CELLULAR THERAPIES FORM
-- Day 100, 6 Months & Annual Follow-Up --

EBMT Unique Identification Code (UIC): _____
(Patient number in EBMT database)

Date of this report: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*

CENTRE IDENTIFICATION

EBMT Centre Identification Code (CIC): _____

Unit: _____

Contact person: _____

PATIENT DATA

Hospital Unique Patient Number or code (UPN): _____
(Compulsory; registrations will not be accepted without this item. All treatments (transplants or CAR T-cell) performed in the same patient must be registered with the same patient identification number or code as this belongs to the patient and not to the treatment.)

Other type of patient identification code(s): _____
(Optional; to be used by the centre to register a patient code for internal use as necessary.)

Initials: _____ / _____ *(first name(s) / family name(s))*

Date of birth: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*

Sex *(at birth)*:
☐ Male
☐ Female

Assessment period covered by this report:
☐ Day 100
☐ 6 Months
☐ Annual Follow-Up

RECOVERY

Absolute neutrophil count (ANC) recovery *(Neutrophils ≥ 0.5x10⁶ cells/L)*:

☐ No: Date of last assessment: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*

☐ Yes: Date of ANC recovery: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*
(first of 3 consecutive values after 7 days without transfusion containing neutrophils)

☐ Never below

☐ Unknown

Platelet reconstitution:

Platelets **≥ 20x10⁹ cells/L**:

☐ No: Date of last assessment: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*

☐ Yes: Date of platelet reconstitution: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*
(first of 3 consecutive values after 7 days without platelet transfusion)

- ☐ Date unknown; patient discharged before levels reached
- ☐ Date unknown; out-patient

☐ Never below

☐ Unknown

Platelets **≥ 50x10⁹ cells/L**:

☐ No: Date of last assessment: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*

☐ Yes: Date of platelet reconstitution: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*
(first of 3 consecutive values after 7 days without platelet transfusion)

- ☐ Date unknown; patient discharged before levels reached
- ☐ Date unknown; out-patient

☐ Never below

☐ Unknown

Date of last platelet transfusion: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* ☐ Not applicable *(not transfused)*

RESPONSE TO CELLULAR THERAPY

Complete only for Day 100 and 6 Months.

Best clinical/biological response after the entire cellular therapy treatment:

If the indication was the treatment of a primary disease:

☐ Complete remission (CR) / Normalisation of organ function / No infection present
☐ *for AML only:* Complete remission with incomplete haematological recovery (CRi)
☐ 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)*

LAST CONTACT DATE FOR THIS REPORT

Date of last assessment for this report: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*
(enter date of advanced cellular therapy plus the set period - Day 100, 6 Months, Annual Follow-Up - approximately)

CURRENT HAEMATOLOGICAL FINDINGS

Was a haematological investigation performed?

☐ No

☐ Yes:

Hb	_____ g/dl
Platelets	_____ 10^9 cells/L
Were platelets transfused within 7 days before date of test?	☐ No ☐ Yes
White blood cells	_____ 10^9 cells/L
Haematocrit	_____ %
Were RBC transfused within 30 days before date of test?	☐ No ☐ Yes
Percentage Lymphocytes	_____ %
Percentage Neutrophils	_____ %

B-cell aplasia since last assessment:

☐ Absent

☐ Present: Percentage of B-cells: _____ % *(If the patient received tretament for B-cell aplasia, add details in "Post-Therapy Treatment' on page 16)*

☐ Unknown

PERFORMANCE SCORE

Performance score at the last assessment *(choose only one)*:

Type of score used:	Score:
☐ Karnofsky ☐ Lansky	☐ 10 ☐ 20 ☐ 30 ☐ 40 ☐ 50 ☐ 60 ☐ 70 ☐ 80 ☐ 90 ☐ 100
☐ ECOG	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4

COMPLICATIONS SINCE THE LAST REPORT
-- GvHD --

Do not report complications that were resolved before the cellular therapy; do not report complications that were previously reported as resolved, unless they reoccured.

