

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: _____

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: _____

Treatment or prevention of complications:

(derived from a previous treatment or expected from a subsequent treatment)

Date of the last treatment: ____/____/____ (YYYY/MM/DD)

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

Reason for cellular therapy:

- GvHD
- Treatment of GvHD
- Preventive treatment for GvHD

- Graft function
- Graft failure treatment
- Prevention of rejection/Promotion of cell engraftment
- Graft enhancement

- Immune reconstitution

Other indication; specify: _____

BASIC INFORMATION ON THE PLANNED CELLULAR THERAPY

Clinical setting:
(check only one)

<input type="checkbox"/> As per marketing approval / Standard of care / Institutional guidelines	
<input type="checkbox"/> Hospital exemption	
<input type="checkbox"/> Compassionate use / Accelerated access	
<input type="checkbox"/> Investigational drug product (IDP)/ Clinical trial	Phase: <input type="checkbox"/> 1 <input type="checkbox"/> 1/2 <input type="checkbox"/> 2 <input type="checkbox"/> 2/3 <input type="checkbox"/> 3 Blind trial: <input type="checkbox"/> No <input type="checkbox"/> Yes Randomised trial: <input type="checkbox"/> No <input type="checkbox"/> Yes EudraCT number: _____ USA NCT number: _____ UMIN CT number: _____ <input type="checkbox"/> Tick here if this registration should be hidden. Date by which the registration can be made available for research: ____/____/____ (YYYY/MM/DD)

Cell origin:

<input type="checkbox"/> Autologous <i>(Proceed to 'Planned cellular therapy infusion product(s)' section on page 3)</i>
<input type="checkbox"/> Allogeneic: <p style="margin-left: 20px;"><u>This product is manufactured from:</u></p> <input type="checkbox"/> A known donor never used to treat this patient <i>(e.g. from a donor registry or related)</i> <i>(Proceed to 'Donor information' section on page 3.)</i>
<input type="checkbox"/> A donor that is already registered as part of a previous treatment <i>(Proceed to 'Planned cellular therapy infusion product(s)' section on page 3.)</i>
<input type="checkbox"/> An unknown donor with no data available <i>(e.g. from a commercial product)</i> <i>(Proceed to 'Planned cellular therapy infusion product(s)' section on page 3.)</i>



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

Treatment Type CT
 Treatment Date ____/____/____ (YYYY/MM/DD)

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

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: _____



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

Treatment Type CT
Treatment Date ____/____/____ (YYYY/MM/DD)

PLANNED CELLULAR INFUSION PRODUCT(S)

Is the planned cell infusion product a commercial product?

- No
 Yes

Identification:

Name of manufacturer:

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

Name of product:

- Abecma
 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*



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

Treatment Type CT
 Treatment Date ____/____/____ (YYYY/MM/DD)

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?

<input type="checkbox"/> No: Reason why the treatment did not take place: <i>Select all reasons that apply</i>	<input type="checkbox"/> Production failure <input type="checkbox"/> Out of specification product rejected by physician <input type="checkbox"/> Disease progression or patient condition worsening <input type="checkbox"/> Patient became ineligible for treatment <input type="checkbox"/> Patient died <input type="checkbox"/> Other reason; specify: _____
---	---

<input type="checkbox"/> Yes: B-cell aplasia at time of cellular therapy? <input type="checkbox"/> Absent <input type="checkbox"/> Present: Percentage of B-cells: _____ % <input type="checkbox"/> Not evaluated



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

Treatment Type CT
 Treatment Date ____/____/____ (YYYY/MM/DD)

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 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



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

Treatment Type CT
Treatment Date ____/____/____ (YYYY/MM/DD)

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

Was the patient treated before this cellular therapy procedure?

