Cell Therapy - Pre-Infusion Data

PATIENT INFORMATION

1. PATIENT IDENTIFICATION

Hospital:
UPN:
Usual residence:
Postcode:
Race:
Indigenous status:
Patient consent:

Name id (optional):
DOB: _____ /_____ / _____
Sex:

CIBMTR ID (CRID):
AID:

Cell Therapy PRE-INFUSION

1. PATIENT IDENTIFICATION

Referral centre:
Referring doctor:
Date of first referral for cell therapy: _____ /_____ /_____

2. CELL THERAPY

Participating in CT clinical trial: Y | N
If yes: ☐ Corporate ☐ Investigator initiated ☐ other _____
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 ☐ NA, compassionate use
Axicabtagene funding: (complete if Commercial MBS funded)
☐ 2nd line setting
☐ 3rd line setting
Indication for Carvykti:
☐ 5th line + RRMM - prior PI, IMiD and anti-CD38 antibody
☐ 4th line + RRMM - prior PI, IMiD and anti-CD38 antibody
☐ 2nd line + RRMM - prior PI + IMiD and lenalidomide refractory

3. PRIOR CELL THERAPY (CT)

This is first course of cell therapy (non HCT): Y | N |Unk
If no: reported to: ☐ ANZTCT ☐ CIBMTR ☐ EBMT
Number prior CTs: ___ Date of CT: ____ /____ /____
Where performed: Indication:
Cell source(s): ☐ Auto ☐ Allo-unrelated ☐Allo-related
Complete copies of above questions if >1 prior CT

4. PRIOR TRANSPLANT (HCT)

Received prior HCT: Y | N |Unk
If yes, reported to: ☐ ANZTCT ☐ CIBMTR ☐ EBMT
Prior HCT date: ___ /___ /___ Where performed:
HCT type: ☐ Auto ☐ Allo-unrelated ☐ Allo-related
Complete copies of above questions if >1 prior HCT

5. PRODUCT IDENTIFICATION

Product/s (this course) genetically modified: Y | N
Donor type: ☐ Autologous ☐ Allo-unrelated ☐ Allo-related
If related, donor relation:
Same donor used for prior CT/HCT: Y | N |Unk |NA
Donor age: Donor sex:
Unrelated donor: GRID:
Donor Registry:
Donor country:
Number of products: (per protocol) as part of this course of CT: ___
Complete copies of above questions if > 1 donor used

Product name: _____

Date of product request: _____ /_____ /_____
Date manufacturing started: _____ /_____ /_____
Final product ready for shipping: _____ /_____ /_____
Final product shipped: _____ /_____ /_____
Date receipt of product: ____ /_____ /_____

Planned setting of infusion: ☐ Inpatient ☐ Outpatient
Actual setting of infusion: ☐ Inpatient ☐ Outpatient

Cell Therapy PRE-INFUSION (continued)

6. PLANNED HCT

Subsequent HCT planned as part of protocol: Y | N

Subsequent HCT type: ☐ Autologous ☐ Allogeneic

Circumstance for subsequent HCT:

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

7. INDICATION

Indication for cell therapy:

- ☐ Malignant haematological disorder -> complete disease forms
- ☐ Other, specify:

If other indication, Date of diagnosis: ____ /____ /____

8. BRIDGING THERAPY

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

Type of bridging therapy:

- ☐ Chemotherapy
- ☐ Immunotherapy
- ☐ Radiation therapy

Date started: _____ /_____ /_____

Date stopped: _____ /_____ /_____

9. LYMPHODEPLETING THERAPY

Lymphodepleting therapy given prior infusion: Y | N

Drug	Total dose/mg*	Date started	Dose reduction, % and reason
		___ /__ /___	
		___ /___ /__	
		___/___/___	

* *Total dose = daily dose x number of days*

10. TOXICITY PROPHYLAXIS

CRS prophylaxis agents given:

Neurotoxicity prophylaxis agents given:

11. LAB ASSESSMENTS PRIOR TO LYMPHODEPLETION

Date of 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

	Value	Units	Date of sample
LDH		U/L	
LDH ULN		U/L	
Total serum ferritin		ug/L	
C-reactive protein		mg/L	
C-reactive protein ULN		mg/L	
Serum Creatinine		umol/L	

12. PATIENT ASSESSMENT

Karnofsky/Lansky Score: ____ ECOG: ___

13. COMORBID CONDITIONS

Prior viral exposure/infections: (select from checklist)

Comorbidities (Sorror et al)

- ☐ Arrhythmia
- ☐ Cardiac
- ☐ Cerebrovascular
- ☐ Diabetes
- ☐ Heart valve dis
- ☐ Hepatic, mild
- ☐ Hepatic, mod/sev
- ☐ Infection
- ☐ Inflammatory bowel disorder
- ☐ Obesity
- ☐ Peptic Ulcer
- ☐ Psychiatric
- ☐ Pulmonary, mod
- ☐ Pulmonary, severe
- ☐ Renal, mod/severe -> on dialysis: Y|N
- ☐ Rheumatologic
- ☐ Prior malignancy, specify: _____
- ☐ Other comorbidity: _____

Prior solid organ transplant: Y | N

Specify organ: _____

Year of solid organ transplant: _____

Cell Therapy PRODUCT

1. PRODUCT SOURCE

Date product collected (leukapheresis): _____ /_____ /_____

Tissue source: marrow | peripheral blood | other: _____

Cell type:

Lymphocytes unselected | CD4+ | CD8+ | other: _____

Where manufactured / processed:

Novartis |Kite pharma | Celgene | Janssen |

Cell processing lab on site | other: ____

2. AUTOLOGOUS PRODUCT

Method of collection:

BM aspirate |Leukapheresis | other: _____

Number of collections: _____

3. CELL MANIPULATION -

Not required for commercial products

Cells selected /modified/engineered: Y | N

Portion manipulated: Entire product |Portion

If portion, unmanipulated portion also infused: Y | N

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

Method used: _____

Complete following if genetically manipulated:

Transfection -> Viral transduction | Non-viral transfection

Gene editing -> specify gene

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

->T-cell receptor | CAR | Suicide gene, specify

Other genetic manipulation

Manipulated to recognize specific target/antigen:

If yes, specify target:

4. CELL PRODUCT ANALYSIS

Not required for commercial products

Transfection efficiency performed (genetically engineered cells):

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 |Other

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: _____

(number of infusions specified in the protocol)

Cell Therapy INFUSION

1. CELL PRODUCT IDENTIFIERS

Cell product ID _____ (e.g. Kite Konnect)

ISBT DIN number _____

Batch number _____ (Kymriah, Carvykti)

Lot number _____ (Yescarta, Tecartus)

If Product was not infused

Reason why not infused:

- ☐ Disease progression
- ☐ Clinical deterioration
- ☐ Comorbidities
- ☐ Product/manufacturing related
- ☐ OOS product
- ☐ CAR-T no longer indicated
- ☐ Patient declined
- ☐ Other: _____

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

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 __

Other, specify cell type and dose _____

4. CONCOMITANT THERAPY

Recipient receive concomitant therapy: Y | N

If yes, specify drugs: _____

When given: Simultaneous | Post cell therapy | Unknown