Did graft versus host disease (GvHD) occur?

☐ No *(proceed to 'Complications since last report - Toxicities (non-infectious)' on page 5)*

☐ Yes: Type of GvHD *(check all that apply)*:

☐ **Acute GvHD:** Maximum grade: ☐ I ☐ II ☐ III ☐ IV ☐ Present but grade unknown ☐ Not evaluated

Type: ☐ New onset ☐ Recurrent ☐ Persistent

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 terapy: ☐ No ☐ Yes

Resolved: ☐ No ☐ Yes

Treatment for acute GvHD:
☐ No
☐ Yes:
- ☐ Corticosteroids
- ☐ Monoclonal Antibodies (MoAB)
- ☐ ATG/ALG
- ☐ Extra-corporeal photopheresis (ECP)
- ☐ Other; specify: _____

☐ **Chronic GvHD:** Episode:
- ☐ First episode
- ☐ Recurrence
- ☐ Continuous since last reported episode
- ☐ Yes, but resolved
- ☐ Yes, but resolved and reccured again

Date of onset: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*

Maximum extent during this period: ☐ Limited ☐ Extensive ☐ Unknown

Maximum NIH score during this period: ☐ Mild ☐ Moderate ☐ Severe ☐ Not calculated

COMPLIANCES SINCE THE LAST REPORT
-- Toxicities (non-infectious) --

Do not report complications that were resolved before the cellular therapy; do not report complications that were previously reported as resolved, unless they reoccured.

Toxicities/Non-infectious complications:

☐ No *(proceed to "Complications since last report - Infections' on page 10)*

☐ Yes *(report all non-infectious complications below)*

☐ Unknown *(proceed to "Complications since last report - Infections' on page 10)*

Cytokine release syndrome (CRS): ☐ **No** ☐ **Yes**

Onset date: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*

Maximum grade: _____ Scale/Criteria used to determine CRS grade:
☐ ASBMT/ASTCT
☐ Penn
☐ CTCAE
☐ Lee 2014
☐ MDACC
☐ CARTOX
☐ Other; specify: _____
☐ Unknown

Treatment given?
☐ No
☐ Yes *(If patient was treated for CRS add details in 'Post-Therapy Treatment' on page 16)*

Resolved: ☐ No ☐ Yes ☐ Unknown

Neurotoxicity: ☐ **No** ☐ **Yes**

☐ Altered mental status: Onset date: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* Grade: _____

Treatment given? ☐ No ☐ Yes *(add details in 'Post-Therapy Treatment' on page 16)*

Resolved: ☐ No ☐ Yes ☐ Unknown

☐ Aphasia: Onset date: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* Grade: _____

Treatment given? ☐ No ☐ Yes *(add details in 'Post-Therapy Treatment' on page 16)*

Resolved: ☐ No ☐ Yes ☐ Unknown

COMPLICATIONS SINCE THE LAST REPORT
-- Toxicities (non-infectious) --

Do not report complications that were resolved before the cellular therapy; do not report complications that were previously reported as resolved, unless they reoccured.

Neurotoxicity *continued*:

☐ Hemiparesis or other focal motor deficit: Onset date: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* Grade: _____

Treatment given? ☐ No ☐ Yes *(add details in 'Post-Therapy Treatment' on page 16)*

Resolved: ☐ No ☐ Yes ☐ Unknown

☐ Seizures: Onset date: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* Grade: _____

Treatment given? ☐ No ☐ Yes *(add details in 'Post-Therapy Treatment' on page 16)*

Resolved: ☐ No ☐ Yes ☐ Unknown

☐ Tremors: Onset date: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* Grade: _____

Treatment given? ☐ No ☐ Yes *(add details in 'Post-Therapy Treatment' on page 16)*

Resolved: ☐ No ☐ Yes ☐ Unknown

☐ Visual hallucinations: Onset date: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* Grade: _____

