Cell Therapy Data Collection Guidelines for CORE FORMS

Contents

Version 3; February 2026

PURPOSE OF THESE GUIDELINES

The ANZTCT cell therapy data collection is aligned with CIBMTR data collection.

These are the guidelines to the Core cell therapy forms, i.e. Cell therapy Pre-infusion, Product, Infusion and EQ5D. Please refer to the accompanying guidelines for the associated disease forms.

In these guidelines, the explanation or definition of every field may not be included if they seem self-explanatory. For the comprehensive guidelines and definitions please refer to the CIBMTR Instruction Manual website: www.cibmtr.org/manuals/fim

There are questions that are additional to the CIBMTR data collection required to comply with the MSAC requirements and along with our local Australian needs.

This document will contain guidelines for these additional questions as well any extra information which may be useful for further clarification of the CIBMTR questions and forms.

If you would like to suggest any improvements, please contact us at: Registry@anztct.org.au

ANZTCT REGISTRY PROTOCOL

The details on the purpose and operations of the Australia New Zealand Transplant and Cellular Therapies Registry are located at: https://anztct.org.au/wp-content/uploads/2026/01/ANZTCT-Registry-Protocol-4.4.pdf

ANZTCT REGISTRY DATABASE ACCESS

REDCap™ is utilised for submission of cell therapy data. The web-based application allows centres to electronically submit the required forms for the collection of cell therapy data.

Assistance with database access and support is provided by the ANZTCT Registry. You can contact us via email: registry@anztct.org.au

The ANZTCT Registry will provide an introduction to the data collection forms and training to new users. This is recommended to all new users.

CELL THERAPY – DEFINITIONS

The intent of cell therapy is **other** than to restore haematopoiesis.

Cell therapy may be given to treat disease and infection without prior HCT, examples include but are not limited to CAR T-cells.

Donor lymphocytes infusions (following HCT) are no longer reported using the Cell Therapy forms.

REGISTRATION REQUIREMENTS

Forms required at registration:

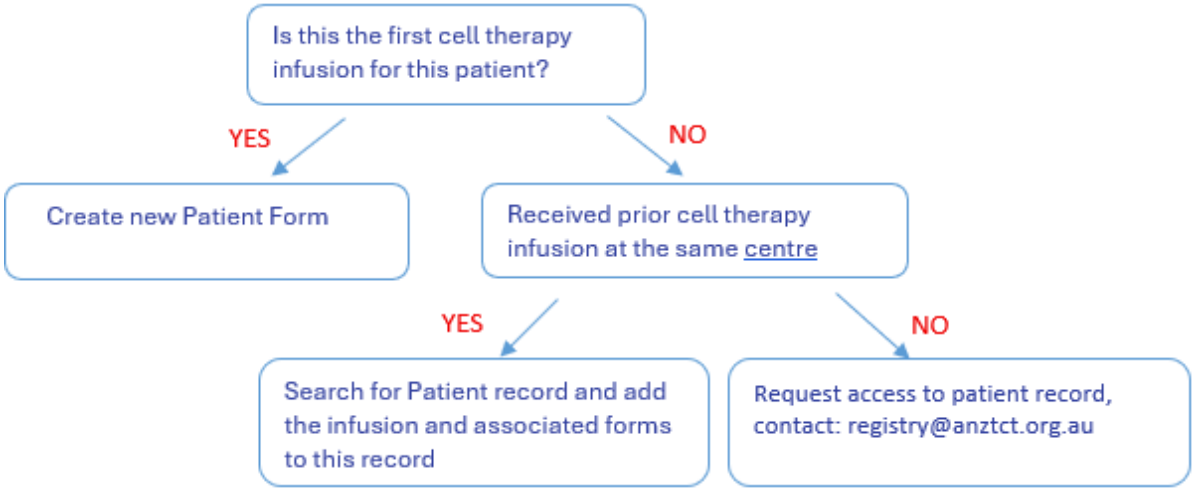
- Patient Information
- Disease Classification
- Disease Specific Pre-Infusion:
    - ALL (Acute Lymphoblastic Leukaemia)
    - Lymphoma
    - Myeloma
- Cell therapy (CT) Pre-infusion
- Cell therapy (CT) Product - for each product
- Cell therapy (CT) Infusion - for each infusion of each product
- Quality of Life EQ-5D

