ABMTRR Cell Therapy – Critical Fields

The following list of data fields are the minimum requirement for reporting to the Therapeutic Goods Administration (TGA). Reporting is mandatory based on the approved usage of the Car-T commercial product.

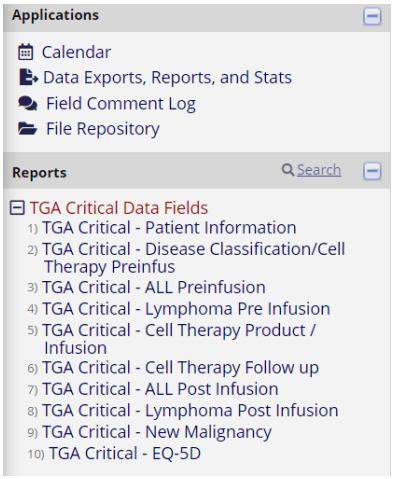
A separate mandatory / critical field list, for FACT accreditation centres will be available in a separate document and will be more comprehensive list.

The critical fields are grouped into Data Collection instruments:

Data Collection Instrument	Patient	Cell Therapy	Cell Therapy Follow Up
Patient Information	●		
Disease Classification		●	
ALL Preinfusion		●	
Lymphoma Pre Infusion		●	
CELL THERAPY Preinfusion		●	
CELL THERAPY Product		●	
CELL THERAPY Infusion		●	
CELL THERAPY Follow Up			●
ALL Post Infusion			●
Lymphoma Post Infusion			●
Quality Of Life EQ-5D-5L		●	●
Quality of Life EQ-5D-Y		●	●
New Malignancy			●
Preinfusion Documentation		●	
Postinfusion Documentation			●

Reports in REDCap

You can access the TGA Critical Fields Reports in REDCap.



Detailed documentation and PDF forms can be found on the ABMTRR website:
https://www.abmtrr.org/index.php/resources/data-management/

Field	Guideline
Patient Information	
Current Hospital	
Patient UPN	
Sex	
Date of birth	
Country of residence, State (Aust), Postcode	Australian and New Zealand patients
Patient consent	
Survival Status	
Date of latest contact	
Primary cause of death	Displays if deceased
Contributing causes of death	
Disease Classification	
Date of diagnosis	
Primary Disease for HCT / Cellular Therapy	Associated questions will display when **option** is selected
ACUTE LYMPHOBLASTIC LEUKAEMIA	
ALL Classification	
CNS disease: Did recipient have CNS leukaemia	
Disease Status at Infusion	
In CR by flow cytometry: Y|N	if in CR
Date assessed	
LYMPHOMA	
NHL B-cell classification	
Transformed from CLL	
Transformed from different lymphoma	
Prior histology	if transformed
PET (or PET/CT) scan performed Y|N	prior to preparative regimen / infusion
PET (or PET/CT) scan positive?	Positive lymphoma involvement at any disease site
Deauville Scale	Report the highest score if there are multiple values.
Disease Status prior Infusion	
Date assessed	
Total number of lines of therapy received	
ALL Pre Infusion	
Treatment was given: Y|N	
Treatment 1, 2, 3… given: Y|N	each line reported separately
Therapy type	e.g. induction, bridging to cell infusion
Intrathecal therapy Y|N	
Systemic therapy Y|N	
Specify systemic agents	
Radiation therapy Y|N	
Cell therapy Y|N	
Flow cytometry performed: Y|N	

Field	Guideline
BM / blood: date, %disease detected	
Lymphoma Pre Infusion	
Section 2 – Laboratory values at Diagnosis - *IPU Score*	
LDH LDH upper normal limit	
Section 3 – Nodal and Organ Involvement at Diagnosis - *IPI Score*	
Extranodal or splenic involvement: Y|N	
Sites of involvement	
Stage of organ involvement	
ECOG Score	
Section 7 – Disease Treatment Prior to Infusion	
Was therapy given: Y|N	
1st (2nd, 3rd...) line therapy given	each line reported separately
Systemic therapy Y|N	
Specify regimen	given as part of this line of therapy
Intrathecal therapy Y|N	
Radiation therapy Y|N	
Surgery Y|N	
Cellular therapy (e.g. CAR-T cells) Y|N	
This line of therapy given as bridging to cell infusion?	
CELL THERAPY Pre Infusion	
Referral Centre	
Referring doctor	
Date of first referral	
Section 2 – Cell Therapy	
Product Funding	
Section 3 – Prior Cell Therapy	
First cell therapy for this patient	
If “No”, number, date of prior cell therapies	
Section 4 – Prior Transplant HCT	
Received prior HCT	
Prior HCT date	
Section 5 – Product Identification	
Name of product	Required for field branching in form
Date of product request	Date of order placed in system
Date of manufacturing start	
Final product ready for shipping	*Gilead*
Final product shipped	*Gilead*
Date receipt of product	Date of product arrival at centre
Actual setting of infusion	*Gilead*
Section 6 – Planned HCT	
Subsequent HCT planned part of protocol	
Subsequent HCT type	
Section 8 – Disease Assessment	