Treatment given? ☐ No ☐ Yes *(add details in 'Post-Therapy Treatment' on page 16)*

Resolved: ☐ No ☐ Yes ☐ Unknown

☐ Encephalopathy: Onset date: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* Grade: _____

Treatment given? ☐ No ☐ Yes *(add details in 'Post-Therapy Treatment' on page 16)*

Resolved: ☐ No ☐ Yes ☐ Unknown

☐ Cerebral oedema: Onset date: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* Grade: _____

Treatment given? ☐ No ☐ Yes *(add details in 'Post-Therapy Treatment' on page 16)*

Resolved: ☐ No ☐ Yes ☐ Unknown

☐ Other; specify: Onset date: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* Grade: _____

Treatment given? ☐ No ☐ Yes *(add details in 'Post-Therapy Treatment' on page 16)*

Resolved: ☐ No ☐ Yes ☐ Unknown

COMPLICATIONS SINCE THE LAST REPORT
-- Toxicities (non-infectious) --

Do not report complications that were resolved before the cellular therapy; do not report complications that were previously reported as resolved, unless they reoccured.

Grade 3 and 4 organ toxicities as per CTCAE: ☐ **No** ☐ **Yes** *(select and complete all that apply)*

☐ Skin: Onset date: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* Grade: _____

Treatment given? ☐ No ☐ Yes *(add details in 'Post-Therapy Treatment' on page 16)*

Resolved: ☐ No ☐ Yes ☐ Unknown

☐ Liver: Onset date: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* Grade: _____

Treatment given? ☐ No ☐ Yes *(add details in 'Post-Therapy Treatment' on page 16)*

Resolved: ☐ No ☐ Yes ☐ Unknown

☐ Lung: Onset date: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* Grade: _____

Treatment given? ☐ No ☐ Yes *(add details in 'Post-Therapy Treatment' on page 16)*

Resolved: ☐ No ☐ Yes ☐ Unknown

☐ Heart: Onset date: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* Grade: _____

Treatment given? ☐ No ☐ Yes *(add details in 'Post-Therapy Treatment' on page 16)*

Resolved: ☐ No ☐ Yes ☐ Unknown

☐ Kidney: Onset date: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* Grade: _____

Treatment given? ☐ No ☐ Yes *(add details in 'Post-Therapy Treatment' on page 16)*

Resolved: ☐ No ☐ Yes ☐ Unknown

☐ Gastrointestinal: Onset date: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* Grade: _____

Treatment given? ☐ No ☐ Yes *(add details in 'Post-Therapy Treatment' on page 16)*

Resolved: ☐ No ☐ Yes ☐ Unknown

☐ Other organ; specify: _____ Onset date: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* Grade: _____

Treatment given? ☐ No ☐ Yes *(add details in 'Post-Therapy Treatment' on page 16)*

Resolved: ☐ No ☐ Yes ☐ Unknown

COMPLICATIONS SINCE THE LAST REPORT
-- Toxicities (non-infectious) --

Do not report complications that were resolved before the cellular therapy; do not report complications that were previously reported as resolved, unless they reoccured.

Tumor lysis syndrome (TLS): ☐ **No** ☐ **Yes**

Onset date: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* Grade: _____

Treatment given? ☐ No ☐ Yes *(add details in'Post-Therapy Treatment' on page 16)*

Resolved: ☐ No ☐ Yes ☐ Unknown

Bone marrow aplasia: ☐ **No** ☐ **Yes**

Onset date: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* Specify: _____

Treatment given? ☐ No ☐ Yes *(add details in 'Post-Therapy Treatment' on page 16)*

Resolved: ☐ No ☐ Yes ☐ Unknown

Hypogammaglobulinemia: ☐ **No** ☐ **Yes**

Onset date: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*

Was hypogammaglobulinemia present before cellular therapy?
☐ No
☐ Yes: Was it worsened by the cellular therapy? ☐ No ☐ Yes

