Cell Therapy Follow Up Data

1. PATIENT IDENTIFICATION

Hospital: AID (ABMTRR id):

UPN:

DOB: __/__/__ CT Infusion date: __/__/__

Follow up: 30 day | 100day | 6mth| 1yr | 2 yr | >2yr, specify year ___

Product name (most recent CT infusion):

Tisagenlecleucel| Axicabtagene| Brexucabtagene | Ciltacabtagene | Other, specify

2. SURVIVAL

Date of actual contact to determine medical status for this report:

__/__/__

Survival status: Alive | Dead

Cause of death: _____

3. SUBSEQUENT CELL INFUSIONS

New course CT given since last report (unplanned): Y | N

If yes:

Reason given: Failure to respond/in response to disease assessment | New indication

Date of cell therapy: __/__/__

Complete new Cell Therapy Pre-infusion form

HCT given since last report: Y | N

If yes, date of HCT: __/__/__

Reason for transplant: Relapse | Progression| Planned | New malignancy | other: _____

Complete new HCT form

4. BEST RESPONSE TO CELL THERAPY

Skip this section if indication was ALL, Lymphoma, Myeloma or for the prevention of: disease relapse/infection/GVHD

Best response to cell therapy: _____

Date best response: __/__/__ ☐ previously reported

5. PERIPHERAL BLOOD COUNT RECOVERY

Complete at 30 day, 100 day, and 6 months

Initial neutrophil recovery

Date ANC ≥ 0.5 x10^9/L: __/__/__ ☐ previously reported

or Not achieved | N/A, never below 0.5

If ANC achieved, Subsequent ANC decline: Y | N

Decline date: __/__/__

ANC recovery date: __/__/__ ☐ did not recover

Initial platelet recovery (no platelet transfusion 7 days prior)

Date platelets ≥ 20x10^9/L: __/__/__ ☐ previously reported

or Not achieved | N/A; never below 20

6. DISEASE RELAPSE / PROGRESSION

Non-malignant indications: Relapse/progression occurred: Y | N

If yes, date relapse/progression: __/__/__

Evidence of antigen escape: Y | N

(only complete for CD19+ directed CAR-T products i.e. Tisagenlecleucel, Axicabtagene and Brexucabtagene)

If yes, Method of detection: _____

Date of antigen escape: __ /__/__

7. CURRENT HAEMATOLOGY VALUES

Complete at 30 day, 100 day, 6 months, 1 and 2 years only

Date latest complete blood count: __/__/__

	Value	Units
WBC		x 10^9/L
Neutrophils x 109/L		x 10^9/L
Lymphocytes x 10^9/L		x 10^9/L
Haemoglobin g/L		g/L
Haematocrit %		%

RBC transfused ≤ 30 days prior: Y | N

Platelets x 10^9/L		x 10^9/L

Platelets transfused ≤ 7 days prior: Y | N | Unk

Growth factor given within 7 days prior (or long-acting growth factors within 14 days): Y | N

8. NEW MALIGNANCY, LYMPHOPROLIFERATIVE OR MYELOPROLIFERATIVE DISEASE / DISORDER

include clonal cytogenetic abnormalities and PTLD

New malignancy diagnosed: Y | N | previously reported

If yes: Malignancy diagnosis:

Date of diagnosis: __/__/__

Pathology or autopsy report submitted: Y | N

Malignancy is donor/cell product derived: Y | N| Not tested

If yes, documentation submitted: Y | N

If new malignancy is PTLD, complete following:

EBV reactivation present in blood: Y | N | Unknown

If yes, method diagnosed:

- ❑ Qualitative PCR of blood
- ❑ Quantitative PCR of blood
  - ○ Viral load (copies/ml)
  - ○ Quantitative PCR blood repeated: Y | N
  - ○ If yes, max EBV viral load of blood (copies/ml): _____
- ❑ Other method, specify:

Was there lymphomatous involvement? eg. a mass: Y | N

If yes, specify sites:

