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 |

Other: _____

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 or for the prevention of the following: disease relapse, infection or 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

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

Relapse or Progression since last report: Y | N

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

Evidence of antigen escape: Y | N

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

	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: __ /__/__

10. GRAFT VS HOST DISEASE

Allogeneic 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: 0 | 1 | 2 | 3 | 4

Lower GIT: 0 | 1 | 2 | 3 | 4

Upper GIT: 0 | 1

Liver: 0 | 1 | 2 | 3 | 4

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 | Tocilzumab | 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

⇒ Vasopressors:

Other therapy, specify

Hypotension controlled with therapy: Y | N | Unk

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

Y | N | Unk -> Date of onset: __/__/__

Hypoxia requiring more than minimal supplemental oxygen (FiO2 >= 40%): Y | N | Unk -> Date of onset: __/__/__

Positive pressure ventilatory support required: Y | N | Unk

Date Started: __/__/__

CRS resolved: Y | N | Unk -> Date resolved: __/__/__

MAS/HLH

Features resembling HLH/MAS: Y | N -> Date of onset: __/__/__

MAS/HLH therapy given:

Confirmed by BM biopsy: Y | N

Splenomegaly associated with MAS/HLH: Y | N

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

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

MAS/HLH-like toxicities resolved: Y | N

If yes, date resolved: __/__/__

12. NEUROTOXICITY

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

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

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

Scoring assessment: ☐ICE ☐CARTOX

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

NEUROTOXICITY contd

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 resolve: Y | N | Unk

If yes, date resolved:__/__/__

Other toxicities, specify with onset and resolution dates

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. FUNCTIONAL 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