Treatment given? ☐ No ☐ Yes *(add details in 'Post-Therapy Treatment' on page 16)*

Resolved: ☐ No ☐ Yes ☐ Unknown

Insertional mutagenesis: ☐ **No** ☐ **Yes**

Onset date: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*

Resolved: ☐ No ☐ Yes ☐ Unknown

Exacerbation of existing neurological disorder: ☐ **No** ☐ **Yes**

Onset date: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* Specify: _____

Treatment given? ☐ No ☐ Yes *(add details in 'Post-Therapy Treatment' on page 16)*

Resolved: ☐ No ☐ Yes ☐ Unknown

Hemorrhagic stroke: ☐ **No** ☐ **Yes**

Onset date: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* Grade: _____

Treatment given? ☐ No ☐ Yes *(add details in 'Post-Therapy Treatment' on page 16)*

Resolved: ☐ No ☐ Yes ☐ Unknown

COMPLICATIONS SINCE THE LAST REPORT
-- Toxicities (non-infectious) --

Do not report complications that were resolved before the cellular therapy; do not report complications that were previously reported as resolved, unless they reoccured.

Other toxicity/complication: ☐ **No** ☐ **Yes**

Onset date: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* Specify: ___________________________

Grade *(if applicable)*: __________

Treatment given? ☐ No ☐ Yes *(add details in 'Post-Therapy Treatment' on page 16)*

Resolved: ☐ No ☐ Yes ☐ Unknown

Other toxicity/complication: ☐ **No** ☐ **Yes**

Onset date: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* Specify: ___________________________

Grade *(if applicable)*: __________

Treatment given? ☐ No ☐ Yes *(add details in 'Post-Therapy Treatment' on page 16)*

Resolved: ☐ No ☐ Yes ☐ Unknown

Other toxicity/complication: ☐ **No** ☐ **Yes**

Onset date: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* Specify: ___________________________

Grade *(if applicable)*: __________

Treatment given? ☐ No ☐ Yes *(add details in 'Post-Therapy Treatment' on page 16)*

Resolved: ☐ No ☐ Yes ☐ Unknown

COMPLICATIONS SINCE THE LAST REPORT
-- Infections --

Do not report complications that were resolved before the cellular therapy; do not report complications that were previously reported as resolved, unless they reoccured.

Infection-related complications:
(Report only grade 3 and 4 infections as per CTCAE)

☐ No *(proceed to 'Secondary Malignancies' on page 15)*

☐ Yes *(report all infection-related complications below)*

☐ Unknown *(proceed to 'Secondary Malignancies' on page 15)*

Bacteremia: ☐ **No** ☐ **Yes** *(report all episodes below; in case of the same pathogen report episodes occuring after 14 days)*

1) Onset date: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* Pathogen: _____

Treatment given? ☐ No ☐ Yes *(add details in 'Post-Therapy Treatment' on page 16)*

Resolved: ☐ No ☐ Yes ☐ Unknown

2) Onset date: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* Pathogen: _____

Treatment given? ☐ No ☐ Yes *(add details in 'Post-Therapy Treatment' on page 16)*

Resolved: ☐ No ☐ Yes ☐ Unknown

3) Onset date: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* Pathogen: _____

Treatment given? ☐ No ☐ Yes *(add details in 'Post-Therapy Treatment' on page 16)*

Resolved: ☐ No ☐ Yes ☐ Unknown

4) Onset date: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* Pathogen: _____

Treatment given? ☐ No ☐ Yes *(add details in 'Post-Therapy Treatment' on page 16)*

Resolved: ☐ No ☐ Yes ☐ Unknown

5) Onset date: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* Pathogen: _____

Treatment given? ☐ No ☐ Yes *(add details in 'Post-Therapy Treatment' on page 16)*

Resolved: ☐ No ☐ Yes ☐ Unknown

If more than 5 episodes copy this page as necessary.