Forms required at follow up

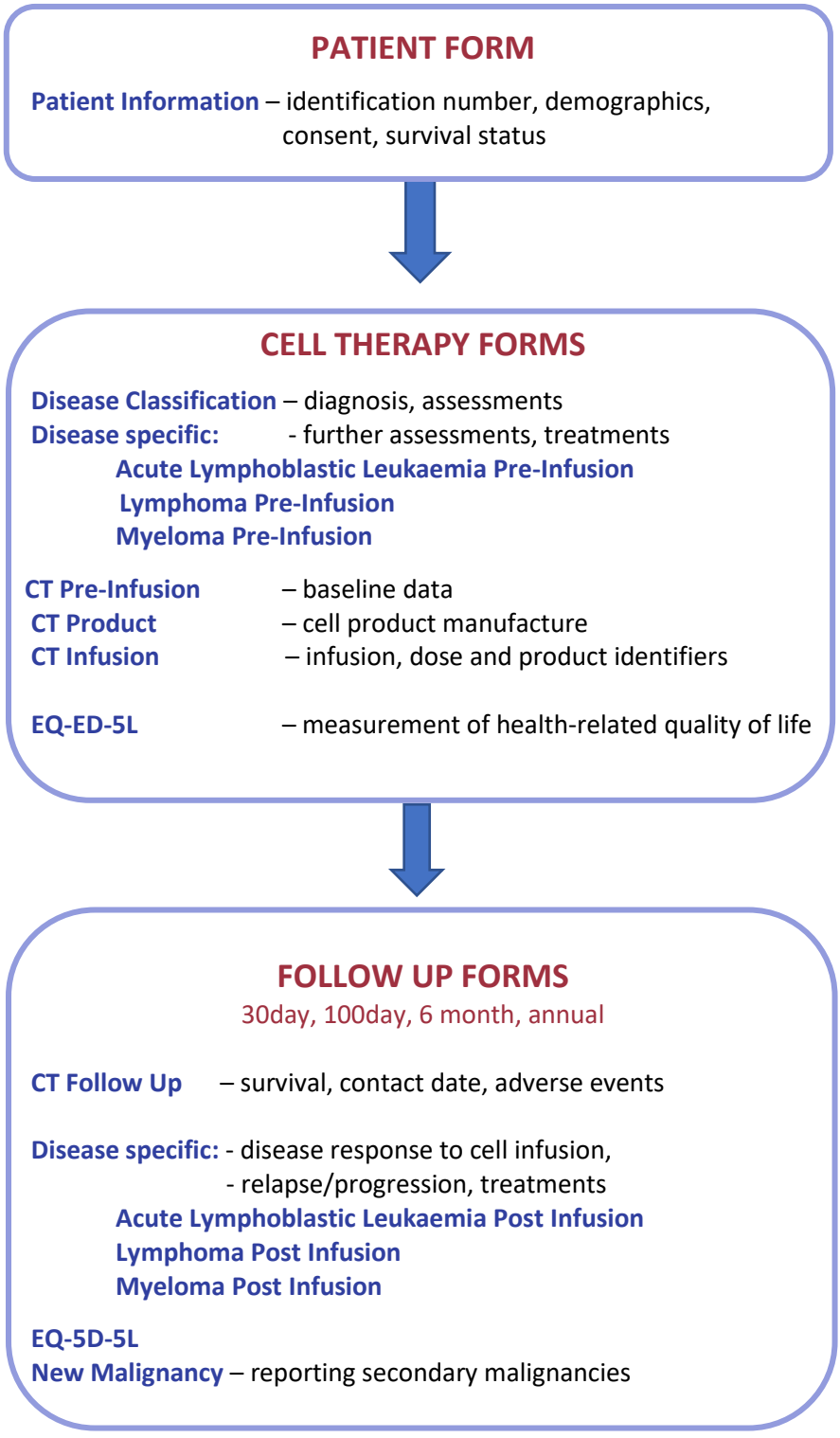
These are required at 30 days, 100 days, 6 months, and then annually thereafter

- Cell therapy (CT) Follow Up
- Quality of Life EQ-5D
- Disease Specific Post Infusion
    - ALL (Acute Lymphoblastic Leukaemia)
    - Lymphoma
    - Myeloma
- New Malignancy - if new malignancy is diagnosed (different diagnosis to cell therapy indication)

When a new patient record should be created:



FORM SUBMISSION WORKFLOW



GENERAL GUIDELINES FOR COMPLETING FORMS

The pdf versions of the forms is available on our website under data management resources : https://anztct.org.au/registry/data-management-resources/

These may be used as a guide to assist with the data collection. Please note that not all options to the questions (as they appear in REDCap) are shown on these forms.

