EBMT Registry

Cellular therapy

Day 0

Guide to the completion v2.2 of the EBMT data collection form:

CT_Day0_v2.2

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EBMT Registry

EBMT Clinical Research & Registry Department

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Introduction

Please make sure you have already checked the **Introduction to the EBMT Registry Completion Guidelines** document latest version available under *Manuals and Reference Documents* section on EBMT website.

For patients whose registration needs to be hidden, please enter into the EBMT Registry the embargo end date by following the next steps:

1. Open the patient in the EBMT Registry
2. Enter the patient menu section 'Edit patient details'.
3. Enter the Embargo end date into the dedicated data field.

The patient will become visible for the EBMT studies and analysis automatically after the embargo period ends. More details on embargo functionality in the EBMT Registry can be found in the EBMT Registry User Manual for Data Editors and Data Viewers.

Cellular therapy

The Cellular Therapy (CT) Day 0 form should be filled and submitted online in the EBMT Registry database straight after the CT infusion (including CAR-T). If the CT product was not infused for whatever reason, this form still needs to be submitted to record such failed events. In the context of EBMT Registry, the terms 'advanced cellular therapy', 'cellular therapy' and CT are used as synonyms and represent the same type of treatment.

The CT Day 0 form includes the following main sections:

1. Pre-infusion, that covers details about the planned treatment and the planned cellular therapy product(s).
2. Cellular therapy, that covers the details about the cellular therapy infusion unit(s) and the infusion episode(s).

In addition to the CT Day 0 form, the Status at HCT/CT/GT/IST form should be submitted to fully cover the Day 0 reporting, since it covers patient status, comorbidities and other important topics.

Advanced cellular therapies belong to the group of advanced therapy medicinal products (ATMP) which are defined as medicines for human use that are based on genes, tissues or cells. Advanced cellular therapies can be infused individually, sequentially or in combination with other treatments, including hematopoietic cell transplantation (HCT).

Gene therapy should **not** be reported through this form but with the Autologous Hematopoietic Gene Therapy (GT) Day 0 form.

To understand how many forms need to be filled in, consult the flowchart in Appendix A. Additionally, the following definitions are important:

- **Cellular therapy** is the infusion of one or more units with the same indication as selected on the CT day 0 form and administered after one course of lymphodepletion/preparative regimen. If another course of lymphodepletion/preparative regimen was required for subsequent infusion of one or more cellular therapy infusion units, it should be reported as a new cellular therapy treatment.
- **Cellular therapy infusion unit:** an infusion unit is a product consisting of one or more bags with the same type of manipulated cells, from the same donor and with a unique batch or product number. We consider multiple infusion units if:
    - Different cell types were used for manipulation;
    - Cells from multiple donors were used;
    - Or there are different identification codes for multiple bags/infusion units.
- **Cellular therapy infusion episode:** the infusion of one or more units can be done in one or over different days. If the cellular therapy infusion units were infused over multiple days (usually within 100 days after the first infusion day) but within one cellular therapy treatment, this is regarded as multiple infusion episodes. The dates of subsequent infusions within this cellular therapy treatment, will be recorded in the Cell Infusion Episode(s) section of the corresponding CT Day 0 Form.

Pre-infusion

Cell collection procedure - Apheresis

Date of collection

Report the date when actual cell collection (apheresis) started, independent of whether a preparatory regimen was necessary or not. If there was more than one collection, enter the date of the first collection. If the date is not known, mark the corresponding **Date unknown** checkbox (e.g. allogeneic product from unknown donor).

Number of collections

Report the number of occasions when cells were collected from the donor or patient. Include only those collections that were used for this particular cellular therapy product.

Was the first collection used for production?

Indicate **Yes** if the first collection was used as starting material for production. If the collection was not used for production select **No**. In some cases, more than one collection is needed (e.g. sterility issues).

Was a second, unplanned collection performed?

If the first collection was not used for production, indicate **Yes** if a second, unplanned collection was performed. Select **No** if there was no second, unplanned collection performed.

Was the second collection used for production?

If a second, unplanned collection was performed, but not used for production, answer **No**. If the second collection was used for production of this reported cellular therapy, answer **Yes**, and specify the **date of collection**.

Type of cellular therapy?

Indicate the type of cellular therapy reported:

- **CAR-NK cells** - chimeric antigen receptor natural killer cells;
- **CAR-T cells** - chimeric antigen receptor T-cells;
- **CAR-CIK cells** - chimeric antigen receptor cytokine-induced killer cells;
- **TIL therapy** - Tumor-infiltrating lymphocyte;
- **Other cellular therapy**, please specify.

