ _/ _ _	_ _ _ _/ _ _/ _ _
		_ _ _ _/ _ _/ _ _	_ _ _ _/ _ _/ _ _
		_ _ _ _/ _ _/ _ _	_ _ _ _/ _ _/ _ _
		_ _ _ _/ _ _/ _ _	_ _ _ _/ _ _/ _ _
		_ _ _ _/ _ _/ _ _	_ _ _ _/ _ _/ _ _
		_ _ _ _/ _ _/ _ _	_ _ _ _/ _ _/ _ _
		_ _ _ _/ _ _/ _ _	_ _ _ _/ _ _/ _ _
		_ _ _ _/ _ _/ _ _	_ _ _ _/ _ _/ _ _
		_ _ _ _/ _ _/ _ _	_ _ _ _/ _ _/ _ _

If there were more drugs given during one line of treatment add more copies of this page.

Radiotherapy:

☐ No

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

Date ended: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*

☐ Unknown

Other treatment:

☐ No

☐ Yes; specify: ___________________________

☐ Unknown

PREVIOUS THERAPIES GIVEN BEFORE TRANSPLANT/CELLULAR THERAPY (inlcuding bridging therapies) continued

Copy and repeat the whole 'Previous Therapies' section for each line of treatment. Do not include preparative/lymphodepleting regimen.

Response to this line of treatment:
(complete only the section that is relevant to the main diagnosis for which this cellular treatment is given)

Acute Leukaemias:
- ☐ Complete remission (CR); maintained or achieved
- ☐ Relapse/Progression
- ☐ Not evaluable

MDS and MPN:
- ☐ Complete remission (CR); maintained or achieved
- ☐ Relapse/Progression
- ☐ Improvement but no CR
- ☐ Not evaluable

Plasma cell disorders incl. Multiple Myeloma:
- ☐ Stringent complete remission (sCR)
- ☐ Complete remission (CR)
  - Number of this sCR or CR:
    - ☐ 1st
    - ☐ 2nd
    - ☐ 3rd or higher
- ☐ Very good partial remission (VGPR)
- ☐ Partial remission (PR)
  - Number of this VGPR or PR:
    - ☐ 1st
    - ☐ 2nd
    - ☐ 3rd or higher
- ☐ Stable disease *(no change; includes old MR)*
- ☐ Progression
- ☐ Not evaluable

Haemoglobinopathy:
- ☐ No transfusion required *(in Promise select 'Complete remission'.)*
- ☐ Transfusions required *(in Promise select 'Never in CR'.)*

Lymphomas:
- ☐ Complete remission (CR); maintained or achieved
  - ☐ Unconfirmed
  - ☐ Confirmed, by: ☐ CT scan ☐ PET
- ☐ Partial remission (>50%)
- ☐ No response (<50%)
- ☐ Progression
- ☐ Not evaluable

Bone marrow failure syndrome (incl. Aplastic Anaemia)
- ☐ Complete remission (CR)
- ☐ Partial remission (transfusion and growth factor independent)
- ☐ No response
- ☐ Progression
- ☐ Not evaluable
- ☐ Other

Solid tumours:
- ☐ Complete remission (CR)
- ☐ Stable disease
- ☐ Very good partial remission
- ☐ Progressive disease
- ☐ Partial remission (>50)
- ☐ Minor response (>25% and <50%)
- ☐ Not evaluable

Other diagnoses:
- ☐ Cured *(in Promise select 'Complete remission'.)*
- ☐ Improved *(in Promise select 'Partial remission'.)*
- ☐ Worse *(in Promise select 'Progression'.)*
- ☐ No response
- ☐ Not evaluable

PATIENT STATUS AT CELLULAR THERAPY
(All Diagnoses)

Performance score at initiation of treatment *(choose only one)*:

Type of score used:	Score:									
☐ Karnofsky ☐ Lansky	☐ 10	☐ 20	☐ 30	☐ 40	☐ 50	☐ 60	☐ 70	☐ 80	☐ 90	☐ 100
☐ ECOG	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4					

Patient weight at time of cellular therapy: _____ kg

Patient height at time of cellular therapy: _____ cm

B-cell aplasia at time of cellular therapy?

