



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| 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:
Complete new HCT form

4. BEST RESPONSE TO CELL THERAPY
ALL, Lymphoma: Go to disease specific forms

Not required if indication was gvhd/infection prophylaxis or relapse

- Complete response
Normalization of organ function
Partial response
Partial normalization of organ function
No response
Disease progression or worsening of organ function
Unknown

Date best response: previously reported

5. PERIPHERAL BLOOD COUNT RECOVERY

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:

7. CURRENT HAEMATOLOGY VALUES

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

Date latest complete blood count:
WBC x 10^9/L
Neutrophils x 10^9/L
Lymphocytes x 10^9/L
Haemoglobin g/L
Haematocrit %
=> RBC transfused <= 30 days prior: Y | N
Platelets x 10^9/L
=> Platelets transfused <= 7 days prior: Y | N | Unk
Growth factor given within 7 days prior: Y | N

8. NEW MALIGNANCY, LYMPHOPROLIFERATIVE OR MYELOPROLIFERATIVE DISEASE / DISORDER
include clonal cytogenetic abnormalities and PTLD

New malignancy occurred: Y | N | previously reported
If yes:
Malignancy diagnosis:
Date of diagnosis:
Malignancy is donor/cell product derived: Y | N | Not tested
=> If yes, documentation submitted e.g. cell origin evaluation (VTNR, cytogenetics, FISH): Y | N
Pathology or autopsy report also 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, highest 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	Infused cells detected
Molecular assay (e.g. PCR)	__/__/__		Y N
Flow cytometry (immunophenotyping)	__/__/__		Y N
			B-cell aplasia identified? Y N na
Immuno-histochemistry	__/__/__		Y N
Other method, specify	__/__/__		Y N

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, grade not applicable)

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, grade not applicable)

Date maximum overall grade: __/__/__

Chronic GVHD

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

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

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

If yes,

Max grade since last report (best clinical judgement):

Mild | Mod | Severe | Unknown

Extent cGVHD: Limited | Extensive

Date maximum grade: __/__/__

Immunosuppressive agents

Currently taking systemic steroids: 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 first incidence: __/__/__ 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 \geq 40%): Y | N | Unk -> Date of onset: __/__/__

Positive pressure ventilatory support required: Y | N | Unk

Date Started: __/__/__

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

Confirmed by BM biopsy: Y | N

Splenomegaly assoc with MAS/HLH: Y | N

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

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

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

12. NEUROTOXICITY

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

Date of onset: __/__/__ previously reported

Assessment score (*highest grade observed in 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

Seizure: Y | N | Unk

⇒ Seizure type:

⇒ Severity grade: 3 | 4

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

NEUROTOXICITY contd

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
 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

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 copies of 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 copies of 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		__/__/__

16. INFECTION

Clinically significant infection occurred since last report:
 Y | N | Unk
 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 toxicities 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 |
 Intrauterine foetal death | Spontaneous abortion | Elected abortion
 | Unknown
 Any congenital abnormalities? (Live Birth): Y | N | Unk
 Delivery Date: __/__/__ date unknown