Note: please do not report cell infusion (e.g. DLI) here. DLI infusions should be reported on the HCT /CT follow-up form Appendix 6 Cell Infusion Sheet.

Indication for planned cellular therapy

Select the indication for the cellular therapy treatment:

- Treatment of a primary disease;
- Other indication; specify it in the text field.

Treatment of a primary disease

Select this option if the treatment was for a primary disease or disorder. Do not select diseases the patient may have had in the past, unless the procedure being reported is meant to treat these diseases.

Indication diagnosis for this cellular therapy

If the CT indication was treatment of a primary disease, enter the main indication diagnosis for this cellular therapy. Make sure the indication diagnosis has been registered in EBMT Registry first, using the relevant indication diagnosis form.

During online data entry the indication diagnosis can be selected from the drop down list of all registered indication diagnoses for this patient.

Reason for cellular therapy

If CT indication was treatment of a primary disease, select the reason for this cellular therapy from the list below. Multiple answers are possible:

- Induction therapy;
- Prevention of disease relapse or progression;
- Rescue from disease relapse or progression;
- Minimal residual disease reduction;
- Refractory disease;
- Other; specify it in the text field.

Other indication

Choose this answer option **Other indication** if the indication for the cellular therapy was other than *Treatment of a primary disease*. Specify the other indication in the text field.

Basic information on the planned cellular therapy

Clinical setting

Choose only one answer option from the given list to describe the clinical setting for the planned CT. In case of doubt, consult with the treating physician.

As per marketing approval/Standard of care/Institutional guidelines

Select this option if the patient is treated with a marketed cellular therapy product, according to the centre's standard of care policies and institutional guidelines. A product is considered to be given in a post-marketing setting when it is approved by EMA. In some countries the product also needs approval for reimbursement by the relevant health authorities. Examples of marketed CT products include: Kymriah, Yescarta, Tecartus, Breyanzi, Abecma, Carvykti.

Hospital exemption

The hospital exemption is for in-house (or possibly in another collaborating center) produced products that have not gone through the rigid research testing process through the cascade of clinical trials and are never intended for an EMA or national license. This is small volume,local application , and individual patient treatments.

Select this option if the patient is treated with cellular therapy manufactured under the hospital exemption rule. The hospital exemption rule is a provision under which some cellular therapy products can be manufactured by academic or commercial facilities, and administered to patients either as orphan treatment where no equivalent commercial product is available or in the context of early clinical trials (preceding Phase 1) designed to provide proof-of-concept information.

By definition, any approved CT product already placed on the market cannot be manufactured in the context of the hospital exemption.

Compassionate use/Accelerated access

Compassionate use is normally a product that is in a clinical trials on one indication, but the trials are not finished or have not been analysed and submitted for an approval by the regulatory authorities. A not uncommon scenario is that a product has been approved in the USA but not yet in Europe. It can also be for a product approved for one indication but is used for another in countries where physicians don´t have the right to prescribe a drug off label.
Accelerated access is a more diffuse term but can be for example , refer to a national agreement to provide the drug after it has been approved but before its commercially available.

Select this option if the patient is treated under compassionate use. These are regulatory provisions under which a cellular product can be administered to a specific patient outside of a clinical trial, upon request and approval from regulatory agencies. Regulations may vary from country to country and some countries may not provide such opportunities. In case of doubt, please check with a clinician in the treating centre.

Investigational drug product (IDP)/Clinical trial

Select this option if the patient is enrolled in a clinical trial, whether academic-sponsored or industry-sponsored. If the product was administered in a clinical trial setting or as an investigational product, provide further details in the subquestions.

Phase

Indicate the phase of the IDP or clinical trial by marking if it is:

- 1
- 1/2
- 2
- 2/3
- 3

Blind trial

Indicate if this is a blind trial. This is a trial where neither the treating doctor nor the patient knows which of the treatments offered in the trial is being given (e.g. placebo vs active substance).

Randomised trial

Indicate if the treatment is allocated randomly to the trial subjects.

EudraCT number

Indicate the EudraCT number given to the trial when registered with the European Clinical Trials Database.

USA NCT number

Indicate the clinical trial number (NCT number). If the number is not clearly documented, it can be found using the 'Find a Study' feature on www.clinicaltrials.gov.

UMIN CT number

Japanese clinical trials number, only applicable to trials (also) conducted in Japan.

Cell origin

Indicate the origin of the cells infused by selecting if it is:

- Autologous- to mark that the cells were collected from the same patient.
- Allogeneic - to mark that cells were collected from another person (donor).