COMPLICATIONS SINCE THE LAST REPORT
-- Infections continued--

Do not report complications that were resolved before the cellular therapy; do not report complications that were previously reported as resolved, unless they reoccured.

Invasive fungal disease including candidemia: ☐ **No** ☐ **Yes**

1) Onset date: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* Pathogen: _____

Treatment given? ☐ No ☐ Yes *(add details in 'Post-Therapy Treatment' on page 16)*

Resolved: ☐ No ☐ Yes ☐ Unknown

2) Onset date: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* Pathogen: _____

Treatment given? ☐ No ☐ Yes *(add details in 'Post-Therapy Treatment' on page 16)*

Resolved: ☐ No ☐ Yes ☐ Unknown

3) Onset date: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* Pathogen: _____

Treatment given? ☐ No ☐ Yes *(add details in "Post-Therapy Treatment' on page 16)*

Resolved: ☐ No ☐ Yes ☐ Unknown

4) Onset date: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* Pathogen: _____

Treatment given? ☐ No ☐ Yes *(add details in 'Post-Therapy Treatment' on page 16)*

Resolved: ☐ No ☐ Yes ☐ Unknown

5) Onset date: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* Pathogen: _____

Treatment given? ☐ No ☐ Yes *(add details in 'Post-Therapy Treatment' on page 16)*

Resolved: ☐ No ☐ Yes ☐ Unknown

If more than 5 episodes copy this page as necessary.

COMPLICATIONS SINCE THE LAST REPORT
-- Infections continued--

Do not report complications that were resolved before the cellular therapy; do not report complications that were previously reported as resolved, unless they reoccured.

CNS infection: ☐ **No** ☐ **Yes**

Onset date: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* Pathogen: _____

Treatment given? ☐ No ☐ Yes *(add details in 'Post-Therapy Treatment' on page 16)*

Resolved: ☐ No ☐ Yes ☐ Unknown

Pneumonia ☐ **No** ☐ **Yes**

Onset date: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* Pathogen: _____

Treatment given? ☐ No ☐ Yes *(add details in 'Post-Therapy Treatment' on page 16)*

Resolved: ☐ No ☐ Yes ☐ Unknown

C. difficile infection: ☐ **No** ☐ **Yes**

Onset date: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* Pathogen: _____

Treatment given? ☐ No ☐ Yes *(add details in 'Post-Therapy Treatment' on page 16)*

Resolved: ☐ No ☐ Yes ☐ Unknown

Abdominal infection: ☐ **No** ☐ **Yes**

Onset date: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* Pathogen: _____

Treatment given? ☐ No ☐ Yes *(add details in 'Post-Therapy Treatment' on page 16)*

Resolved: ☐ No ☐ Yes ☐ Unknown

Hepatitis: ☐ **No** ☐ **Yes**

Onset date: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* Pathogen: _____

Treatment given? ☐ No ☐ Yes *(add details in 'Post-Therapy Treatment' on page 16)*

Resolved: ☐ No ☐ Yes ☐ Unknown

Retinitis: ☐ **No** ☐ **Yes**

Onset date: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* Pathogen: _____

Treatment given? ☐ No ☐ Yes *(add details in 'Post-Therapy Treatment' on page 16)*

Resolved: ☐ No ☐ Yes ☐ Unknown

COMPLICATIONS SINCE THE LAST REPORT
-- Infections continued--

Do not report complications that were resolved before the cellular therapy; do not report complications that were previously reported as resolved, unless they reoccured.