Guide for entering data

Date fields

Dates are entered as: dd/mm/YYYY

Please do not leave these blank if an estimate can be entered, using the following guidelines:

- only the month and year is known - enter as 15/mm/YYYY
- only the year is known - enter as 01/07/YYYY

In some cases, this rule may not make sense e.g., the diagnosis is in May and it is known that treatment was started on a given date in mid-May, then the diagnosis date may be entered as the 1st May.

Reporting lab values <, > and range of numbers.

Fields that are set as accepting numbers only will not accept '<' or '>' characters. Please report these results as described below:

- For < Less Than values: n – 1
- For > Greater Than values: n + 1
- When a value is reported as a range of numbers, report the median value of the range

Examples:

- Reporting <5% blasts in the bone marrow should be reported as 4% blasts
- Chimerism results indicating >95% donor cells should be reported as 96% donor cells
- 60-70% blasts in the bone marrow should be reported as 65% blasts

A fraction is given as 45-50%. If required to report a whole number, the median value is 47.5%, then apply rounding to give a value of 48%

Attaching documents

There are provisions to upload documents such as cytogenetic reports and other pathology reports to accompany assessment results. These are not required by the ANZTCT Registry however may be useful for confirmation of results.

DATA REQUIREMENTS FOR CELL PRODUCTS NOT INFUSED

Patients eligible for a commercial cell therapy product who undergo apheresis but fail to receive the cells are also required to be registered.

The minimum data requirement for these is shown below:

Form Name	Section heading	Field name
Patient form		All questions Patient name fields are optional
Disease Classification	Diagnosis	Primary Disease for Cellular Therapy NHL, B-cell classification (lymphoma only)
CT Pre-infusion	2. Cell Therapy	Product funding Axicabtagene funding (Axicel only)
CT Infusion	 1.Cell Product Identifier *(specific to the product)*	Name of Product Product was infused Reason why not infused Cell product ID / Batch No / Lot number

FORMS

PATIENT INFORMATION FORM

These questions can be found in the Cell Therapy – Pre-Infusion Data Form

DEMOGRAPHICS

AID

The unique identifier assigned to the patient by the REDCap database at the time the patient information is first entered.

If the patient has received a prior transplant, the AID will be subsequently reassigned with the Record ID existing in the transplant database.

Current Hospital

This is the hospital responsible for follow up at the time of reporting. This may be changed from the infusion centre if the patient relocates to another centre that also reports to ANZTCT.

Patient UPN

This is the Unique Patient Number that the centre assigns to each patient or infusion. The patient's Hospital Medical Record Number should not be used.

Name ID - optional fields. These are only used to assist the transplant centre in identifying the recipient e.g., for follow up or queries.

Date of birth

Sex

Usual residence (Country and State)

This is where the patient normally resides. Do not enter a temporary accommodation the patient may be staying at during their treatment.

Postcode

CIBMTR ID (CRID) - identifier assigned by CIBMTR (Centre for International Blood and Marrow Transplant Research) to recipients whose transplants and/or cell therapies have been reported to them.

EBMT ID - identifier assigned by EBMT (European Society for Blood and Marrow Transplantation) to recipients whose transplants and/or cell therapies have also been reported to them.

Other Registry ID

Enter identifiers from other registries that the patient may also be contributing data to, e.g. Disease specific registry

Name of registry - appears if information is entered into the previous field

Race - more than one may be indicated

Indigenous status - currently applies to Australians only

Patient consent

Patient consent is required for the transfer of information describing themselves, their cell therapy procedures and outcomes to the ANZTCT Registry.

Reporting of treatment and outcomes for patients receiving MBS funded commercial CAR-T products is required for safety and quality purposes and for TGA reporting. it is also required for the data to also be available for research and collaboration.

The patient consent procedure will be dependent on the individual hospital's policy.

For more information and a sample patient information and consent form, refer to the ANZTCT Protocol: https://anztct.org.au/registry/data-management-resources/

SURVIVAL

Survival Status / Date of latest contact

This date is used in survival analyses and should be the latest date available at the time of reporting (date of actual contact). This date may be obtained from correspondence or pathology results etc.

If the patient has died, then this will be the date of death.

