ABMTRR Cell Therapy Data - Pre-Infusion

1. PATIENT IDENTIFICATION

Hospital: UPN:

Surname ID: First name ID:

DOB: __/__/__ Sex:

Usual residence: Postcode:

Race: Indigenous status:

Consented: Y | N

AID (ABMTRR id): CIBMTR ID (crid):

SURVIVAL

Survival status: Alive | Dead Latest contact date: __/__/__

2. CELL THERAPY

Participating in CT clinical trial: Y | N

If yes: Corporate | Investigator initiated| other, and details:

Study id number:

Complete copies of above questions if on multiple trials

If no, reason why not in clinical trial:

Institutional guidelines | Hospital exemption |Compassionate use

Product funding: Clinical Trial | MBS | MTOP | Self-funded

3. PRIOR CELL THERAPY (CT)

This is first course of cell therapy (non HCT): Y | N |Unk

If no: All reported to: ABMTRR |CIBMTR|EBMT

Number prior CTs: ___ Date of CT: __/__/__

Where performed: Indication:

Cell source(s): Auto|Allo-unrel |Allo-related

Complete copies of above questions if >1 prior CT

4. PRIOR TRANSPLANT (HCT)

Received prior HCT: Y | N |Unk

If yes, All reported to: ABMTRR |CIBMTR|EBMT

HCT date: __/__/__ Where performed:

HCT type: Auto| Allo-unrel | Allo-related

Complete copies of above questions if >1 prior HCT

5. PRODUCT IDENTIFICATION

Product/s (this course) genetically modified: Y | N

Donor type: Auto| Allo-unrel | Allo-related

Donor relation: Syngeneic |HLA ident sib |HLA matched other relative | HLA m/m relative

Same donor used for prior CT/HCT: Y | N |Unk |NA

GRID:

Donor Registry: Donor country:

Donor age: Donor sex:

Number of products: (per protocol) as part of this course of CT: ___

Complete copies of above questions if > 1 donor used

Product: Tisagenlecleucel| Axicabtagene| other, specify

Date of product request: __/__/__

Date manufacturing started: __/__/__

Date receipt of product: __/__/__

Planned setting of infusion: Inpatient |Outpatient

6. PLANNED HCT

Subsequent HCT planned as part of protocol: Y | N

Subsequent HCT type: Auto| Allo

Circumstance for subsequent HCT:

- ☐ Regardless of response to cell therapy
- ☐ Only if responds to cell therapy
- ☐ Only if fails or incomplete response

7. INDICATION

Considered as DLI: Y | N

Indication for cell therapy:

If Malignant disease - Complete Disease Form

Date of diagnosis: __/__/__

8. DISEASE ASSESSMENT PRIOR TO CELL THERAPY

Bridging therapy was given prior to CT infusion: Y | N

If yes, Date started: __/__/__

	Date sample	Disease detected	Considered relapse/prog
Molecular	__/__/__	Y|N|Unk|NA	Y | N
Flow cytometry	__/__/__	Y|N|Unk|NA	Y | N
Karyotyping	__/__/__	Y|N|Unk|NA	Y | N
FISH	__/__/__	Y|N|Unk|NA	Y | N
Radiological	__/__/__	Y|N|Unk|NA	
Clinical/haem	__/__/__	Y|N|Unk|NA	

Disease status immediately prior CT: CR | Not in CR

Date assessed: __/__/__

9. LYMPHODEPLETING THERAPY

Lymphodepleting therapy given prior infusion: Y | N

Drug	Total dose/mg	Date started
		__/__/__
		__/__/__
		__/__/__

10. PATIENT ASSESSMENT

Karnofsky/Lansky Score prior cell therapy: ____

COVID-19 positive any time prior: Y | N

Hospitalised: Y | N Mechanically ventilated: Y | N

Comorbidities (Sorror et al) *malignant indications only*

- ☐ Arrhythmia
- ☐ Cardiac
- ☐ Cerebrovascular
- ☐ Diabetes
- ☐ Heart valve disease
- ☐ Hepatic, mild
- ☐ Hepatic, mod/severe
- ☐ Infection
- ☐ Inflam bowel disease
- ☐ Obesity
- ☐ Peptic Ulcer
- ☐ Psychiatric
- ☐ Pulmonary, mod
- ☐ Pulmonary, severe
- ☐ Renal, mod/severe
- ☐ Rheumatologic
- ☐ Prior malignancy, specify: Year diagnosed __/__/__