Cystitis: ☐ **No** ☐ **Yes**

Onset date: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* Pathogen: _____

Treatment given? ☐ No ☐ Yes *(add details in 'Post-Therapy Treatment' on page 16)*

Resolved: ☐ No ☐ Yes ☐ Unknown

Skin infection: ☐ **No** ☐ **Yes**

Onset date: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* Pathogen: _____

Treatment given? ☐ No ☐ Yes *(add details in 'Post-Therapy Treatment' on page 16)*

Resolved: ☐ No ☐ Yes ☐ Unknown

Upper respiratory tract iunfection: ☐ **No** ☐ **Yes**

Onset date: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* Pathogen: _____

Treatment given? ☐ No ☐ Yes *(add details in 'Post-Therapy Treatment' on page 16)*

Resolved: ☐ No ☐ Yes ☐ Unknown

CMV reactivation: ☐ **No** ☐ **Yes**
(DNA-emia in serum/plasma/blood)

Onset date: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*

Highest number of copies: _____ cp/ml Date of highest copy number: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*

Treatment given? ☐ No ☐ Yes *(add details in 'Post-Therapy Treatment' on page 16)*

Resolved: ☐ No ☐ Yes ☐ Unknown

EBV reactivation: ☐ **No** ☐ **Yes**
(DNA-emia in serum/plasma/blood/PMN)

Onset date: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*

Highest number of copies: _____ cp/ml Date of highest copy number: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*

Treatment given? ☐ No ☐ Yes *(add details in 'Post-Therapy Treatment' on page 16)*

Resolved: ☐ No ☐ Yes ☐ Unknown

COMPLICATIONS SINCE THE LAST REPORT
-- Infections continued--

Do not report complications that were resolved before the cellular therapy; do not report complications that were previously reported as resolved, unless they reoccured.

HHV6 reactivation: ☐ **No** ☐ **Yes**
(DNA-emia in serum/plasma)

Onset date: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*

Highest number of copies: _____ cp/ml Date of highest copy number: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*

Treatment given? ☐ No ☐ Yes *(add details in 'Post-Therapy Treatment' on page 16)*

Resolved: ☐ No ☐ Yes ☐ Unknown

Adenovirus reactivation: ☐ **No** ☐ **Yes**
(DNA-emia in serum/plasma)

Onset date: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*

Highest number of copies: _____ cp/ml Date of highest copy number: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*

Treatment given? ☐ No ☐ Yes *(add details in 'Post-Therapy Treatment' on page 16)*

Resolved: ☐ No ☐ Yes ☐ Unknown

Other virus reactivation: ☐ **No** ☐ **Yes**
(DNA-emia in serum/plasma)

Onset date: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*

Highest number of copies: _____ cp/ml Date of highest copy number: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*

Treatment given? ☐ No ☐ Yes *(add details in 'Post-Therapy Treatment' on page 16)*

Resolved: ☐ No ☐ Yes ☐ Unknown

Other infectious complication: ☐ **No** ☐ **Yes**

Onset date: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* Pathogen: _____

Treatment given? ☐ No ☐ Yes *(add details in 'Post-Therapy Treatment' on page 16)*

Resolved: ☐ No ☐ Yes ☐ Unknown

SECONDARY MALIGNANCIES

Did a secondary malignancy or autoimmune disorder occur?

☐ No

☐ Yes: Diagnosis: _____

Date of diagnosis: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*

Histologic type *(if applicable)*: _____

Location *(if applicable)*: _____

Secondary malignancy material preserved:

☐ No

☐ Yes

POST-THERAPY TREATMENT

Include only systemic treatments; do not include treatment for acute GvHD as this should be reported in the GvHD section.

Did the patient undergo additional treatment during or immediately after the advanced cellular therapy or since the last reported assessment?

☐ No
☐ Yes: Date started: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*
☐ Unknown

List all chemotherapy/drugs given during one line of treatment:

Drug/ Regimen:	**Indication:** *(as specified in 'Complications' section)*	**Date started:** *(YYYY/MM/DD)*	**Treatment ongoing?**	**Date ended:** *(YYYY/MM/DD)*
		_ _ _ _/ _ _/ _ _	☐ No ☐ Yes	_ _ _ _/ _ _/ _ _
		_ _ _ _/ _ _/ _ _	☐ No ☐ Yes	_ _ _ _/ _ _/ _ _
		_ _ _ _/ _ _/ _ _	☐ No ☐ Yes	_ _ _ _/ _ _/ _ _
		_ _ _ _/ _ _/ _ _	☐ No ☐ Yes	_ _ _ _/ _ _/ _ _
		_ _ _ _/ _ _/ _ _	☐ No ☐ Yes	_ _ _ _/ _ _/ _ _
		_ _ _ _/ _ _/ _ _	☐ No ☐ Yes	_ _ _ _/ _ _/ _ _

Did the patient receive any other type of additional treatment?