This product is manufactured from

If the origin of the cells is allogeneic, also specify if the product for infusion was manufactured from:

- **A known donor never used to treat this patient** (e.g. from a donor registry or related donor). This option should be selected if it is the first time that the cells of this donor are infused to this patient and all the information about the donor is available. If this answer option is chosen, proceed to the Donor information section to provide more details on the donor.
- **A donor that is already registered as part of a previous treatment**. Select this option if this donor is already registered as part of previous allogeneic HCT or CT and proceed to **Planned cellular therapy infusion product(s)** section.
- **An unknown donor with no data available** (e.g. from a commercial product). Select this option if there is no information available about the donor and proceed to the **Planned cellular therapy infusion product(s)** section.

Donor Information

Complete this section only if the cell source was allogeneic and if it is a known donor that was never used to treat this patient. If this donor was used to treat this patient in the past and was registered in a previous allogeneic HCT or CT, this section can be left blank.

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

Centres should download and fill in the Donor Consent Form in the appropriate language for each of their donors, as the law requires that the donor consents to the data being transferred to the EBMT.

EBMT shall provide the Informed Consent Form to the participating sites for data reporting to EBMT. The reporting centre shall be responsible for ensuring that the Informed Consent Form is in compliance with applicable laws and meets the minimum requirements as indicated by the Informed Consent templates on this web page. No centre is exempt from obtaining donor consent before submitting data to the EBMT.

Indicate if the donor consented to share the data with the EBMT registry by selecting **Yes** or **No**. If you do not know the status of consent, or the donor did not want to share their data, select **No**.

If the donor did not consent or consent is unknown and no is elected, only data items marked with an asterisk (*) can be filled out.

Date of birth

If the donor (or their legal guarding) have signed the informed consent form and consent donor's data being submitted and processed by the EBMT Registry, fill in the donor's exact full date of birth (year, month and day).

In case providing the full date of birth is not possible, provide the donor age in the next question.

*Age at time of donation

Answer this question only if the donor exact full date of birth cannot be reported.

If the full date of birth cannot be reported (due to legislation or other regulations), report the age of the donor at the time of donation in years. The full number of years should be reported, e.g. if the donor is 35 years and 11 months old at the time of donation, this field should be filled in with 35.

*Age in months (if the donor was younger than 2 years

Answer this question only if the date of birth cannot be reported and the donor was younger than 2 years at the moment of donation. This field is mandatory even for non-consenting donors.

Report here the full number of months, e.g. if the donor was 11 months and 20 days old at time of donation, report 11 months.

*Sex (at birth)

Indicate if the donor's sex at birth is **Male** or **Female**.

Donor Identification

If the donor (or their legal guarding) have signed the informed consent form and consent donor's data being submitted and processed by the EBMT Registry, specify the following donor-related details:

Donor ID given by the treating centre (mandatory)

Indicate the donor ID that was assigned to the donor by the treating centre. The word mandatory is used here to call data entry manager's attention as this field is extremely important and should be filled in for all consenting donors.

Global registration identifier for donors (GRID)

If available, fill in the 19-character global registration identifier for donors (GRID) that was assigned to the donor. More information on the GRID can be found here: https://wmda.info/professionals/optimising-search-match-connect/why-global-identifier/.

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

Fill in the Issuing Organisation Number (ION) of the donor registry or cord blood bank. If the code is unknown, it can be found using https://share.wmda.info/display/WMDAREG/Database. The word mandatory is used here to call data entry manager's attention as this field is extremely important and should be filled in for all consenting donors.

Eurocord code for the Cord Blood Bank (if applicable)

If cord blood was used for cellular therapy, fill in the Eurocord code.

Name of Donor Registry or Cord Blood Bank

Enter the name of the donor registry or cord blood bank, and full name of donor centre (if applicable).

Donor ID given by the Donor Registry or Cord Blood Bank

Enter the identification code that was assigned to the donor by the donor registry or cord blood bank (specified above in the field *Name of Donor Registry or Cord Blood Bank*).

Patient ID given by the Donor Registry or Cord Blood Bank

Enter the identification code that was assigned to the patient by the donor registry or cord blood bank (specified above in the field *Name of Donor Registry or Cord Blood Bank*).

Planned Cellular Infusion Product(s)

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

Answer **No** if planned cellular infusion product will consist of one infusion unit.

Answer **Yes** if planned cellular infusion product will consist of more than one infusion unit and report the **Number of infusion units**.

Mark **Unknown** if there is no information yet on the number of infusion units in the cellular infusion product. Please return and update this field once information is known.

The definition of **Cellular therapy infusion unit** can be found in the beginning of this document.

