CIC: ..... Hospital UPN: ..... Date of the first cell therapy infusion..... .... - .... - .....
(Do not write here the date of any HSCT) *yyyy* *mm* *dd*

Cell Therapy - MED - A

SECOND REPORT – 100 DAYS AFTER CELL THERAPY

CENTRE IDENTIFICATION

EBMT Code (CIC): .... Hospital: ..... Unit: .....

Contact person..... e-mail: .....

PATIENT DATA

Date of this Report: ..... - ..... - .....
yyyy *mm* *dd*

EBMT Registry Unique Identification Code (UIC) .....

Hospital Unique <u>Patient</u> Number or Code (UPN): .....

Initials: ....._..... (first name(s) _family name(s))

Date of Birth: ..... - ..... - .....
yyyy *mm* dd

RESPONSE

TO BE ANSWERED ONLY WHEN THE INDICATION WAS THE TREATMENT OF A PRIMARY DISEASE INCLUDING INFECTIONS

Best clinical/biological response after the entire cell therapy treatment

- ☐ Complete remission / Normalisation of organ function / No infection present
- ☐ Partial remission / Partial or non normalisation of organ function
- ☐ No response
- ☐ Disease progression or worsening of organ function
- ☐ Not evaluated

Date response evaluated: ..... - ..... - ..... …..
yyyy *mm* *dd*

TO BE ANSWERED ONLY WHEN THE INDICATION WAS THE TREATMENT OF COMPLICATIONS DERIVED FROM A PREVIOUS TRANSPLANT

Complication	**Response**				
GvHD	☐ Resolved	☐ Improved	☐ No response	☐ Progressed	☐ Not evaluated
Graft failure	☐ Resolved	☐ Improved	☐ No response	☐ Progressed	☐ Not evaluated
Immune reconstitution	☐ Resolved	☐ Improved	☐ No response	☐ Progressed	☐ Not evaluated

Date response evaluated: ..... - ..... - ..... …..
yyyy *mm* *dd*

LAST CONTACT DATE FOR 100 DAY ASSESSMENT

*If patient died **<u>before</u>** the 100 days had elapsed, enter the date of death, otherwise enter Date of Cell therapy + 100 DAYS approximately.*

Day 100 assessment : ..... - ..... - ..... ☐ Not applicable
yyyy *mm* *dd*

Date of death: ..... - ..... - ..... ☐ Not applicable
yyyy *mm* *dd*

Toxicity during the first 100 days after the cell therapy was initiated

DO NOT INCLUDE INFORMATION ON COMPLICATIONS THAT WERE RESOLVED BEFORE THE CELL THERAPY THIS FORM REFERS TO

Acute Graft Versus Host Disease *(Cells of allogeneic origin only)*
Maximum Grade:
☐ 0 (none) ☐ I ☐ II ☐ III ☐ IV ☐ Present but grade unknown ☐ Not evaluated

Date of onset .... - .... - ....
yyyy *mm* *dd*

Stage:

Skin	☐ 0 (none)	☐ 1	☐ 2	☐ 3	☐ 4
Liver	☐ 0 (none)	☐ 1	☐ 2	☐ 3	☐ 4
Lower GI tract	☐ 0 (none)	☐ 1	☐ 2	☐ 3	☐ 4
Upper GI tract	☐ 0 (none)	☐ 1			
Other site affected	☐ No	☐ Yes			

Related to Cell Therapy ☐ No ☐ Yes
Resolved? ☐ No ☐ Yes

Chronic Graft Versus Host Disease present
(allogeneic treatment only)

☐ No *(never)*
☐ Yes: Date of diagnosis of cGvHD ..... - ..... -.....
yyyy *mm* *dd*

Maximum extent <u>during this period</u>
☐ Limited ☐ Extensive ☐ Unknown

Maximum NIH score <u>during this period</u>
☐ Mild ☐ Moderate ☐ Severe ☐ Not calculated

Other complications or toxicities during this period
☐ No -> Skip TOXICITIES table below and go straight to SECONDARY MALIGNANCIES on the next page
☐ Yes -> Continue with the TOXICITIES table below
☐ Unknown