☐ No
☐ Yes; specify: ___________________________
☐ Unknown

Is the patient receiving any medication not related to cell therapy or its indications?

☐ No
☐ Yes
☐ Unknown

FIRST RELAPSE/PROGRESSION OR SIGNIFICANT WORSENING AFTER ADVANCED CELLULAR THERAPY

Only applicable when indication was the treatment of a primary disease including infections.

First relapse/progression or significant worsening of organ function of the primary disease:
(detected by any method)

☐ No
☐ Yes: Date of relapse: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*
☐ Continuous progression since advanced cellular therapy

LAST DISEASE STATUS

Only applicable when indication was the treatment of a primary disease including infections.

Last disease status:

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

Histological verification of relapse *(only applicable to lymphoma with status relapse)*:

☐ No
☐ Yes

Transfusion status *(only applicable to haemoglobinopathies)*:

☐ No transfusion required
☐ Transfusion required

Disease burden:

LDH level:

☐ Normal
☐ Elevated
☐ Not evaluated

Inflammatory state (C-reactive protein [CPR] concentration):

☐ Normal
☐ Elevated: Maximum CRP concentration: _____ Unit *(check only one)*: ☐ mg/dL ☐ mg/L
☐ Not evaluated

Date of C-reactive protein level assessment: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*

HOSPITAL ADMISSION

Complete only for Day 100 and 6 Months.

Was inpatient admission and care needed?

☐ No
☐ Yes
☐ Unknown

Was the patient transferred to the intensive care unit (ICU)?

☐ No
☐ Yes
☐ Unknown

PREGNANCY AFTER CELLULAR THERAPY

Complete only for 6 Months and Annual Follow-Up.

Has the patient or partner become pregnant after this cellular therapy?

☐ No

☐ Yes: Did the pregnancy result in a live birth?

- ☐ No: Pregnancy outcome:
  - ☐ Abortion (elective, therapeutic, spontaneous)
  - ☐ Stillbirth
- ☐ Yes: Newborn status:
  - ☐ Healthy
  - ☐ Affected by a disease
  - ☐ Information not provided
- Length of term:
  - ☐ Full-term
  - ☐ Premature
  - ☐ Information not provided
- ☐ Unknown

☐ Unknown

PERSISTENCE OF THE INFUSED CELLS

Were tests performed to assess persistence of the infused cellular products during this period?

☐ No

☐ Yes: Date of the last test: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*

Source of cells used for testing:
- ☐ Bone Marrow
- ☐ Peripheral blood
- ☐ Tumour
- ☐ Other; specify: _____

Technique used for testing:
- ☐ Molecular (PCR)
- ☐ Flow cytometry
- ☐ Chimaerism
- ☐ Imaging
- ☐ Immunohistochemistry
- ☐ Other; specify: _____

Were cells detected:
- ☐ No
- ☐ Yes

SURVIVAL STATUS

Survival status:

☐ Alive

☐ Dead: Date of death *(if death happened since last report)*: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*

☐ Lost to follow-up

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

☐ Relapse or progression/persistent disease

☐ Secondary malignancy

☐ Cellular therapy-related

☐ HSCT-related *(only if patient previously had a transplant)*

☐ Unknown

☐ Other; specify: _____

Contributory causes of death:
(check all that apply)

☐ 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; specify: _____

END OF FOLLOW-UP REGISTRATION

Change history:

Version	Date	Description
v1.0	9-Feb-2022	First final version