Tissue source

Select all the tissue(s) from which the cells were collected:

- Bone marrow;
- Peripheral blood;
- Cord blood;
- Tumour;
- Other; specify the tissue source in the textbox.

Is the planned cell infusion product a commercial product?

If the product is manufactured by a pharmaceutical company after market authorization was obtained, the product is considered to be a commercial product and it should be answered **Yes**. If the product was made by the hospital or administered before market authorization, the product is not commercial and this question should be answered **No**.

Identification

Report below the Identification details of the planned cellular infusion product.

Name of manufacturer

Select the name or type of the facility which manufactured the infusion product (pharmaceutical or biotech company, cell processing laboratory or another site) from the following options:

- Autolus;
- Celgene/Bristol-Myers Squibb;
- Celyad;
- GlaxoSmithKline (GSK);
- Johnson & Johnson;
- Kite Gilead;
- Miltenyi;
- Novartis;
- Local hospital or university.

If no answer from the list is applicable, select **Other** and specify the name in the text box.

Name of the product

Select the CT product name out of the following options:

- Abecma (brand name for Idecabtagene vicleucel);
- Breyanzi (brand name for Lisocabtagene maraleucel);
- Carvykti (brand name for Ciltacabtagene autoleucel);
- Kymriah (brand name for Tisagenlecleucel);
- Tecartus (brand name for Brexucabtagene autoleucel);
- Yescarta (brand name for Axicabtagene ciloleucel).

If the product name is not on the list, select **Other** and specify the name in the text field. Select **No product name available** if the product does not have a name.

This is the end of the CT Pre-infusion section.

Please proceed with completing the Cellular Therapy section to complete the CT Day 0 report.

Cellular therapy

Date of (planned) cell infusion

Report the date of the first cell infusion, or the planned date of the infusion if the infusion did not take place.

Important note: this date is considered as the date of cellular therapy treatment in the patient timeline and should be entered while creating (adding) a Cellular therapy treatment event in the EBMT Registry online application. Since the date is added at event creation, during data entry this data field in the event form will already have the date pre-populated. It can be edited, if needed.

Centre where infusion took place (CIC)

Enter the Centre Identification Code (CIC) of the centre where infusion took place. If the product was not infused, report the centre where the infusion was planned to take place.

Every centre that is submitting data to the EBMT receives a CIC, which is populated automatically in EBMT Registry when a user selects the corresponding centre as a context during data entry.

Patient UPN for this treatment

Report the hospital or unit's UPN (unique patient number) for the patient at this treatment.

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

Select the team or unit where the treatment took place. Multiple options can be selected. If **Other; specify** is selected, you must give further information on the name of the team or unit where the treatment took place. For example, your team or unit name may be derived from your geographical location (e.g. south unit or north unit).

Unit number (not Other team or unit; specify)

Unit numbers have been assigned by national registries to different teams submitting data under the same CIC. This will allow data in filtered searches and exports to be team specific.

If your centre does not have separate teams with assigned unit numbers select **Not applicable**.

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

Indicate if the cells that were collected for manufacturing were infused to the patient during this treatment/procedure by answering **Yes** or **No**.

Reason why the treatment did not take place

If the product was not infused, select all the appropriate reason(s):

- **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 the reason in the text box.

If no infusion took place, the data entry for this form is stopped here. The status at treatment form needs to be completed, using the date of planned infusion as treatment date. Follow-up forms need to be completed as per the follow-up schedule.

Please provide the absolute B-cell count

If the cellular therapy product was infused, report here the most recent absolute B-cell count obtained prior to the start of lymphodepleting therapy. Laboratory values collected on the first day of lymphodepleting therapy may also be reported, as long as the blood sample was taken before any lymphodepleting therapy was administered. Specify the unit, by marking if it is $x10^9$/L or $x10^6$/L (cells/µL).

If the absolute B-cell count is not known, select **unknown**. Select **Not evaluated** if the cell count was not performed.

Please provide the absolute total immune cell count

If the cellular therapy product was infused, report here the most recent absolute total immune cell count (lymphocyte count) obtained prior to the start of lymphodepleting therapy. Laboratory values collected on the first day of lymphodepleting therapy may also be reported, as long as the blood sample was taken before any lymphodepleting therapy was administered. Specify the unit, by marking if it is $x10^9$/L or $x10^6$/L (cells/µL). If the absolute total immune cell count is not known, select **unknown**. Select **Not evaluated** if the cell count was not performed.

