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