Toxicities

	No	Yes	Grade	Date of diagnosis	Related to cell therapy	Ongoing at last assessment	Date of resolution
Cytokine storm	☐	☐		.....-..... -	☐ No ☐ Yes	☐ Yes ☐ No:	..... -..... - .....
Neurotoxicity	☐	☐		.....-..... -	☐ No ☐ Yes	☐ Yes ☐ No:	..... -..... - .....
Grade IV Organ toxicity as per WHO							
Liver	☐	☐		.....-..... -	☐ No ☐ Yes	☐ Yes ☐ No:	..... -..... - .....
Lungs	☐	☐		.....-..... -	☐ No ☐ Yes	☐ Yes ☐ No:	..... -..... - .....
Heart	☐	☐		.....-..... -	☐ No ☐ Yes	☐ Yes ☐ No:	..... -..... - .....
Kidney	☐	☐		.....-..... -	☐ No ☐ Yes	☐ Yes ☐ No:	..... -..... - .....
Other, specify	☐	☐		.....-..... -	☐ No ☐ Yes	☐ Yes ☐ No:	..... -..... - .....
Bone marrow aplasia/failure	☐	☐		.....-..... -	☐ No ☐ Yes	☐ Yes ☐ No:	..... -..... - .....
Other, specify ……..	☐	☐		.....-..... -	☐ No ☐ Yes	☐ Yes ☐ No:	..... -..... - .....
				yyyy mm dd			*yyyy mm dd*

Secondary Malignancy

Did a secondary malignancy, lymphoproliferative or myeloproliferative disorder occur?

☐ No ☐ Yes:

Date of diagnosis: ..... - ..... - .....
yyyy *mm* *dd*

Diagnosis: .....

IF THE PATIENT HAS RECEIVED AN ALLOGRAFT PRIOR TO THE DIAGNOSIS OF ACUTE LEUKAEMIA, ANSWER THE FOLLOWING QUESTION

Is this secondary malignancy a donor cell leukaemia or a malignancy of the cellular product**?**

☐ No ☐ Yes ☐ Not applicable

Graft assessment

ONLY FOR PATIENTS THAT HAVE RECEIVED A PREVIOUS TRANSPLANT

Graft loss

☐ No ☐ Yes ☐ Not evaluated

First Relapse/Progression or Significant worsening after Cell therapy

TO BE ANSWERED ONLY WHEN THE INDICATION WAS THE TREATMENT OF A PRIMARY DISEASE INCLUDING INFECTIONS

First Relapse or Progression or Significant worsening of organ function of the primary disease
(detected by any method)

☐ No

☐ Yes: Date first seen ..... - ..... - .....
yyyy *mm* *dd*

☐ Continuous progression since cell therapy

Last Disease Status

TO BE ANSWERED ONLY WHEN THE INDICATION WAS THE TREATMENT OF A PRIMARY DISEASE INCLUDING INFECTIONS

Last disease status

☐ Complete remission / Normalisation of organ function / No infection present

☐ Partial remission / Partial or non normalisation of organ funcition

☐ No response

☐ Disease progression or worsening of organ function

☐ Not evaluated

Survival Status

☐ Alive ☐ Dead ☐ Check here if patient lost to follow up

Main Cause of Death *(check only one main cause)*:
☐ Relapse or Progression/Persistent disease
☐ Secondary Malignancy
☐ Cell Therapy related: .....
☐ HSCT Related Cause
☐ Unknown
☐ Other: .....

Contributory Cause of Death *(check as many as appropriate)*:
☐ GVHD
☐ Cytokine release syndrome
☐ Interstitial pneumonitis
☐ Pulmonary toxicity
☐ Infection:
- ☐ bacterial
- ☐ viral
- ☐ fungal
- ☐ parasitic
- ☐ unknown

☐ Rejection/Poor graft function
☐ History of severe Veno occlusive disorder (VOD)
☐ Haemorrhage
☐ Cardiac toxicity
☐ Central nervous system (CNS) toxicity
☐ Gastrointestinal (GI) toxicity
☐ Skin toxicity
☐ Renal failure
☐ Multiple organ failure

☐ Other:.....

Persistence of the Infused Cells

Were tests performed to detect the persistence of the cellular products druing this period?

☐ No ☐ Yes: Date of the last test ..... - ..... - .....
yyyy *mm* *dd*

Technique used ***/***

☐ Molecular (PCR) ☐ Flow cytometry ☐ Chimaerism ☐ Imaging ☐ Immunohistochemistry

☐ Other, specify ……..……..

Were cells detected?

☐ No

☐ Yes