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

Treatment Date _ _ _ _/ _ _/ _ _ *(YYYY/MM/DD)*
Embargo end date _ _ _ _/ _ _/ _ _ *(YYYY/MM/DD)*

CELLULAR THERAPY
Day 0

PRE-INFUSION

Cell collection procedure - Apheresis:

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

☐ Date unknown
(e.g. allogeneic product from unknown donor)

Number of collections: _____

Was the first collection used for production? ☐ No ☐ Yes

If first collection was not used for production:

Was a second, unplanned collection performed? ☐ No ☐ Yes

Was the second collection used for production?

☐ No

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

Type of cellular therapy? *(Please do not report cell infusion (e.g. DLI) here. Cell infusion should be reported in cell infusion sheet section found in the Follow up forms.)*

☐ CAR-NK cells
☐ CAR-T cells
☐ CAR-CIK cells
☐ TIL therapy
☐ Other cellular therapy, please specify: _____

INDICATION FOR PLANNED CELLULAR THERAPY

☐ **Treatment of a primary disease:**

Indication diagnosis for this cellular therapy:_____
(make sure the indication diagnosis has been registered first, using the relevant diagnosis form)

Reason for cellular therapy: (select all that apply)

☐ Induction therapy
☐ Prevention of disease relapse or progression
☐ Rescue from disease relapse or progression
☐ Minimal residual disease reduction
☐ Refractory disease
☐ Other; specify: _____

☐ **Other indication;** specify: _____

BASIC INFORMATION ON THE PLANNED CELLULAR THERAPY

Clinical setting:
(check only one)

- ☐ As per marketing approval / Standard of care / Institutional guidelines
- ☐ Hospital exemption
- ☐ Compassionate use / Accelerated access
- ☐ Investigational drug product (IDP)/ Clinical trial

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

EudraCT number: _____

USA NCT number: _____

UMIN CT number: _____

Cell origin:

- ☐ Autologous *(Proceed to 'Planned cellular therapy infusion product(s)' section on page 4)*
- ☐ Allogeneic:

This product is manufactured from:

- ☐ A known donor never used to treat this patient *(e.g. from a donor registry or related)*
  (Proceed to 'Donor information' section on page 3.)
- ☐ A donor that is already registered as part of a previous treatment
  (Proceed to 'Planned cellular therapy infusion product(s)' section on page 4.)
- ☐ An unknown donor with no data available *(e.g. from a commercial product)*
  (Proceed to 'Planned cellular therapy infusion product(s)' section on page 4)

DONOR INFORMATION

Complete only if cell source was allogeneic

Did the donor consent to having their data in the EBMT registry?

☐ No (complete only fields marked with '*' in this section)

☐ Yes

(Skip if the source of stem cells is cord blood)

Date of birth: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* **OR:** ***Age at time of donation: _____ years**

If the donor was younger than 2 years:
***Age in months:** ____

***Sex** ***(at birth)*:**

☐ Male

☐ Female

Donor Identification:

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

Global registration identifier for donors (GRID): _____

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: _____

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

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

PLANNED CELLULAR INFUSION PRODUCT(S)

Will the planned cellular infusion product consist of more than one infusion unit?

☐ No
☐ Yes: **Number of infusion units**: _____
☐ Unknown

Tissue source *(check all that apply)***:**

☐ Bone marrow
☐ Peripheral blood
☐ Cord blood
☐ Tumour
☐ Other; specify: _____

Is the planned cell infusion product a commercial product?

☐ No
☐ Yes

Identification:

Name of manufacturer:

☐ Autolus
☐ Celgene/ Bristol-Myers Squibb
☐ Celyad
☐ GlaxoSmithKline (GSK)
☐ Johnson & Johnson
☐ Kite Gilead
☐ Miltenyi
☐ Novartis
☐ Local hospital or university
☐ Other; specify: _____

Name of product:

☐ Abecma
☐ Aucatzyl
☐ Breyanzi
☐ Carvykti
☐ Kymriah
☐ Tecartus
☐ Yescarta
☐ No product name available
☐ Other; specify: _____

END OF PRE-INFUSION SECTION

PLEASE PROCEED WITH THE CELLULAR THERAPY SECTION TO COMPLETE

THE CELLULAR THERAPY DAY 0 REPORT

CELLULAR THERAPY

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

Centre where infusion took place (CIC): ____
(if the product was not infused, report the centre where the infusion was planned to take place)

Patient UPN for this treatment: _____

Team or unit where treatment took place *(select all that apply):*

☐ Adults ☐ Pediatrics ☐ Haematology ☐ Oncology ☐ Allograft ☐ Autograft ☐ Other; specify: _____

Unit number: _____ ☐ Not applicable

Was the cellular therapy product infused during this treatment/procedure?