CAUSE OF DEATH

DOD audit, date estimated

Tick this checkbox if the exact date of death is not available and then provide a date in the Date of latest contact, using the following guide

- only the month and year is known - enter as 15/mm/YYYY
- only the year is known - enter as 01/07/YYYY

Cause of death confirmed by autopsy

Primary cause of death

Report only one main cause of death; and report the contributing causes in the following question.

The primary cause should be the underlying cause of death, which is 'the disease or injury that initiated the chain of events that led directly or inevitably to death.' Do not report the mode of death e.g., cardiac or respiratory arrest.

Examples:

- If an infection leads to heart failure, report the infection as the primary cause of death.
- If the patient dies of acute renal failure which was associated with progressive myeloma, then report myeloma as the primary cause of death.

If the recipient has recurrent/persistent/progressive disease at the time of death, consider if the disease was the primary cause or contributing cause of death. It should not be assumed that the presence of disease indicates that the disease was the primary cause of death.

It may be reported on a post-mortem as the primary cause, however, for registry reporting, use the criteria below to help determined how to report this.

- **Disease is present and progressing -** the main cause of death should be reported as 'Relapse/Progression/Persistent disease', regardless of any accompanying complications or infections during the post-transplant period.
- **Disease is present and stable or there had been an improvement** after transplant/cell therapy, and the patient dies of complications or infections, then the main cause of death would then be the complication or infection.

Contributing causes of death

Select as many contributing factors as relevant.

CELL THERAPY PRE-INFUSION

This form captures the baseline recipient data for **one** course of cell therapy.

1. PATIENT IDENTIFICATION

UPN

Hospital - site of infusion

Patient Postcode

Referral centre and doctor

Date of first referral (for cell therapy)

2. CELL THERAPY

Participating cellular therapy clinical trial

List all studies if participating in more than one.

If yes **- Study sponsor**, i.e. sponsor type: Corporate/Industry, investigator initiated, other.

Name of the sponsor and study identification number, if applicable.

Refer to: ANZCTR, ClinicalTrials.gov Identification Number or use other official reference number.

If no – **Reason why not in clinical trial**

Options include:

- Institutional guidelines/standard treatment
- Hospital exemption
- Compassionate use

Name of Product

This will be the name of the commercial product or select 'other product' for non- commercial products

Product Funding

Options include:

- Clinical Trial
- Commercial - MBS
- Commercial - MTOP
- Commercial – self-funded

Axicabtagene funding

This displays if 'Axicabtagene ciloleucel' is selected for the **Name of Product** and 'Commercial – MBS' is selected for **Product Funding**.

Indicate if Axicabtagene ciloleucel' is used as 2nd line therapy or 3rd line or later.

3. PRIOR CELL THERAPY

First cell therapy for this patient

Is this the first cell therapy given to this patient? Do not include transplants.

Cell therapies given at other centres are included here to give the most complete treatment history.

If this is not the first cell therapy, the following questions will display including:

Prior cell therapy/ies were reported to ANZTCT/CIBMTR/EBMT

Specify number of prior cell therapies

Date of prior cell therapy

Centre where infusion took place

Indication for prior cell therapy

Prior cell source

Complete these for each cell therapy infusion if there were multiple infusions

4. PRIOR TRANSPLANT (HCT)

Received prior HCT

If the recipient has received a transplant at any centre, the following will display including:

Prior HCT(s) were reported to ANZTCT/CIBMTR/EBMT

Prior HCT date(s)

Centre where infusion(s) took place

Prior HCT(s) type

There are additional questions to capture this information for additional prior transplants if these have not been reported to the ANZTCT Registry.

5. PRODUCT IDENTIFICATION

Product(s) associated with this course of cell therapy genetically modified

Indicate if the product (or any of the products if more than one) were genetically modified.

This includes manipulation such as gene editing or insertion of different genes to alter its expression, e.g. CAR T-cells are genetically modified T-cells directed towards specific tumour targets.

Donor type

Options: Autologous, Allogeneic related, Allogeneic unrelated, Autologous cord blood

If more than one donor is used for this cell infusion, additional fields will display to capture the details of the second donor further down in this section.

Depending on the type of donor, the following fields will display

Donor is Allogeneic unrelated

Same donor used for prior cell therapy/HCT

GRID

Donor registry name

Donor country

Donor age, DOB is optional

Donor sex

Donor is Allogeneic related

Donor relation

Same donor used for prior cell therapy/HCT

Donor age, DOB is optional

Donor sex

Specify number of products: (per protocol) (as part of this course of cellular therapy)

This is the number of products to be infused as part of the protocol, given regardless of disease response. This will determine the correct number of CT Product Forms required. A new Product Form is required for each product.

