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

THIRD AND FOURTH REPORTS - 6 MONTH and ANNUAL FOLLOW UP

CENTRE IDENTIFICATION

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

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

PATIENT DATA

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

Indicate period: ☐ 6 month ☐ Annual

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

Date of last follow up or death: ..... - ..... - .....
yyyy *mm* *dd*

TOXICITY DURING THIS PERIOD

DO NOT INCLUDE INFORMATION ON TOXICITIES OR COMPLICATIONS THAT WERE RESOLVED <u>BEFORE</u> THE CELL THERAPY THIS FORM REFERS TO OR THAT HAVE ALREADY BEEN SUBMITTED WITH PREVIOUS FOLLOW UP FORMS

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 during this period

☐ No *(never)*

Yes: ☐ First episode since the last Cellular Therapy

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

☐ Recurrence

Date first evidence of cGVHD during this period:
..... - ..... -.....
yyyy *mm* *dd*

☐ Continuous since last reported episode

Maximum extent during this period
☐ Limited ☐ Extensive ☐ Unknown

Maximum NIH score during this period
☐ Mild ☐ Moderate ☐ Severe ☐ Not evaluated

☐ Resolved since last report *(currently absent)*

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							
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

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

☐ 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
☐ 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 during this period?

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

Technique used

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

☐ Other, specify ……..……..

Were cells detected?

☐ No

☐ Yes