☐ No: Reason why the treatment did not take place:
Select all reasons that apply

- ☐ Production failure
- ☐ Out of specification product rejected by physician
- ☐ Disease progression or patient condition worsening
- ☐ Patient became ineligible for treatment
- ☐ Patient died
- ☐ Other reason; specify: _____

☐ Yes:

Absolute B-cell count: _____ ☐ x10^9/L ☐ x10^6/L (cells/µL) ☐ Not evaluated ☐ Unknown

Absolute total immune cell count: _____ ☐ x10^9/L ☐ x10^6/L (cells/µL) ☐ Not evaluated ☐ Unknown

THERAPY & CELL INFUSION(S)

Chronological number of cellular therapy treatment for this patient: _____
(Please do not include any transplants or DLIs the patient 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 product as for the previous cellular therapy?

☐ No

☐ Yes

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

Type of the last cellular therapy before this one:

☐ Autologous

☐ Allogeneic: Was the same donor used both for 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.

Did the patient receive a previous HCT?

☐ No

☐ Yes: **Date of the last HCT before this CT**: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*

Type of the last HCT before this CT: ☐ Autologous ☐ Allogeneic

For same indication as the cellular therapy? ☐ No ☐ Yes

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

Was the patient treated before this cellular therapy procedure (not including HCT/CT/GT/IST)?

☐ No (*proceed to 'Cellular therapy infusion unit(s)' on page 8)*

☐ Yes — **complete the "Treatment — non-HCT/CT/GT/IST" form before continuing with 'Cellular therapy infusion unit(s)' on page 8)**

☐ Unknown (*proceed to 'Cellular therapy infusion unit(s)' on page 8)*

CELLULAR THERAPY INFUSION UNIT(S)

Was there more than one cell infusion unit administered during this treatment?
(CAR-T cell product specific instructions are available in the Completion Guidelines (e.g. for Breyanzi).)

☐ No

☐ Yes: Number of different cell infusion units that were part of this treatment: _____

CELLULAR THERAPY INFUSION UNIT(S) DESCRIPTION

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

If more than one cell infusion unit please copy and fill-in this section for each one of them.

Unique ID of the product: _____
(If applicable)

Batch number: _____
(If applicable)

Identification of the cell infusion unit given by the centre: _____
(If there is only one cell infusion unit enter "1")

Was the infused cellular product consistent with the specifications?

☐ No: specify the difference from specifications: _____

☐ Yes

☐ Unknown

Was the cellular therapy product cryopreserved prior to infusion?

☐ No

☐ Yes

☐ Unknown

CELLULAR THERAPY INFUSION UNIT(S) MANIPULATION

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

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

Manipulation:

Processing/Manufacturing facility:

☐ Onsite, by local cell processing facility

☐ Offsite, by a non-commercial facility

Gene manipulation:

☐ No

☐ Yes: Type

Gene transfer:
- ☐ No
- ☐ Yes: Vector:
  - ☐ Retroviral vector
  - ☐ Lentiviral vector
  - ☐ Other vector; specify: _____

Transgene:
- ☐ CAR; specify all targets: _____ *See appendix 1 for a list of target antigens*
- ☐ TCR; specify all targets: _____
  - specify HLA element: _____
- ☐ Suicide gene; specify: _____
- ☐ Other: 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 copy and fill-in this section for each one 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 administered *(check all that apply)*:

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

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

PREPARATIVE REGIMEN

Do not include lines of therapy given for disease treatment, bridging therapy or maintenance, these should be reported in other form.

Preparative conditioning / lymphodepletion regimen given?

☐ No

☐ Yes:

Conditioning/lymphodepleting drugs given? *(any active agent, including chemotherapy, monoclonal antibody, polyclonal antibody, serotherapy, etc.)*

- ☐ No
- ☐ Yes (provide details in the table on pages 12-13)
- ☐ Unknown

Were any prophylactic (preventive) drugs given for CRS/ICANS?

☐ No

☐ Yes: **CRS/ICANS prophylaxis drugs given?** *(select all that apply)*

- ☐ Corticosteroids
- ☐ Anakinra
- ☐ Tocilizumab
- ☐ Other prophylactic drug, specify:_____

☐ Unknown

PREPARATIVE REGIMEN continued

Specification and dose of the preparative regimen:

(Report the total prescribed cumulative dose as per protocol. Multiply daily dose in mg/kg or mg/m² by the number of days; e.g. for Busulfan given 4mg/kg daily for 4days, total dose to report is 16mg/kg.
Report dosages and units only for individual drugs.)