Therapy & cell infusions

Chronological number of cellular therapy treatment for this patient

Indicate the chronological (sequential) number of this cellular therapy counting all CTs the patient had. Only infused treatments should be included in the chronological treatment number; planned but not

infused CTs should not be counted. HCTs or DLIs should not be counted when defining the chronological number of cellular therapy.

Note: if the infusions are given with a lymphodepletion / preoperative regimen between them, or if the indication for the cellular therapy has changed, the therapy should be considered as a new treatment (new CT).

If > 1

Complete the following sub questions only if this is the second or a subsequent cellular therapy for this patient and the previous cellular treatments cannot be registered (e.g. if it took place in a centre that does not report in EBMT Registry).

Important note: If > 1 submit an cellular therapy follow-up form (use the latest assessment date for such follow-up) before proceeding and reporting this cellular therapy; this is so relapse data and other events between transplants/cellular therapies can be captured.

Same product as for the previous cellular therapy?

Select **Yes** to mark that the same cellular therapy infusion product is being used for the current cellular therapy as for the previous CT treatment. Otherwise, answer **No** to mark that there were used different cellular therapy infusion products.

Date of the last cellular therapy before this one

Report the start date of the last cellular therapy before the one that is currently being reported with this CT day 0 form.

Type of the last cellular therapy before this one:

Select if the type of the last cellular therapy before this one was **Autologous** or **Allogeneic**.

Was the same donor used both for prior and current cellular therapy?

If answered Allogeneic to the previous question, specify if the same donor has been used for the previous and current cellular therapies.

Was the last cellular therapy performed at another institution?

Report if the patient has received the last cellular therapy in another institution. If Yes, fill in the subsequent questions:

CIC (if known)

if the patient has received the last cellular therapy in another institution, indicate the other centre's CIC (if known).

Name of institution

if the patient has received the last cellular therapy in another institution, provide the name of the institution where the last cellular therapy before this one took place.

City

if the patient has received the last cellular therapy in another institution, provide the city of the institution where the last cellular therapy before this one took place.

Did the patient receive a previous HCT?

Answer **No** if the patient did not receive an HCT in the past.

Answer **Yes** if the patient received an HCT in the past and answer the subsequent questions:

Date of the last HCT before this CT

Report the date of the last HCT before this CT.

Type of the last HCT before this CT

Report the type of the latest HCT the patient received by marking if it is **Autologous** or **Allogeneic.**

For same indication as the cellular therapy?

Answer **No** if the indication for the last HCT was different from the indication for the cellular therapy.

Answer **Yes** to mark that the indication for the cellular therapy is the same as it was for the past HCT.

Previous therapies including bridging

Previous therapies including bridging before transplant or cellular therapy should be reported through the *Treatment - non-HCT/CT/GT/IST* form that is available under *Patient Registry Data Collection Forms* section on EBMT website, or under *Treatment* in the EBMT Registry. The form shall be used to report not only treatments before HCT, but also treatments that are given between HCT and cellular therapies.

Previous therapies refer to any treatment that is given for the indication for the cellular therapy. Only therapies given for the diagnosis that is the main indication for cellular therapy should be reported.

Was the patient treated before this cellular therapy procedure?

If the patient was not treated, select **No** and proceed to the next section of the form **Cellular therapy infusion unit(s)**.

If the patient has been treated for the diagnosis that is the main indication for this cellular therapy, select **Yes** and complete the *Treatment non-HCT/CT/GT/IST* form in addition to the current form.

Mark as **Unknown** if there is no information available about previous therapies of the patient and proceed to the next section of the form **Cellular therapy infusion unit(s).**

Cellular Therapy Infusion Unit(s)

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

Answer **No** if the patient had only one cell infusion unit during this cellular therapy treatment.

If more than one cell infusion unit was infused, answer **Yes** here and specify the **Number of different cell infusion units** that were part of this treatment. This number will correspond to the number of copies of the **Cellular therapy infusion unit description** section that needs to be filled in and submitted.

Cellular Therapy Infusion Unit(s): Description

If more than one cell infusion unit was infused, while entering data online in EBMT Registry please click on *+ Add Cellular therapy infusion unit(s) - Description* for each additional cell infusion unit administered during this cellular therapy.

If the CT product was not infused, proceed to the *Survival status* section.

Unique ID of the product

Enter here a unique identification code of the product, if it is available (e.g. serial number).

Batch number

Report the batch number of the cell infusion unit, if applicable.

Identification of the cell infusion unit given by the centre

Report the cell infusion unit identification that was assigned to the unit by the treating centre. This information is mandatory if more than one cell infusion unit has been used in the same CT treatment. If there is only one cell infusion unit with no assigned identification number, enter '1'.