Single product examples:

- A donor using the same collection method and mobilisation cycle, and only one set of manufacturing steps are applied to the collected material. The collections may be performed on different days
- The cells are processed by different methods and at the end of manufacturing are combined for a single infusion or administration

Multiple product example:

- Products from the same donor but obtained using different manufacturing steps are considered different products and require multiple Cell Product Forms.

Additional donors were used for these infusions

If more than one donor was used for this course of cell therapy, ticking yes will display the relevant questions as shown above depending on the donor relation, and details of the product.

Timeline of product manufacture is collected in the following date fields:

Date of product request

Date manufacturing started

Final product ready for shipping

Final product shipped

Date receipt of product

Planned setting of infusion

Report if the infusion was planned to be given as an inpatient or outpatient.

Actual setting of infusion

This is asked in case the infusion setting was not as planned.

6. PLANNED HCT

Subsequent HCT planned as part of protocol

If a transplant is planned to be given following the cell infusion, complete this section, even if the transplant does not proceed.

If the patient relapses and then the transplant is 'planned' - this should not be included here.

Subsequent HCT type

Circumstances for subsequent HCT

Select from the options:

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

7. INDICATION FOR CELLULAR THERAPY

Indication for cell therapy

Depending on the indication type, associated forms and questions apply as follows:

The Disease Classification Forms are required for:

- Malignant haematological disorder - additional forms for Lymphoma and ALL
- Non-malignant disorder
- Solid tumour

Indication is associated post HCT –GVHD prophylaxis

- preventing disease relapse
- suboptimal donor chimerism
- immune reconstitution
- GVHD treatment

there are no associated questions, go to the section 8

Indication is given for prevention (may not be associated with HCT)

- infection prophylaxis - specify organism

Other indications e.g. cardiovascular, musculoskeletal, neurologic, ocular, pulmonary, infection

Specify the diagnosis and diagnosis date

8. BRIDGING THERAPY

Bridging therapy was given

If yes, date started

Bridging therapy is treatment given to control the disease leading up to starting lymphodepleting treatment / cell infusion, either after apheresis or during the manufacturing period of the cell therapy product.

Details of the bridging therapy is reported on the disease specific form, in the Disease treatment section.

Disease Assessments – (previously Section 8). This section has been inactivated as this information is captured on the disease specific forms

9. LYMPHODEPLETING THERAPY

Indicate if lymphodepleting therapy was given.

Lymphodepleting agent

Total dose and units

The total dose is the daily dose multiplied by the number of days, e.g. Fludarabine 25mg/m^2 x 3 days is a total dose of 75mg/m^2. Report the actual dose given rather than the prescribed or daily dose.

Was there a dose reduction

Reason for dose reduction

Date started

If a test dose of a drug is given, ensure the date started is the date of the first therapeutic dose.

10. TOXICITY PROPHYLAXIS

CRS prophylaxis

Neurotoxicity prophylaxis

Report all agents given as pre-emptive treatment

11. LAB ASSESSMENTS PRIOR TO LYMPHODEPLETION

Report the values in the correct units and the date the sample was collected for the following:

WBC x 10^9/L

Neutrophils x10^9/L

Lymphocytes x10^9/L

Haemoglobin g/L

Haematocrit %

RBC transfused ≤ 30 days prior

Platelets x 10^9/L

Platelets transfused ≤ 7 days prior

Growth factors were given ≤ 7 days prior (or long-acting growth factors ≤ 14 days prior)

LDH U/L within 30 days prior to lymphodepletion

LDH ULN U/L (upper limit of normal)

Total serum ferritin µg/L

C-reactive protein (mg/L)

C-reactive protein ULN mg/L (upper limit of normal)

Serum Creatinine µmol/L

12. PATIENT ASSESSMENT

Karnofsky/Lansky score prior cell therapy

The patient performance status should be assessed within 30 days prior to the cellular infusion. These should be documented in the source documentation rather than derived from available sources.

