Cell Therapy - Pre-Infusion Data

Patient Information

1. PATIENT IDENTIFICATION

Hospital:
UPN:
Usual residence:
Postcode:
Race:
Indigenous status:
Consented: Y | N

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

3. PRIOR CELL THERAPY (CT)

This is first course of cell therapy (non HCT): Y | N |Unk
If no: reported to: ☐ ABMTRR ☐ 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: ☐ ABMTRR ☐ 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:

If Malignant disease - Complete Disease Classification Form

Date of diagnosis: __/__/__ (n/a for malignant disease)

8. BRIDGING THERAPY

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

If yes, Date started: __/__/__

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

COVID-19 positive any time prior: Y | N

If yes: Hospitalised: Y | N

Mechanically ventilated: Y | N

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:_____

Cell Therapy Product

1. PRODUCT SOURCE

Date product collected: __/__/__

Tissue source: marrow | peripheral blood | other: _____

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

Where manufactured / processed:

Novartis |Kite pharma | 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 of product: 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,specify construct | Suicide gene, specify

Other genetic manipulation

Manipulated to recognize specific target/antigen -> specify target:

4. CELL PRODUCT ANALYSIS

Not required for commercial products

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

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)

Lot number _____ (Yescarta, Tecartus)

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

If Product was not infused

Reason why not infused:

Disease progression| Comorbidities| Other: _____

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

If yes, specify drugs: _____

When given: Simultaneous | Post cell therapy | Unknown