Was the infused cellular product consistent with the specifications?

Answer **Yes** if the product was consistent with the specifications.

Answer **No** if the product was not consistent with the specifications and specify the **difference from specifications** in the text field. Products that are out of specification (OOS) did not meet the acceptance criteria set by the manufacturer. A product that is out of specification, can be used under the responsibility of the treating physician.

Answer **Unknown** if it is not known if the infused cellular product is consistent with the specifications.

Consult the physician who approved the product for infusion in case of doubt.

Was the cellular therapy product cryopreserved prior to infusion?

Select **Yes** if the cellular product has been cryopreserved (frozen at very low temperatures) prior to infusion at any time point between collection and infusion and provide the **date of the cryopreservation** or mark the date as **unknown**. If this was not the case, select **No**.

Answer **Unknown** if it is not known.

Cellular Therapy Infusion Unit(s): Manipulation

Complete this section only for non-commercial CT products. If more than one cell infusion unit was administered, please repeat and fill-in this section for each cell infusion unit.

If earlier answered **Yes** to the question *Pre-infusion - Is the planned cell infusion product a commercial product?* skip this section and continue with the Preparative regimen section.

Identification of the cell infusion unit (given by the centre)

Report the cell infusion unit identification number that was assigned to the unit (you are going to provide details about) by the treating centre. This information is mandatory if more than one cell infusion unit has been used in the same CT treatment. If there is only one cell infusion unit with no assigned identification number, enter '1'.

Manipulation

Processing/Manufacturing facility

Indicate where the cell manipulation took place by choosing either:

- **Onsite, by local cell processing facility**, or
- **Offsite, by a non-commercial facility.**

Gene manipulation

Select **No** if the product was not genetically manipulated. If the product was genetically manipulated, select **Yes** and continue with the subsequent questions to specify the type of gene manipulation used in subquestions. Gene manipulation is for example applied in CAR-T cells.

Gene transfer

Answer **Yes** if gene transfer was used for gene manipulation and specify details in subquestions..

Gene transfer is a procedure that allows the transfer of a gene into a cell or any other organism.

Vector

If gene transfer was used, indicate the vector by choosing one of the following answer options:

- **Retroviral vector;**
- **Lentiviral vector**;
- **Other vector**; specify it in the text field. E.g. non-integrating vectors, including RNA electroporation, should be listed here.

Transgene

If genes were inserted, select the transgene from the following options and specify all targets:

- **CAR (chimeric antigen receptor)**;
    - specify all target antigens in the text field. See appendix 1 of the CT Day 0 form for a list of target antigens (e.g. CD19, CD20, BCMA etc.).
- **TCR (T-cell receptor)**;
    - specify all targets in the text field; and
    - specify HLA element.
- **Suicide gene**: cells underwent manipulation to have cell suicide inducing transgenes inserted into the product.
    - In addition, specify the suicide gene in the text field.
- **Other**: select this option if other transgene than listed above was used and specify it in the text field.

Other

Indicate if other than Gene transfer genetic manipulation was used by answering **Yes** or **No**. If the answer is **Yes**, specify it in the text field.

Manipulation aims

Recognition of a specific target/antigen

Answer **Yes** and provide further details in sub questions if the aim of the manipulation was the recognition of a specific target/antigen or binding to a specific target. Otherwise answer **No**.

Type

If answered Yes to the previous question, mark all applicable type(s) of targets that apply to the product:

- **Viral**: specify also the type of virus recognised:
  - 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 it in the text field.
- **Fungal**: specify also the type, by choosing one of the following options:
  - Candida
  - Aspergillus
  - Other fungus; specify it in the text field.
- **Tumour/cancer antigen(s);** specify all in the text field.
- **Other target**: select this answer option and specify the other in the text field If the target was other than viral, fungal or tumour/cancer antigen.

Cell types administered

Select all the cell types that were infused to the patient after apheresis by marking all the answer options that apply:

- CD3+ lymphocytes
- CD4+ lymphocytes
- CD8+ lymphocytes
- CD34+

- Dendritic cells
- Gamma-Delta cells
- Mesenchymal cells
- NK cells
- Regulatory T-cells
- Other; specify it in the text field.

Expansion

Indicate if expansion was performed or not. This is a procedure meant to increase the number of collected cells in the laboratory before infusion. Mark as **Unknown** if there is no information on it.

Activation

Indicate if activation was used or not. This procedure aims to induce new biological activity(ies) on treated cells. Mark as **Unknown** if there is no information on it.