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

Yes **complete the "Treatment — non-HCT/CT/GT/IST" form**

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



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

Treatment Type CT
 Treatment Date ____/____/____ (YYYY/MM/DD)

CELLULAR THERAPY INFUSION UNIT(S)

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

- No
- Yes: Number of different cell infusion units that 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: **Date of cryopreservation:** ____/____/____ (YYYY/MM/DD) Unknown
- 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):
- | | |
|---|---|
| <input type="checkbox"/> Viral: | <input type="checkbox"/> Fungal: |
| <input type="checkbox"/> Adenovirus | <input type="checkbox"/> Candida |
| <input type="checkbox"/> BK Virus | <input type="checkbox"/> Aspergillus |
| <input type="checkbox"/> Covid-19 (SARS-CoV-2) | <input type="checkbox"/> Other fungus; specify: _____ |
| <input type="checkbox"/> Cytomegalovirus (CMV) | |
| <input type="checkbox"/> Epstein-Barr virus | |
| <input type="checkbox"/> Human herpes virus 6 | |
| <input type="checkbox"/> Human immunodeficiency virus (HIV) | |
| <input type="checkbox"/> RSV-CTL | |
| <input type="checkbox"/> Other virus; 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:

- | | | |
|----------------------------------|----------------------------------|----------------------------------|
| <input type="checkbox"/> No | <input type="checkbox"/> No | <input type="checkbox"/> No |
| <input type="checkbox"/> Yes | <input type="checkbox"/> Yes | <input type="checkbox"/> Yes |
| <input type="checkbox"/> Unknown | <input type="checkbox"/> Unknown | <input type="checkbox"/> Unknown |



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

Treatment Type CT
Treatment Date ____/____/____ (YYYY/MM/DD)

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: **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