☐ Absent
☐ Present: Percentage of B-cells: _____ %
☐ Not evaluated

DISEASE STATUS AT CELLULAR THERAPY

Status at cellular therapy:
(complete only the section that is relevant to the main diagnosis for which this cellular treatment is given)

Acute Leukaemias:
- ☐ Primary induction failure
- ☐ Complete remission (CR)
- ☐ Relapse

Lymphomas:
- ☐ Never treated
- ☐ Complete remission (CR)
- ☐ Partial remission (PR)
- ☐ Stable disease (no change/no response)
- ☐ Untreated relapse (from a previous CR) or progression from a previous PR
- ☐ Chemorefractory relapse or progression, including primary refractory disease

MDS, MPN and MDS/MPN:
- ☐ Primary refractory
- ☐ Complete remission (CR)
- ☐ Improvement but no CR
- ☐ Relapse
- ☐ Progression
- ☐ Never treated

Plasma cell disorders incl. Multiple Myeloma:
- ☐ Stringent complete remission (sCR)
- ☐ Complete remission (CR)
- ☐ Very good partial remission (VGPR)
- ☐ Partial remission (PR)
- ☐ Relapse
- ☐ Progression
- ☐ Stable disease (no change/no response)
- ☐ Never treated

Chronic Leukaemias:

CML:
- ☐ Chronic phase
- ☐ Accelerated phase
- ☐ Blast crisis

CLL/PLL:
- ☐ Complete remission (CR)
- ☐ Partial remission (PR)
- ☐ Stable disease (no change/no response)
- ☐ Relapse
- ☐ Progression
- ☐ Never treated

Solid tumours:
- ☐ Adjuvant
- ☐ Never treated
- ☐ Stable disease (no change/no response)
- ☐ Complete remission (CR)
- ☐ First partial response (PR1)
- ☐ Relapse
- ☐ Progression

Other diagnoses:
- ☐ Cured *(select 'Complete remission'.)*
- ☐ Improved *(select 'Partial remission'.)*
- ☐ Worse *(select 'Progression'.)*
- ☐ No response
- ☐ Not evaluable

COMORBIDITY INDEX

Was there any <u>clinically significant</u> co-existing disease or organ impairment <u>as listed below</u> at time of patient assessment prior to the preparative regimen?

☐ No

☐ Yes *(indicate each comorbidity below)*

☐ Unknown

COMORBIDITY:	Definition:	
Solid tumour, previously present	Treated at any time point in the patient's past history, excluding non-melanoma skin cancer Indicate type: _____	☐ No ☐ Yes ☐ Not evaluated
Inflammatory bowel disease	Crohn's disease or ulcerative colitis	☐ No ☐ Yes ☐ Not evaluated
Rheumatologic	SLE, RA, polymyositis, mixed CTD, or polymyalgia rheumatica	☐ No ☐ Yes ☐ Not evaluated
Infection	Requiring continuation of antimicrobial treatment after day 0	☐ No ☐ Yes ☐ Not evaluated
Diabetes	Requiring treatment with insulin or oral hypoglycaemics but not diet alone	☐ No ☐ Yes ☐ Not evaluated
Renal: moderate/severe	Serum creatinine > 2 mg/dL or >177 µmol/L, on dialysis, or prior renal transplantation	☐ No ☐ Yes ☐ Not evaluated
Hepatic: mild	Chronic hepatitis, bilirubin between Upper Limit Normal (ULN) and 1.5 x the ULN, or AST/ALT between ULN and 2.5 × ULN	☐ No ☐ Yes ☐ Not evaluated
Hepatic: moderate/severe	Liver cirrhosis, bilirubin greater than 1.5 × ULN, or AST/ALT greater than 2.5 × ULN	☐ No ☐ Yes ☐ Not evaluated
Arrhythmia	Atrial fibrillation or flutter, sick sinus syndrome, or ventricular arrhythmias	☐ No ☐ Yes ☐ Not evaluated
Cardiac	Coronary artery disease, congestive heart failure, myocardial infarction, EF ≤ 50%, or shortening fraction in children (<28%)	☐ No ☐ Yes ☐ Not evaluated
Cerebrovascular disease	Transient ischemic attack or cerebrovascular accident	☐ No ☐ Yes ☐ Not evaluated
Heart valve disease	Except mitral valve prolapse	☐ No ☐ Yes ☐ Not evaluated
Pulmonary: moderate	DLco and/or FEV1 66-80% or dyspnoea on slight activity	☐ No ☐ Yes ☐ Not evaluated
Pulmonary: severe	DLco and/or FEV1 ≤ 65% or dyspnoea at rest or requiring oxygen	☐ No ☐ Yes ☐ Not evaluated
Obesity	Patients with a body mass index > 35 kg/m^2	☐ No ☐ Yes ☐ Not evaluated
Peptic ulcer	Requiring treatment	☐ No ☐ Yes ☐ Not evaluated
Psychiatric disturbance	Depression or anxiety requiring psychiatric consultation or treatment	☐ No ☐ Yes ☐ Not evaluated

Were there any additional <u>major</u> clinical abnormalities not listed above and present prior to the preparative regimen?

