Form is adapted from CIBMTR. All CDEs are Supplemental (not required for all studies and use is dependent on study design).

Event Date

Visit [ ]  100 day [ ]  6 months [ ]  1 year [ ]  2 years [ ]  > 2 years, Specify:

1. Name of product (for recent cell therapy infusion)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
2. Date of actual contact with the recipient to determine medical status for this follow-up report

\_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ \_\_\_ (DD-MMM-YYYY)

1. Specify the recipient’s survival status at the date of last contact

[ ]  Alive

[ ]  Dead (Complete Death CRF)

1. **Was there evidence to initial recovery?**

[ ]  Yes (ANC ≥ 500/mcL (mm3) achived and sustained for 3 lab values)

Date ANC ≥ 500/ mcL (mm3) (first of 3 lab values)

[ ]  No (ANC ≥ 500/ mcL (mm3) was not achieved)

[ ]  Not applicable (ANC never dropped below 500/ mcL (mm3) at any time after the start of lymphodepleting therapy / no lymphodepleting therapy given)

[ ]  Previously reported (recipient’s initial recovery was recorded on a previous report)

you are asking for date\_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ \_\_\_ (DD-MMM-YYYY)

1. Was an initial platelet count ≥ 50 x 109/L achieved (without antecedent platelet transfusion/s in the last 7 days)?

[ ]  Yes

Date Platelets ≥ 50 x 109/L (without platelet transfusions in the last 7 days)

[ ]  No

[ ]  Not applicable – Platelet count never dropped below 50 x 10^9/L at any time after the start of lymphodepleting therapy / no lymphodepleting therapy given

[ ]  Previously reported - ≥ 50 x 109/L was achieved and reported previously

1. Date of most recent hemoglobin (see Lab form) \_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ \_\_\_ (DD-MMM-YYYY)
2. Hemoglobin

[ ]  Known [ ]  Unknown

Value

Unit [ ]  g/dL [ ] g/L [ ]  mmol/L

Were RBC’s transfused <= 30 days before date of test? [ ]  Yes [ ]  No

1. **Did a new malignancy, myeloproliferative, or lymphoprliferative disease/disorder occur (include clonal cytogenetic abnormalities, and post-transplant lyphoproliferative disorders) in this reporting period**

[ ]  Yes. Specify type \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date detected\_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ \_\_\_ [ ]  No (DD-MMM-YYYY)

1. **Was tests performed to detect persistence of the genetically modified cellular product since the date of last report?**

[ ]  Yes [ ]  No

1. Was persistence evaluated by molecular assay? (e,g, PCR)

[ ]  Yes [ ]  No

Date Sample collected\_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ \_\_\_ (DD-MMM-YYYY)

Specify the cell source\_\_\_\_\_\_\_\_\_\_\_\_\_\_

[ ]  Bone marrow [ ]  Peripheral blood [ ]  Tumor [ ]  Other source

Specify other cell source\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Vector Copy Number per cell\_\_\_\_\_\_\_\_\_\_\_\_\_ [ ]  Not applicable

Percentage Gene Edited Cells\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ [ ]  Not applicable

**Were the infused gene-modified cells detected? E.g. F cells.**

[ ]  Yes [ ]  No

1. Was persistence evaluated by flow cytometry testing? (for specific type of hemoglobin expression, e.g. HbF, HbA, etc)

[ ]  Yes [ ]  No

1. Name the specific type of hemoglobin assayed by flow cytometry?\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date sample collected\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Specify the cell source\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

[ ]  Bone marrow [ ]  Peripheral blood [ ]  Tumor [ ]  Other source

Specify other cell source\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Specify percentage detected\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Was Hemoglobin Electrophoresis or equivalent performed to detect hemoglobin subtypes? (e.g. HbA, HbF, etc)

[ ]  Yes [ ]  No [ ]  Not applicable

1. Was persistence evaluated by other method?

[ ]  Yes [ ]  No

Specify other method\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date sample collected\_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ \_\_\_ (DD-MMM-YYYY)

Specify the cell source\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

[ ]  Bone marrow [ ]  Peripheral blood [ ]  Tumor [ ]  Other source

Specify other cell source

1. Were the infused cells detected?

[ ]  Yes [ ]  No

Specify quantity or percentage\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Other Toxicities**

Date of onset: \_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ \_\_\_ (DD-MMM-YYYY)

1. Did other toxicity resolve?

[ ]  Yes [ ]  No

Date resolved: \_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ \_\_\_ (DD-MMM-YYYY)

Specify if the recipient has developed any of the following since the data of last report:

1. Has the recipient developed any grade 3 organ toxicity in this reporting period?

[ ]  Yes [ ]  No [ ]  Unknown

Grade 3 Toxicities:

1. Specify organ

[ ]  Cardiovascular

[ ]  Gastrointenstinal

[ ]  Kidneys

[ ]  Liver

[ ]  Lungs

[ ]  Musculoskeletal

[ ]  Nervous asystems

[ ]  Other

Specify the toxicity

Date of onset\_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ \_\_\_ (DD-MMM-YYYY)

1. Did the grade 3 toxicity resolve?

[ ]  Yes [ ]  No

Date resolved: \_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ \_\_\_ (DD-MMM-YYYY)

1. Has the recipient developed any grade 4 organ toxicity during this reporting period?

[ ]  Yes [ ]  No [ ]  Unknown

1. Specify organ

[ ]  Cardiovascular

[ ]  Gastrointenstinal

[ ]  Kidneys

[ ]  Liver

[ ]  Lungs

[ ]  Musculoskeletal

[ ]  Nervous asystems

[ ]  Other

Specify the toxicity

Date of onset:\_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ \_\_\_ (DD-MMM-YYYY)

1. Did the grade 4 toxicity resolve?

[ ]  Yes [ ]  No

Date resolved:\_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ \_\_\_ (DD-MMM-YYYY)

1. **Did the recipient develop a clinically significant infection in this reporting period?**

[ ]  Yes [ ]  No

Report each infection organism, site and date of diagnosis

1. Organism
2. Site (check all that apply)

[ ]  Blood

[ ]  Bone

[ ]  CNS

[ ]  Eyes

[ ]  Genital rea

[ ]  GI tract, Lower

[ ]  GI tract, Upper

[ ]  Joints

[ ]  Liver/Spleen

[ ]  Lung

[ ]  Sinus and/or Upper respiratory tract

[ ]  Skin, cellulitis

[ ]  Skin, necrotizing facitis

[ ]  Urinary tract, Lower

[ ]  Urinary tract, Upper

Date of diagnosis: \_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ \_\_\_ (DD-MMM-YYYY)

1. **Was the recipient pregnant at any time in this reporting period (Female only)**

[ ]  Yes [ ]  No [ ]  Unknown [ ]  Previously reported

1. Was the recipients female partner pregnant at any time in this reporting period? (Male only)

[ ]  Yes [ ]  No [ ]  Unknown [ ]  Previously reported