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
<input type="checkbox"/> Alemtuzumab	_____	<input type="checkbox"/> mg/m ² <input type="checkbox"/> mg/kg
<input type="checkbox"/> Anti-Thymocyte Globulin Anti-Lymphocyte Globulin Product name: _____ Origin: <input type="checkbox"/> Rabbit <input type="checkbox"/> Horse <input type="checkbox"/> Other; specify: _____	_____	<input type="checkbox"/> mg/m ² <input type="checkbox"/> mg/kg
<input type="checkbox"/> Bendamustine	_____	<input type="checkbox"/> mg/m ² <input type="checkbox"/> mg/kg
<input type="checkbox"/> Bleomycin	_____	<input type="checkbox"/> mg/m ² <input type="checkbox"/> mg/kg
<input type="checkbox"/> Busulfan Route of administration: <input type="checkbox"/> Oral <input type="checkbox"/> IV <input type="checkbox"/> Both Drug monitoring performed: <input type="checkbox"/> No <input type="checkbox"/> Yes; total AUC: _____ <input type="checkbox"/> mg x hr/L <input type="checkbox"/> micromol x min/L <input type="checkbox"/> mg x min/mL	_____	<input type="checkbox"/> mg/m ² <input type="checkbox"/> mg/kg
<input type="checkbox"/> Carboplatin Drug monitoring performed: <input type="checkbox"/> No <input type="checkbox"/> Yes; total AUC: _____ <input type="checkbox"/> mg x hr/L <input type="checkbox"/> micromol x min/L <input type="checkbox"/> mg x min/mL	_____	<input type="checkbox"/> mg/m ² <input type="checkbox"/> mg/kg
<input type="checkbox"/> Carmustine	_____	<input type="checkbox"/> mg/m ² <input type="checkbox"/> mg/kg
<input type="checkbox"/> Cisplatin	_____	<input type="checkbox"/> mg/m ² <input type="checkbox"/> mg/kg
<input type="checkbox"/> Clofarabine	_____	<input type="checkbox"/> mg/m ² <input type="checkbox"/> mg/kg
Corticosteroids:		
<input type="checkbox"/> Beclometasone	_____	<input type="checkbox"/> mg/m ² <input type="checkbox"/> mg/kg
<input type="checkbox"/> Budesonide	_____	<input type="checkbox"/> mg/m ² <input type="checkbox"/> mg/kg
<input type="checkbox"/> Dexamethasone	_____	<input type="checkbox"/> mg/m ² <input type="checkbox"/> mg/kg
<input type="checkbox"/> Methylprednisolone	_____	<input type="checkbox"/> mg/m ² <input type="checkbox"/> mg/kg
<input type="checkbox"/> Prednisolone	_____	<input type="checkbox"/> mg/m ² <input type="checkbox"/> mg/kg
<input type="checkbox"/> Cyclophosphamide	_____	<input type="checkbox"/> mg/m ² <input type="checkbox"/> 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
<input type="checkbox"/> Cytarabine	_____	<input type="checkbox"/> mg/m ² <input type="checkbox"/> mg/kg
<input type="checkbox"/> Daunorubicin	_____	<input type="checkbox"/> mg/m ² <input type="checkbox"/> mg/kg
<input type="checkbox"/> Doxorubicin	_____	<input type="checkbox"/> mg/m ² <input type="checkbox"/> mg/kg
<input type="checkbox"/> Epirubicin	_____	<input type="checkbox"/> mg/m ² <input type="checkbox"/> mg/kg
<input type="checkbox"/> Etoposide	_____	<input type="checkbox"/> mg/m ² <input type="checkbox"/> mg/kg
<input type="checkbox"/> Fludarabine	_____	<input type="checkbox"/> mg/m ² <input type="checkbox"/> mg/kg
<input type="checkbox"/> Gemtuzumab ozogamicin	_____	<input type="checkbox"/> mg/m ² <input type="checkbox"/> mg/kg
<input type="checkbox"/> Ibritumomab tiuxetan	_____	<input type="checkbox"/> mCi <input type="checkbox"/> MBq
<input type="checkbox"/> Idarubicin	_____	<input type="checkbox"/> mg/m ² <input type="checkbox"/> mg/kg
<input type="checkbox"/> Ifosfamide	_____	<input type="checkbox"/> mg/m ² <input type="checkbox"/> mg/kg
<input type="checkbox"/> Imatinib	_____	<input type="checkbox"/> mg/m ² <input type="checkbox"/> mg/kg
<input type="checkbox"/> Lomustine	_____	<input type="checkbox"/> mg/m ² <input type="checkbox"/> mg/kg
<input type="checkbox"/> Melphalan	_____	<input type="checkbox"/> mg/m ² <input type="checkbox"/> mg/kg
<input type="checkbox"/> Mitoxantrone	_____	<input type="checkbox"/> mg/m ² <input type="checkbox"/> mg/kg
<input type="checkbox"/> Paclitaxel	_____	<input type="checkbox"/> mg/m ² <input type="checkbox"/> mg/kg
<input type="checkbox"/> Anti-CD20 antibodies	_____	<input type="checkbox"/> mg/m ² <input type="checkbox"/> mg/kg
<input type="checkbox"/> Teniposide	_____	<input type="checkbox"/> mg/m ² <input type="checkbox"/> mg/kg
<input type="checkbox"/> Thiotepa	_____	<input type="checkbox"/> mg/m ² <input type="checkbox"/> mg/kg
<input type="checkbox"/> Tositumomab	_____	<input type="checkbox"/> mCi <input type="checkbox"/> MBq
<input type="checkbox"/> Treosulfan	_____	<input type="checkbox"/> mg/m ² <input type="checkbox"/> mg/kg
<input type="checkbox"/> Other; specify*: _____	_____	<input type="checkbox"/> mg/m ² <input type="checkbox"/> mg/kg <input type="checkbox"/> mCi <input type="checkbox"/> MBq

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

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?

- 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)

- Intravenous
 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: _____ Unit (check only one): 10⁶/kg 10⁶ 10⁸/kg 10⁸
(not adjusted for cell viability)

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



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

Treatment Type CT
Treatment Date ____/____/____ (YYYY/MM/DD)

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
- Integrin β 7
- Lewis-Y
- MAGE-A4
- MAGE-A10
- Mesothelin (MSLN)
- MUC16
- NKG2D
- NY-ESO-1
- PRAME
- PSCA
- SSX
- Survivin
- TACI
- WT-1
- Other (specify)