Chemotherapy	Dose	Units
☐ Alemtuzumab	_____	☐ mg/m² ☐ mg/kg
☐ Anti-Thymocyte Globulin|Anti-Lymphocyte Globulin Product name: _____ Origin: ☐ Rabbit ☐ Horse ☐ Other; specify: _____	_____	☐ mg/m² ☐ mg/kg
☐ Bendamustine	_____	☐ mg/m² ☐ mg/kg
☐ Bleomycin	_____	☐ mg/m² ☐ mg/kg
☐ Busulfan Route of administration: ☐ Oral ☐ IV ☐ Both Drug monitoring performed: ☐ No ☐ Yes; total AUC: _____ ☐ mg x hr/L ☐ micromol x min/L ☐ mg x min/mL	_____	☐ mg/m² ☐ mg/kg
☐ Carboplatin Drug monitoring performed: ☐ No ☐ Yes; total AUC: _____ ☐ mg x hr/L ☐ micromol x min/L ☐ mg x min/mL	_____	☐ mg/m² ☐ mg/kg
☐ Carmustine	_____	☐ mg/m² ☐ mg/kg
☐ Cisplatin	_____	☐ mg/m² ☐ mg/kg
☐ Clofarabine	_____	☐ mg/m² ☐ mg/kg
Corticosteroids:		
☐ Beclometasone	_____	☐ mg/m² ☐ mg/kg
☐ Budesonide	_____	☐ mg/m² ☐ mg/kg
☐ Dexamethasone	_____	☐ mg/m² ☐ mg/kg
☐ Methylprednisolone	_____	☐ mg/m² ☐ mg/kg
☐ Prednisolone	_____	☐ mg/m² ☐ mg/kg
☐ Cyclophosphamide	_____	☐ mg/m² ☐ mg/kg

PREPARATIVE REGIMEN continued

Specification and dose of the preparative regimen:
(Report the total prescribed cumulative dose as per protocol. Multiply daily dose in mg/kg or mg/m² by the number of days; e.g. for Busulfan given 4mg/kg daily for 4days, total dose to report is 16mg/kg.)

Chemotherapy	Dose	Unit
☐ Cytarabine	_____	☐ mg/m² ☐ mg/kg
☐ Daunorubicin	_____	☐ mg/m² ☐ mg/kg
☐ Doxorubicin	_____	☐ mg/m² ☐ mg/kg
☐ Epirubicin	_____	☐ mg/m² ☐ mg/kg
☐ Etoposide	_____	☐ mg/m² ☐ mg/kg
☐ Fludarabine	_____	☐ mg/m² ☐ mg/kg
☐ Gemtuzumab ozogamicin	_____	☐ mg/m² ☐ mg/kg
☐ Ibritumomab tiuxetan	_____	☐ mCi ☐ MBq
☐ Idarubicin	_____	☐ mg/m² ☐ mg/kg
☐ Ifosfamide	_____	☐ mg/m² ☐ mg/kg
☐ Imatinib	_____	☐ mg/m² ☐ mg/kg
☐ Lomustine	_____	☐ mg/m² ☐ mg/kg
☐ Melphalan	_____	☐ mg/m² ☐ mg/kg
☐ Mitoxantrone	_____	☐ mg/m² ☐ mg/kg
☐ Paclitaxel	_____	☐ mg/m² ☐ mg/kg
☐ Anti-CD20 antibodies	_____	☐ mg/m² ☐ mg/kg
☐ Teniposide	_____	☐ mg/m² ☐ mg/kg
☐ Thiotepa	_____	☐ mg/m² ☐ mg/kg
☐ Tositumomab	_____	☐ mCi ☐ MBq
☐ Treosulfan	_____	☐ mg/m² ☐ mg/kg
☐ Other; specify*: _____	_____	☐ mg/m² ☐ mg/kg ☐ mCi ☐ MBq

*Please consult the **LIST OF CHEMOTHERAPY DRUGS/AGENTS AND REGIMENS** on the EBMT website for drugs/regimens names

Has the chemotherapy dose been adjusted according organ dysfunction and/or body weight?

- ☐ No
- ☐ Yes, reason for dose adjustment (select all that apply):
  - ☐ Renal impairment
  - ☐ Hepatic impairment
  - ☐ Overweight/obesity
  - ☐ Underweight
  - ☐ Other reason for adjustment, specify: _____
- ☐ Unknown

Total body irradiation (TBI):

☐ No
☐ Yes; **total prescribed radiation dose as per protocol (Gy): _____**
number of fractions: _____
number of radiation days: _____

CELL INFUSION EPISODE(S)

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

(CAR-T cell product specific instructions are available in the Completion Guidelines (e.g. for Breyanzi).)

☐ No

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

CELL INFUSION EPISODE(S) DESCRIPTION

If more than one cell infusion unit please copy and fill-in this section for each one of them.

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

Route of infusion:
(check all that apply)

☐ Intraveneous

☐ Intrathecal

☐ Intratumour injection

☐ Other route; specify: _____

Did the patient receive concomitant therapy?

☐ 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

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

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

Cell viability %: _____

If more than one cell infusion unit was administered please copy and fill-in this section for each one of them.

END OF THE CELLULAR THERAPY DAY 0 REPORT

proceed to form DISEASE STATUS AT HCT/CT/GT/IST

Appendix 1
-- List of transgene CAR targets --

AFP (alpha fetoprotein)
BAFF-R
BCMA
B7H3
CD11
CD16
CD19
CD20
CD22
CD30
CD33
CD38
CD56
CD123
CD138
CD171
CD229
CLL1
CS-1 (SLAMF7)
EGFR
GD2
GPRC5D
HER2
HPV-16E6
Integrinβ7
Lewis-Y
MAGE-A4
MAGE-A10
Mesothelin (MSLN)
MUC16
NKG2D
NY-ESO-1
PRAME
PSCA
SSX
Survivin
TACI
WT-1
Other (specify)