Induced differentiation

Indicate if the cells were induced to differentiate into different cell types by contact with other cells or stimulation by differentiation inducing factors. Mark as **Unknown** if there is no information on it.

Preparative regimen

Do not include lines of therapy given for disease treatment, bridging therapy or maintenance, these should be reported through *Treatment - non-HCT/CT/GT/IST* form that is available under *Patient Registry Data Collection Forms* section on EBMT website.

Preparative conditioning/lymphodepletion regimen given?

Indicate if the patient received preparative conditioning or lymphodepleting chemotherapy prior to the infusion of the cellular product or not.

In the event of the cellular therapy infusion unit being infused at the same time as an HCT taking place, the HCT conditioning/preparative treatment is not to be reported here. In these cases, the correct answer to this question would be **No**.

If the patient received a lymphodepleting treatment, answer **Yes**.

Patients with Primary Immunodeficiency Disorders receive cellular therapy without preparative (conditioning) regimen and thus the answer should be **No** for such patients.

Drugs given?

Answer **No** if the patient did not receive any drugs as a preparation for this cellular therapy. Mark as **Unknown** if there is no information available as to the drugs received by the patient in the preparation of this CT.

Answer **Yes** if any lymphodepleting drugs were given to the patient in preparation for this CT. This includes any active agent, including chemotherapy, monoclonal antibody, polyclonal antibody, serotherapy, etc. Provide more details on the drugs in the next questions.

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

Answer **No** if the patient did not receive any prophylactic drugs for CRS/ICANS. If the patient received any prophylactic drugs for the prevention of CRS and/or ICANS, answer **Yes.**

Drugs given?

If prophylactic drugs are given, check all that apply from the list of the drugs given.

- **Corticosteroids;**
- **Anakinra;**
- **Tocilizumab;**
- **Other prophylactic drug, specify;**

If another drug is given, select **Other prophylactic drug** and specify the therapy.

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 4 days, total dose to report is 16mg/kg. Report dosages and units only for individual drugs.

Chemotherapy

Indicate the chemotherapy used as a preparative regimen for this cellular therapy by selecting from given options, specify extra details if asked:

- **Alemtuzumab**
- **Anti-Thymocyte Globulin / Anti-Lymphocyte Globulin** - for this chemotherapy specify also:
    - **Product name;**
    - **Origin** - by marking if it is **Rabbit, Horse** or **Other** origin. For Other origin, specify it in the text box.
- **Bendamustine;**

- **Bleomycin;**
- **Busulfan** - specify also:
    - **Route of administration**, by marking if it is **Oral, IV** or **Both**.
    - **Drug monitoring performed** - indicate if drug monitoring was performed (answer **Yes**) or not (answer **No**). Busulfan drug monitoring is done during the conditioning treatment with the aim to adjust the dose; If performed, specify the **total AUC** (measure of total systemic exposure to the drug) and the **AUC units** used (mg x hr/L, or micromole x min/L, or mg x min/mL). AUC means area under the curve and is a common way of assessing drug levels.
- **Carboplatin**:
    - **Drug monitoring performed** - indicate if drug monitoring was performed (answer **Yes**) or not (answer **No**). If performed, specify the **total AUC** (measure of total systemic exposure to the drug) and the **AUC units** used (mg x hr/L, or micromole x min/L, or mg x min/mL).
- **Carmustine;**
- **Cisplatin;**
- **Clofarabine;**
- **Beclometasone;**
- **Budesonide;**
- **Dexamethasone;**
- **Methylprednisolone;**
- **Prednisolone;**
- **Cyclophosphamide;**
- **Cytarabine;**
- **Daunorubicin;**
- **Doxorubicin;**
- **Epirubicin;**
- **Etoposide;**
- **Fludarabine;**
- **Gemtuzumab ozogamicin;**
- **Ibritumomab tiuxetan;**
- **Idarubicin;**
- **Ifosfamide;**
- **Imatinib;**
- **Lomustine;**

- **Melphalan;**
- **Mitoxantrone;**
- **Paclitaxel;**
- **Anti-CD20 antibodies (Rituximab);**
- **Teniposide;**
- **Thiotepa;**
- **Tositumomab;**
- **Treosulfan**.

If other chemotherapy was used that is not listed above, select **Other** answer option and specify it in the text field.

Consult the LIST OF CHEMOTHERAPY DRUGS/AGENTS AND REGIMENS on the EBMT website for drugs/regimens names.

While submitting online, select the drugs/regimens from the dropdown list.

Dose

For each selected chemotherapy, report the total prescribed cumulative dose as per protocol. Do not provide daily or weekly doses, but the final cumulative dose received by the time the regimen has ended. Multiply daily dose by the number of days; e.g. for Busulfan given 4 mg/kg daily for 4 days, total dose to report is 16 mg/kg.)