PTLD confirmed by biopsy: Y | N

Biopsy pathology submitted: Y | N

9. PERSISTENCE OF CELLS

Complete for genetically modified cell products only

Tests performed to detect persistence of cell product: Y | N

	Date sample	Cell source PB/BM	Infused cells detected
Molecular assay (e.g. PCR)	__/__/__		Y | N
Flow cytometry (immunophenotyping)	__/__/__		Y | N
Immunohistochemistry	__/__/__		Y | N
Other method: _____	__/__/__		Y | N

Were B cell monitored: Y | N

If yes, was there B cell recovery Y | N | Unk |previously reported

Date of initial B cell recovery: __ /__/__

Subsequent infusion given for loss of B-cell aplasia? Y | N

10. GRAFT VS HOST DISEASE

Allogeneic cell therapy infusions only

Acute GVHD

Acute GVHD developed since last report: Y | N | Unk

If yes, date aGVHD diagnosis: __/__/__

Overall grade at diagnosis: ☐ I ☐ II ☐ III ☐ IV

☐ N/A, present but cannot be graded

Stage for each organ at diagnosis

Skin: Lower GIT: Upper GIT:

Liver: Other site(s), specify

Or Acute GVHD persisted since last report: Y | N | Unk

Maximum overall grade: ☐ I ☐ II ☐ III ☐ IV

☐ N/A, present, but cannot be graded

Date maximum overall grade: __/__/__

Chronic GVHD

Chronic GVHD developed since last report: Y | N | Unk

If yes, Date of cGVHD diagnosis: __/__/__

or Chronic GVHD persisted since last report: Y | N | Unk

If yes, Maximum grade since last report (best clinical judgement):

Mild | Mod | Severe | Unknown

Extent cGVHD: Limited | Extensive

Date maximum grade: __/__/__

Immunosuppressive agents

Currently taking systemic steroids for GVHD: Y | N | na | unk

Currently taking non-steroidal immunosuppressive agents for GVHD (inc PUVA): Y | N | na | unk

11. CYTOKINE RELEASE SYNDROME (CRS)

CRS occurred in this reporting period? Y | N

Date of diagnosis __/__/__ ☐ previously reported

CRS therapy given: Corticosteroids | Tocilizumab | Siltuximab |

Other specify | None

If Tocilizumab given, number of doses: 1 | 2 or more

CRS symptoms

Fevers (≥38 C): Y | N | Unk

Date of onset: __/__/__ ☐ previously reported

Hypotension requiring therapy: Y | N | Unk

Date of onset: __/__/__

Intravenous fluids given: Y | N | Unk

Vasopressor(s) given: Y | N | Unk

Number of vasopressors: 1 | >=2 | Unk | none

Specify vasopressors:

Other therapy, specify

Hypotension controlled with therapy: Y | N | Unk

Hypoxia requiring minimal supplemental oxygen (FiO2 < 40%):

Y | N | Unk if yes, date of onset: __/__/__

Hypoxia requiring > minimal supplemental oxygen (FiO2 >= 40%):

Y | N | Unk if yes, date of onset: __/__/__

Positive pressure ventilatory support required: Y | N | Unk

If yes, date started: __/__/__

CRS resolved: Y | N | Unk if yes, date resolved: __/__/__

IEC-HS (MAS/HLH)

Features resembling IEC-HS: Y | N if yes, date onset: __/__/__

IEC-HS therapy given: _____

Confirmed by BM biopsy: Y | N

Splenomegaly associated with IEC-HS: Y | N

Fibrinogen min value: _____ mg/L Date sample: __/__/__

Triglyceride max value: _____mmol/L Date sample: __/__/__

Was there a fever associated IEC-HS: Y | N

Were there of the following organ toxicities associated with IEC-HS:

- ☐ Direct hyperbilirubinemia
- ☐ Hepatic transaminase elevation (>5xULN or >5x baseline if baseline was abnormal)
- ☐ Hypoxia
- ☐ Pulmonary oedema
- ☐ Pulmonary infiltrates
- ☐ Renal insufficiency

