Document Type	|	Form
Index Number	|	Registry 96
Version Number	|	1.0
Title	|	Cellular Therapy Day 0
Author	|	Annelot van Amerongen
Authorised By	|	Annelot van Amerongen
Authorised On	|	22-Aug-2023
Release Date:		22-Aug-2023

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:

- ☐ Treatment of primary diagnosis
- ☐ 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
  - ☐ Prevention/Prophylaxis of 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)

☐ 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: _____ ☐ Tick here if this registration should be hidden. Date by which the registration can be made available for research: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*

Cell origin:

☐ Autologous *(Proceed to 'Planned cellular therapy infusion product(s)' section on page 3)*

☐ 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 3.)

☐ An unknown donor with no data available *(e.g. from a commercial product)*
(Proceed to 'Planned cellular therapy infusion product(s)' section on page 3.)

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 1 year:
***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

☐ Umbilical cord blood

☐ Tumour

☐ Other; specify: _____

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

CELLULAR THERAPY

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

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

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: **B-cell aplasia at time of cellular therapy?**

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

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 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: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*
Type: ☐ Autologous
☐ Allogeneic
For same indication as the cellular therapy? ☐ No ☐ Yes

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

Do not include preparative/lymphodepleting regimen. Copy and fill-in the whole 'Previous therapies incl. bridging' section for each line of treatment.

Was the patient treated before this cellular therapy procedure?

☐ No (*proceed to 'Cellular therapy infusion unit(s)' on page 10)*

☐ Yes

☐ Unknown (*proceed to 'Cellular therapy infusion unit(s)' on page 10)*

Has the information requested in this section been submitted with a previous HCT/cellular therapy registration for this patient? *(Please note that not only treatments before HCT/cellular therapy should be reported, but also treatments that are given between HCT and cellular therapies)*

☐ No

☐ Yes (*proceed to 'Cellular therapy infusion unit(s)' on page 10)*

Chemotherapy/Drugs given?

☐ No

☐ Yes *(report in the table at page 8 and continue with questions below)*

☐ Unknown

Radiotherapy:

☐ No

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

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

☐ Unknown

Other treatment:

☐ No

☐ Yes; specify: _____

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

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

☐ Unknown

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

Do not include preparative/lymphodepleting regimen.

Line of treatment	Drug(s)/ Regimen(s)*:	Date started: *(YYYY/MM/DD)*	Date ended: *(YYYY/MM/DD)*	Ongoing:
1		_ _ _ _/ _ _/ _ _	_ _ _ _/ _ _/ _ _	☐
2		_ _ _ _/ _ _/ _ _	_ _ _ _/ _ _/ _ _	☐
3		_ _ _ _/ _ _/ _ _	_ _ _ _/ _ _/ _ _	☐
4		_ _ _ _/ _ _/ _ _	_ _ _ _/ _ _/ _ _	☐
5		_ _ _ _/ _ _/ _ _	_ _ _ _/ _ _/ _ _	☐
6		_ _ _ _/ _ _/ _ _	_ _ _ _/ _ _/ _ _	☐
7		_ _ _ _/ _ _/ _ _	_ _ _ _/ _ _/ _ _	☐
8		_ _ _ _/ _ _/ _ _	_ _ _ _/ _ _/ _ _	☐
9		_ _ _ _/ _ _/ _ _	_ _ _ _/ _ _/ _ _	☐

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

If there were more treatment lines, add more copies of this page.

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

Do not include preparative/lymphodepleting regimen. Copy and fill-in the whole 'Previous therapies incl. bridging' section for each line of treatment.

Response to this line of treatment:
(complete only the section that is relevant to the indication 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
- ☐ Transfusions required

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
- ☐ Improved
- ☐ Worse
- ☐ No response
- ☐ Not evaluable

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

☐ 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: _____

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 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+
☐ Regulatory T-cells
☐ Mesenchymal cells
☐ Dendritic cells
☐ Gamma-Delta cells
☐ NK cells
☐ Mononuclear cells (DLI)
☐ 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 sections.

Preparative (conditioning) regimen given?

☐ No *(Primary Immunodeficiency Disorders only)*

☐ Yes

Drugs given? *(any active agent, including chemotherapy, monoclonal antibody, polyclonal antibody, serotherapy, etc.)*

☐ No

☐ Yes (provide details in the table on pages 14-15)

☐ 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.)

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	Units
☐ 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
☐ Rituximab	_____	☐ 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

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)

☐ 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.

SURVIVAL STATUS

Survival status:

☐ Alive

☐ Dead: **Date of death:** _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*

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

☐ Relapse or progression/persistent disease	
☐ Secondary malignancy	
☐ Cellular therapy-related	**Select treatment related cause:** ☐ Graft versus Host Disease ☐ Non-infectious complication ☐ Infectious complication: *(select all that apply)* ☐ Bacterial infection ☐ Viral infection ☐ Fungal infection ☐ Parasitic infection ☐ Infection with unknown pathogen
☐ HCT-related	
☐ Unknown	
☐ Other; specify: _____	

END OF CELLULAR THERAPY SECTION

END OF THE CELLULAR THERAPY DAY 0 REPORT

proceed to DISEASE STATUS AT HCT/CT/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)