Specify: _____

CELLULAR THERAPY TREATMENT

Was the cellular product infused during this treatment/procedure?

☐ Yes

☐ No; Reason why the treatment did not take place:
- ☐ Production failure
- ☐ Out-of-specification product refused by physician
- ☐ Disease progresion
- ☐ Patient condition worsened (ineligible for treatment) or patient died
- ☐ Other; specify: _____

Date of the first cell infusion: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*
(if the cellular therapy product was infused)

OR

Date of last assessment: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*
(only applicable if the cellular therapy product was not infused)

CELLULAR THERAPY INFUSION UNIT(S)

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

☐ No

☐ Yes: Indicate number of cell infusion units for this treatment: _____

CELLULAR THERAPY INFUSION UNIT(S)
Description

If more than one cell infusion unit 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

CELLULAR THERAPY INFUSION UNIT(S)
Description continued

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

Identification continued:

Name of product *(if applicable)*:

- ☐ Abecma
- ☐ Breyanzi
- ☐ Cilta-cel
- ☐ Eli-cel
- ☐ Kymriah
- ☐ Tecartus
- ☐ Yescarta
- ☐ Other

Unique ID of the product: _____
(If applicable; enter only if the CT product was infused.)

Batch number: _____
(If applicable; enter only if the CT product was infused.)

Identification of the cell infusion unit given by the centre: _____
(If there is only one cell infusion unit enter "1"; enter only if the CT product was infused)

If the CT product was not infused proceed to 'Survival Status' on page 14.

Was the infused cellular product consistent with the specifications?

- ☐ No
- ☐ Yes

Was the cellular therapy product cryopreserved prior to infusion?

- ☐ No
- ☐ Yes

CELLULAR THERAPY INFUSION UNIT(S)
Manipulation

Complete only for non-commercial products. If more than one cell infusion unit please replicate this section for each of them.

Identification of the cell infusion unit (given by the centre)**:** _____

***Ex-vivo* manipulation of the product contained in the cellular therapy infusion unit:**

☐ No (*proceed to 'Therapy and Cell Infusion' on page 11*)
☐ Yes (*continue with 'Manipulation' section below.)*
☐ Unknown

Manipulation:

Processing/Manufacturing facility:

☐ Onsite, by local cell processing facility
☐ Offsite, by a non-commercial facility
☐ Offsite, by a commercial facility

Gene manipulation:

☐ No

☐ Yes: Type *(check all that apply)*:

☐ Gene transfer: Vector: ☐ Retroviral vector
☐ Lentiviral vector
☐ Other vector; specify: _____

Transgene: ☐ CAR; specify all targets: _____
☐ TCR; specify all targets: _____
specify HLA element: _____
☐ Suicide gene; specify: _____
☐ Other: specify: _____

☐ Gene editing: ☐ No
☐ Yes: Manipulated gene: ☐ CCR5
☐ Factor IX
☐ Factor VIII
☐ Other gene; specify: _____

☐ Other: ☐ No
☐ Yes: specify: _____

CELLULAR THERAPY INFUSION UNIT(S)
Manipulation continued

Complete only for non-commercial products. If more than one cell infusion unit please replicate this section for each of them.

Manipulation aims:

Recognition of a specific target/antigen:

☐ No

☐ Yes: Type *(check all that apply)*:

☐ Viral:
- ☐ Adenovirus
- ☐ BK Virus
- ☐ Covid-19 (SARS-CoV-2)
- ☐ Cytomegalovirus (CMV)
- ☐ Epstein-Barr virus
- ☐ Human herpes virus 6
- ☐ Human immunodeficiency virus (HIV)
- ☐ RSV-CTL
- ☐ Other virus; specify: _____

☐ Fungal:
- ☐ Candida
- ☐ Aspergillus
- ☐ Other fungus; specify: _____

☐ Tumour/cancer antigen(s); specify all: _____

☐ Other target; specify: _____

Cell types *(check all that apply)*:

☐ CD3+ lymphocytes
☐ CD4+ lymphocytes
☐ CD8+ lymphocytes
☐ Gamma-Delta cells
☐ Regulatory T-cells
☐ Mesenchymal
☐ Dendritic cells
☐ CD34+
☐ NK cells
☐ Mononuclear cells (DLI)
☐ Other; specify: _____

Expansion:	**Activation:**	**Induced differentiation:**
☐ No	☐ No	☐ No
☐ Yes	☐ Yes	☐ Yes

THERAPY & CELL INFUSION(S)

Chronological number of cellular therapy treatment for this patient: _____
(Please do not include any transplants the patient has had in the past)

Complete this section only if this is the second or a subsequent cellular therapy for this patient and the previous cellular treatments cannot be registered.