IEC-HS toxicities resolved: Y | N

If yes, date resolved: __/__/__

12. NEUROTOXICITY

Neurotoxicity occurred in this reporting period: Y | N | Unk

If yes, date of onset: __/__/__ ☐ previously reported

ICE score *(highest grade observed in this reporting period)*

Lowest score: _____ (highest grade)

CAPD highest score (<12yrs): _____ (highest grade)

Depressed level of consciousness: Yes | No| Unk

Maximum depressed level of consciousness

⇒ Specify most severe level:

Dysphasia: Yes | No| Unk

⇒ Grade: 1 | 2

⇒ Aplasia (grade 3 dysplasia): Y | N | Unknown

Seizure: Y | N | Unk

⇒ Seizure type:

⇒ Severity grade: 3 | 4

Hemiparesis/paraparesis/other motor deficit: Y | N| Unk

Cerebral oedema: Y | N | Unk

⇒ Specify type:

Hallucinations: Y | N | Unk

Tremors: Y | N | Unk

Cerebral vascular accident: Y | N | Unk

⇒ Date of onset: __/__/__

⇒ CVA type: Haemorrhagic | Ischaemic

Leukoencephalopathy: Y | N | Unk

Other neurotoxicity symptoms, specify:

Did neurotoxicity resolve: Y | N | Unk

Date resolved: __/__/__

Treatment for neurotoxicity given: Y | N

Specify therapy:

13. OTHER TOXICITIES

Hypogammaglobulinemia: Y | N | Unk

If yes, date onset: __/__/__ or ☐ previously reported

Hypogammaglobulinema resolved: Y | N | Unk

If yes, date resolved: __/__/__

Require immunoglobulin replacement therapy: Y | N

If yes, date started: __/__/__ or ☐ previously reported

Recipient still requiring replacement therapy: Y | N

If no, date ceased: __/__/__

Tumour lysis syndrome (TLS): Y | N | Unk

If yes, date onset: __/__/__ or ☐ previously reported

Grade: 3 | 4 | 5

TLS resolved: Y | N | Unk

If yes, date resolved: __/__/__

Other toxicities: Y | N

Specify toxicity: _____

Date onset: __/__/__

Date resolved: __/__/__

Complete these questions as many times as required

14. GRADE 3 OR 4 TOXICITIES (CTCAE CRITERIA)

at 30 day, 100 day and 6 months only

Developed grade 3 organ toxicity: Y | N | Unk

Organ involved:

Specify toxicity:

Date of onset: __/__/__ ☐ previously reported

Grade 3 toxicity resolved: Y | N

Date resolved: __/__/__

Complete this section as many times as required

Developed Grade 4 organ toxicity: Y | N | Unk

Organ involved:

Specify toxicity:

Date of onset: __/__/__ ☐ previously reported

Grade 4 toxicity resolved: Y | N

Date resolved: __/__/__

Complete this section as many times as required

15. MAXIMUM LAB VALUES SINCE LAST REPORT

	Value	Date sample
Interleukin-6 ☐ pg/mL ☐ IU/ml		__/__/__
Soluble interleukin-2 receptor α ☐ pg/mL ☐ IU/mL		__/__/__
Total serum ferritin, ug/L		__/__/__
C-reactive protein, mg/L		__/__/__

16. INFECTION

Clinically significant infection since last report: Y | N | Unk

If yes, Organism

Site:

Date of diagnosis: __/__/__

Complete this section as many times as required

17. HOSPITALISATION

Hospital admission: Y | N

Total inpatient days (for this reporting period): _____

Reason(s) for hospital admission: _____

ICU admission: Y | N

ICU number of days: _____

Reason(s) for ICU admission: _____

18. HIGH COST MEDICATIONS USAGE

List any medications considered high cost that have not been reported in previous sections

19. PREGNANCY STATUS

Recipient (or female partner) pregnant in this reporting period: Y | N | Unk | Previously reported

If yes: Pregnancy outcome: Live birth - term | Live birth - premature | other: _____

Any congenital abnormalities? (Live Birth): Y | N | Unk

Delivery Date: __/__/__ ☐ date unknown