Units

Specify the units of the total prescribed cumulative dose, by marking if it is **mg/m^2** or **mg/kg**. In case using Other chemotherapy answer option, it is possible to select from **mg/m^2**, **mg/kg, mCi, mg/kg** or **MBq**.

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

Indicate if the chemotherapy dose of the preparative regimen for the current cellular therapy has been adjusted to organ dysfunction and/or body weight.

Reason(s) for dose adjustment

If the chemotherapy dose was adjusted, indicate the reason(s) for dose adjustment:

Renal impairment;

Hepatic impairment;

Overweight/obesity;

Underweight;

Other reason for adjustment, specify.

Total body irradiation (TBI)

Indicate if a patient received total body irradiation as a part of preparative regimen for the current cellular therapy. Select **No** if the patient did not receive total body irradiation, select **Yes** if the patient received total body irradiation and continue with the subsequent questions.

Total prescribed radiation dose as per protocol

If TBI was administered, specify the total prescribed radiation dose as per protocol in Gy.

Number of fractions

If TBI was administered, specify the number of fractions.

Number of radiation days

If TBI was administered, specify the number of radiation days.

Cell Infusion Episode(s)

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

If multiple cell infusions took place, answer **Yes** here and indicate the **Number of cell infusion episodes** during this treatment/procedure.

If two different cell infusion units are infused simultaneously or within a short interval (within hours), it is considered one cell infusion episode. If the same cell infusion unit is infused on two different days, it is considered two cell infusion episodes.

Cell Infusion Episode(s): Description

Add Cell Infusion Episode(s) Description and fill in this section for each cell infusion unit that was administered during each cell infusion episode. Complete it for each additional cell infusion episode by clicking on *+ Add Cell Infusion Episode(s) - Description* while online data entry in the EBMT Registry.

Date of cell infusion episode

Report the date of the cellular therapy infusion episode that is part of the cellular therapy.

For patients receiving cellular therapy for a complication of HCT, for the first cell infusion episode please put the date of the first cellular therapy treatment, not the date of HCT.

Route of infusion

Indicate how the cells were infused to the patient by marking if it is:

- **Intravenous**: refers to an infusion into the veins; examples include infusion via central line or via catheter.
- **Intrathecal**: refers to an infusion within the cerebrospinal fluid at any level of the cerebrospinal axis, including injection into the cerebral ventricles.
- **Intratumour injection** (intratumoral injection): refers to a direct injection into the tumour.

If the route of infusion is not listed, select **Other route** and specify the infusion route.

Did the patient receive concomitant therapy?

Concomitant therapy is any therapy given to enhance the function of the cellular therapy, and can be given simultaneously to the cellular therapy or after the cellular therapy episode was finished. In cases where a recipient has both HCT and cellular therapy, this question applies to the cellular therapy infusion, not the HCT. Reasons for concomitant therapy could be:

- cytokine Support: administered to promote proliferation, survival, or activation of infused cells;
- immune checkpoint blockade: used to increase anti-tumor function of cellular therapy;
- targeted / disease-directed agents: sometimes continued or added to synergize with cellular therapy.

Answer **Yes** if the patient received concomitant therapies in addition to the reported cellular therapy, and specify the drugs given as concomitant therapy in the text field. Answer **No** if there was no concomitant therapy given besides this cellular therapy.

Note: do not report therapy given to prevent toxicities, such as prophylaxis for CRS or ICANS.

Treatment given

If the patient received concomitant therapies in addition to the reported cellular therapy, indicate if concomitant therapy was 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 unit given by the centre as described in the *Cell Infusion Unit* section

If more than one unit was used, indicate the identification of the cell infusion unit given by the centre as described above. This item is mandatory if more than one cell infusion unit was used. If there is only one cell infusion unit with no assigned identification number, enter '1'.

Is the exact number of cells infused available?

Indicate if the exact number of infused cells is available by answering **Yes** or **No**.

If more than one cell infusion unit was administered, report this question and sub questions for each cell infusion unit.

Number of cells

If the exact number of infused cells is available, specify the number of cells. Enter the value that is not adjusted for cell viability.

Unit

If the number of cells infused is known, select the units for the number of cells that were infused and reported in the question above by selecting one of the following options:

- 10^6/kg;
- 10^6;
- 10^8/kg;
- 10^8.

Cell viability

Report the **percentage** of viable cells for the corresponding administered cell infusion unit.

Appendix A

Data entry flowchart