Field	Guideline
Bridging therapy given prior to cell therapy	
Section 9 – Lymphodepleting Therapy	
Lymphodepleting therapy given Y|N	
Drug, total dose and units, date started	e.g. NHL: Flu 75mg/m2 + Cy 750mg/m2 ALL: Flu 120mg/m2 + Cy 1000mg/m2 (unless dose modified)
Dose reduction	If "Yes", % dose reduction & Reason dose reduction
Section 10 – Patient Assessment	
Karnofsky / Lansky Score	
ECOG prior to cell therapy	
Section 11 – Comorbid Conditions	
Co-existing diseases or organ impairment present (HCT-CI)?	If "Yes", comorbidities
CELL THERAPY Product	
Name of product	Required for field branching in form
Date product collected	e.g. apheresis date
Tissue source	
Cell type	
Product is out of specification	
Reason out of spec	
Section 6 – Product Infusion	
Total number planned infusions of this product	
CELL THERAPY Infusion	
Name of product	Required for field branching in form
Product was infused	
Reason why not infused	
Section 1 – Cell Product Identifiers	
Batch number	*Kymriah*
Lot number	*Yescarta*
Section 2 – Infusion	
Date of infusion	
Section 3 – Cell Doses	
Recipient weight	
Total number of cells / x10^__	
CELL THERAPY Follow Up	
Hospital	
UPN	
Date of Cell Therapy infusion	
Follow up period	**30 d / 100 d / 6 mth / annual**
Section 2 – Survival	
Date of actual contact	
Survival status	
Cause of death	Report on the Patient Information Page
Section 3 – Subsequent Cellular Infusions	

Field	Guideline
New course of cell therapy given since last report: Y|N	complete new Pre-infusion form
Reason given	
HCT given since last report	
Date of HCT	
Initial neutrophil recovery	and associated questions
Initial platelet recovery	and associated questions
Section 7 – Current Haematology Values	
Neutrophils x10^9/L	
Haemoglobin g/L	
RBC transfused 30 days prior	
Platelets x10^9/L	
Platelets transfused 7 days prior	
Section 8 – New Malignancy	
New malignancy diagnosed: Y|N	
Section 11 – CRS	
Cytokine Release Syndrome (CRS) Y|N	If 'Yes', all associated questions required
Section 12 – Toxicities - Neurotoxicity	
Neurotoxicity Y|N	If 'Yes', all associated questions required
Section 13 – Other Toxicities	
Hypogammaglobulinemia Y|N	If 'Yes', all associated questions required
Tumour lysis syndrome: Y|N	
Section 14 – Grade 3 or 4 Toxicities	
Developed grade 3 organ toxicity Y|N	If 'Yes', all associated questions required
Developed grade 4 organ toxicity Y|N	if 'Yes', all associated questions required
Section 16 – Infection	
Developed clinically significant infection since last report Y|N	If 'Yes', all associated questions required
Section 17 – Hospitalisation	
Hospital admission Y|N	If 'Yes', all associated questions required
Section 18 – High Cost Medication Usage	
High cost medications used	
Section 19 – Functional Status	
Recipient/female partner pregnant in this reporting period Y|N	If 'Yes', all associated questions required
ALL Post Infusion	
Hospital	
UPN	
Date of Cell therapy infusion	
Follow up period	**30 d / 100 d / 6 mth / annual**
Section 1 – Best response to HCT or Cell Therapy	
Best response to Cellular Therapy	
Date of best response or previously reported	
Tests performed at time of best response	
Molecular testing	If 'Yes', all associated questions required
Flow cytometry	If 'Yes', all associated questions required

Field	Guideline
Cytogenetics tested	If 'Yes', all associated questions required
Section 3 – Disease detection since last report	
Disease was detected by any assessment method: Y|N If 'Yes'	
Molecular testing	If 'Yes', all associated questions required
Flow cytometry	If 'Yes', all associated questions required
Cytogenetic testing	If 'Yes', all associated questions required
Lymphoma Post Infusion	
Hospital	
UPN	
Date of Cell therapy infusion	
Follow up period	**30 d / 100 d / 6 mth / annual**
Section 1 – Best response to HCT / Cell Therapy	
Best response **by PET (metabolic)** criteria since last report	
Date assessed	
Section 3 – Disease Relapse or Progression since last report	
Relapse or progression occurred	
Disease detected by:	
Molecular testing Date sample	
Cytogenetic testing: FISH, date Karyotyping, date	
Radiological assessment Date assessed	
Section 5 – Disease status at time of evaluation	
Current disease status by PET (metabolic) criteria	
Deauville Score **at 12 months**	
Date assessed	
If 'Not assessed', Reason not assessed	
New Malignancy	
Hospital	
UPN	
Date of Cell therapy infusion	
Follow up period	**30 d / 100 d / 6 mth / annual**
New Malignancy details	
New malignancy diagnosis	
Date of diagnosis	
Quality of Life EQ-5D / EQ-5D-Y	
Quality Of Life EQ-5D-5L	**At Infusion / 30 d / 100 day / 6 mth / annual**