If > 1:

Same package/product as for the previous cellular therapy?

☐ No
☐ Yes

Date of last cellular therapy before this one: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*

Type of last cellular therapy before this one:

☐ Auto
☐ Allo: Was the same donor used for all prior and current cellular therapy? ☐ No ☐ Yes

Was the last cellular therapy performed at another institution?

☐ No
☐ Yes:
CIC (if known): _____
Name of institution: _____
City: _____

If > 1 submit an annual follow-up form before proceeding using the latest assessment date before this cellular therapy; this is so relapse data and other events between transplants/cellular therapies can be captured.

Reason for this cellular therapy (check all that apply)**:**

If indication is the <u>treatment of a primary disease</u>:

☐ Treatment of primary diagnosis
☐ Prevention of disease relapse or progression
☐ Rescue from disease relapse or progression
☐ Minimal residual disease reduction
☐ Refractory disease
☐ Other; specify: _____

If indication is the <u>treatment or prevention of a complication derived from a previous treatment</u>:

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

Graft function
☐ Unrelated to graft function
☐ Preventionof rejection/Promotion of cell engraftment
☐ Graft enhancement
☐ Graft failure treatment

Immune reconstitution
☐ Unrelated to immune reconstitution
☐ Immune reconstitution

THERAPY & CELL INFUSION(S)
Preparative Treatment

Did the patient receive preparative (lymphodepleting) treatment?

☐ No

☐ Yes: Specification and dose of the preparative regimen:

Include any systemic drugs (chemotherapy, growth factors, antibodies, etc.

Name of drug *(any given before day 0)*	**Total prescribed cumulative dose*** *(as per protocool)*	**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**

** 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 preparative treatment:

☐ No

☐ Yes; specify: _____

CELL INFUSION EPISODE(S)

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

☐ No

☐ Yes: Number of different cell infusion episodes during this treatment/procedure: _____

CELL INFUSION EPISODE(S)
Description

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

Date of cell infusion episode: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*

Route of infusion:

☐ Intravenous

☐ Intrathecal

☐ Intratumour injection

☐ Other route; specify: _____

Combined/concomitant therapies planned before this cellular therapy to optimize efficiency?

☐ No

☐ Yes; specify: _____

Treatment given: ☐ Simultaneously to the cellular therapy

☐ After the cellular therapy episode was finished

If more than one unit was used, indicate the identification of the cell infusion given by the centre as described in the 'Cell Infusion Unit' section *(This item is mandatory if more than one cell infusion unit was used.)*: _____

Is the exact number of cells infused available?

☐ No, only a range is available

☐ Yes: Number of cells: _____ *(not adjusted for cell viability)*

Unit *(tick only one)*: ☐ 10^6/kg ☐ 10^6 ☐ 10^8/kg ☐ 10^8

Cell viability: _____ **%**

If more than one unit was used, indicate the identification of the cell infusion given by the centre as described in the 'Cell Infusion Unit' section *(This item is mandatory if more than one cell infusion unit was used.)*: _____

Is the exact number of cells infused available?

☐ No, only a range is available

☐ Yes: Number of cells: _____ *(not adjusted for cell viability)*

Unit *(tick only one)*: ☐ 10^6/kg ☐ 10^6 ☐ 10^8/kg ☐ 10^8

Cell viability: _____ **%**

SURVIVAL STATUS

Survival status:

☐ Alive

☐ Dead: Date of death *(if death happened around time of cellular therapy)*: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*

Main cause of death:
(check only one main cause)

☐ Relapse or progression/persistent disease
☐ Secondary malignancy
☐ Cellular therapy-related
☐ HSCT-related *(only if patient previously had a transplant)*
☐ Unknown
☐ Other; specify: _____

Contributory causes of death:
(check all that apply)

☐ 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; specify: _____

END OF DAY 0 REGISTRATION

Change history:

Version	Date	Description
v1.0	9-Feb-2022	First final version
v2.0	23-May-2022	Typos corrected Disease status at time of CT: label sets for MDS, MPN and MDS/MPN; Solid Tumors and Plasma cell disorders incl. Multiple Myeloma updated