

## 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 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  $\geq 0.5 \times 10^9/L$ : \_\_/\_\_/\_\_  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  $\geq 20 \times 10^9/L$ : \_\_/\_\_/\_\_  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: \_\_/\_\_/\_\_  
 Tisagenlecleucel / Axicabtagene / Brexucabtagene only:  
 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		$\times 10^9/L$
Neutrophils $\times 10^9/L$		$\times 10^9/L$
Lymphocytes $\times 10^9/L$		$\times 10^9/L$
Haemoglobin g/L		g/L
Haematocrit %		%

RBC transfused  $\leq 30$  days prior: Y | N

Platelets $\times 10^9/L$		$\times 10^9/L$
---------------------------	--	-----------------

Platelets transfused  $\leq 7$  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  
   o Viral load (copies/ml)  
   o Quantitative PCR blood repeated: Y | N  
   o 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: 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 ( $\geq 38$  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 |  $\geq 2$  | Unk | none

Vasopressors:

Other therapy, specify

Hypotension controlled with therapy: Y | N | Unk

Hypoxia requiring minimal supplemental oxygen (FiO<sub>2</sub> < 40%):

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

Hypoxia requiring > minimal supplemental oxygen (FiO<sub>2</sub>  $\geq$  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: \_\_/\_\_/\_\_

### MAS/HLH

Features resembling HLH/MAS: Y | N if yes, date 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

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

### 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:

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 <input type="checkbox"/> pg/mL <input type="checkbox"/> IU/ml		__/__/__
Soluble interleukin-2 receptor α <input type="checkbox"/> pg/mL <input type="checkbox"/> IU/mL		__/__/__
Total serum ferritin, ug/L		__/__/__
C-reactive protein, mg/L		__/__/__

### 13. OTHER TOXICITIES

Hypogammaglobulinemia: Y | N | Unk  
 If yes, date onset: \_\_/\_\_/\_\_ or  previously reported  
 Hypogammaglobulinemia 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

### 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:

### 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*

### 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