On dialysis immediately prior lymphodepleting therapy: Y|N

Other comorbid condition:

Cell Therapy Product

1. PRODUCT SOURCE

Date product collected: __/__/__

Tissue source: BM | PB | Cord Blood | other specify

Cell type: Lymphocytes unsel | CD4+ | CD8+ | NK cells | other

Where manufactured / processed:

Novartis |Kite pharma |Celgene | Cell processing lab on site | Cell processing lab off site | specify other

2. AUTOLOGOUS PRODUCT

Method of collection: BM aspirate |Leukapheresis | other specify

Number of collections:

3. CELL MANIPULATION

Not required for Kymriah/Yescarta

Cells selected /modified/engineered prior infusion: Y | N

Portion manipulated: Entire product |Portion of product

⇒ If portion, unmanipulated portion also infused: Y | N

Same manipulation method on entire/all portions of product: Y | N

Method(s) used: Cultured | Cell selection specific antigen affinity | Genetic manipulation |other specify

Complete following if genetically manipulated:

Transfection:

- Viral transduction – Lentivirus| Retrovirus
- Non-viral transfection – Transposon| Electroporation |other specify

Gene editing, specify gene:

Cells engineered to express a non-native protein: Y | N

If yes, specify protein inserted

- T-cell receptor
- CAR - specify CAR construct
- Suicide gene – specify suicide gene

Other genetic manipulation:

Manipulated to recognize specific target/antigen: Y | N

If yes, specify target:

- Viral, specify
- Tumour/cancer antigen, specify
- other target, specify

4. CELL PRODUCT ANALYSIS

Transfection efficiency performed? (genetically engineered cells): Y | N |Unk

⇒ If yes: Date performed: __/__/__

Transfection efficiency % ____ target achieved: Y | N

Viability of cells performed: Y | N |Unk

⇒ If yes: Date performed: __/__/__

Viability of cells % _____

Method: 7-AAD |Propidium iodide| Trypton blue |Other specify

5. Out of specification (Commercial products only)

Product is out of specification: Y | N | Unk

If yes, reason:_____

6. PRODUCT INFUSION

Total number planned infusions of this product: _____
(this course of cell therapy)

Cell Therapy Infusion

1. CELL PRODUCT IDENTIFIERS

Cell product ID _____

ISBT DIN number _____

Batch number _____

Lot number _____

2. INFUSION

Date of infusion: __/__/__

Entire product volume infused: Y | N

⇒ If no, reserved portion fate:

Discarded | Cryopreserved | other specify

Route of infusion: IV| other specify route/site

Or Product was not infused

Reason why not infused:

Disease progression| Comorbidities| Other specify

3. CELL DOSES

Recipient weight /kg _____

Recipient height /cm _____

Report total number of cells given (not cells per kg)

Total number of cells	_____ x 10 __
Lymphocytes unselected	_____ x 10 __
CD4+ lymphocytes	_____ x 10 __
CD8+ lymphocytes	_____ x 10 __
Natural killer cells (NK cells)	_____ x 10 __
Dendritic cells / tumour cell hybridomas	_____ x 10 __
Mesenchymal stromal stem cells (MSCs)	_____ x 10 __
Unspecified mononuclear cells	_____ x 10 __
Endothelial progenitor cells	_____ x 10 __
Human umbilical cord perivascular cells	_____ x 10 __
Cardiac progenitor cells	_____ x 10 __
Islet cells	_____ x 10 __
Oligodendrocytes	_____ x 10 __

Other, specify cell type and dose _____

4. CONCOMITANT THERAPY

Recipient receive concomitant therapy: Y | N

- ☐ Atezolizumab
- ☐ Avelumab
- ☐ Durvalumab
- ☐ GM-CSF
- ☐ IL-2
- ☐ IL-15
- ☐ Ipilimumab
- ☐ Lenalidomide
- ☐ Nivolumab
- ☐ Pembrolizumab
- ☐ Pomalidomide
- ☐ Other specify

When given: Simultaneous | Post cell therapy | Unknown