	Karnofsky Scale (recipient age≥16 years)	Lansky Scale (recipient age <16 years)
(80-100)	Able to carry on normal activity; no special care is needed	Able to carry on normal activity; no special care is needed
100	Normal, no complaints, no evidence of disease	Fully active
90	Able to carry on normal activity	Minor restriction in physically strenuous play
80	Normal activity with effort	Restricted in strenuous play, tires more easily, otherwise active
(50-70)	Unable to work, able to live at home cares for most personal needs, a varying amount of assistance is needed	Mild to moderate restriction
70	Cares for self, unable to carry on normal activity or to do active work	Both greater restrictions of, and less time spent in active play
60	Requires occasional assistance but is able to care for most needs	Ambulatory up to 50% of time, limited active play with assistance/supervision
50	Requires considerable assistance and frequent medical care	Considerable assistance required for any active play, fully able to engage in quiet play

(10-40)	Unable to care for self, requires equivalent of institutional or hospital care, disease may be progressing rapidly	Moderate to severe restriction
40	Disabled, requires special care and assistance	Able to initiate quiet activities
30	Severely disabled, hospitalization indicated, although death not imminent	Needs considerable assistance for quiet activity
20	Very sick, hospitalization necessary	Limited to very passive activity initiated by others (e.g. TV)
10	Moribund, fatal process progressing rapidly	Completely disabled, not even passive play

ECOG prior to cell therapy

ECOG	Description
0	Fully active, able to carry on all pre-disease performance without restriction.
1	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work.
2	Ambulatory and capable of all selfcare but unable to carry out any work activities. Up and about more than 50% of waking hours.
3	Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours.
4	Completely disabled. Cannot carry on selfcare. Totally confined to bed or chair

Toxicity And Response Criteria Of The Eastern Cooperative Oncology Group.
Am J Clin Oncol 5:649-655, 1982.

13. COMORBID CONDITIONS

Questions associated with COVID-19 have been removed.

Prior viral exposure/infection(s)

Report if the patient was positive for any of the viral exposures or infections from the checklist. Please note that this a list of viruses for concern rather than a complete list.

For an equivocal result, these should be selected if it is noted as a concern. Do not select if the result was negative.

Were there any co-existing diseases or organ impairment present according to the HCT comorbidity index (HCT-CI)?

Comorbidities (HCT CI Score)

Report a comorbidity in the following areas if any of the specified criteria are met.

Report co-morbidities that were detected within six months of the cell therapy, which is different than HCT reporting. The six-month rule applies to assessments that need to be performed in order to determine if a comorbidity is present e.g. PFT, LFTs, creatinine, BMI.

If the co-morbidity is denoted as "ANY history", the six-month rule does not apply.

Comorbidity	**Definition / criteria**
Arrhythmia	Any history of (but not limited to) one or more of the following which required antiarrhythmic treatment: • Bradycardia (< 50 bpm and sustained) • Tachycardia (> 120 bpm and sustained) • Atrial fibrillation • Sick sinus syndrome • Ventricular arrhythmias
Cardiac (Cardiovascular disease)	The presence of one or more of the following: • Any history of coronary artery disease (one or more vessels requiring medical treatment, stent, or bypass) • Any history of myocardial infarction • Any history of congestive heart failure (regardless of an LVEF >50% at the start of preparative regimen) • LVEF ≤ 50% (or a shortening fraction (SF) of < 26% for paediatric cases) on most recent evaluation prior to the start of the preparative regimen / lymphodepleting therapy
Cerebrovascular disease	Any history of one or more of the following: • Transient ischemic attack • Cerebrovascular accident/stroke • Subarachnoid, subdural, epidural, or intraparenchymal haemorrhage
Diabetes	Current (within 4 weeks prior to HCT / CT) history of diabetes or steroid-induced hyperglycaemia requiring insulin or oral hypoglycemics, not controlled by diet alone.
Heart valve disease	One or more of the following, found on the most recent echocardiogram: • At least a moderate or severe degree of valve stenosis, regurgitation or insufficiency as determined by echo, whether the valve is mitral, aortic, tricuspid or pulmonary • Prosthetic mitral or aortic valve • Symptomatic mitral valve prolapse
Hepatic, mild See note below	One or more of the following: • Chronic hepatitis • Any diagnosed history of Hepatitis B or Hepatitis C • Bilirubin > ULN to 1.5 x ULN • AST or ALT > UL to 2.5 x ULN
Hepatic, moderate/severe See note below	One or more of the following: • Liver cirrhosis • Bilirubin > 1.5 x ULN • AST or ALT > 2.5 x ULN

Infection	One or more of the following requiring therapeutic antimicrobial / antifungal / antiviral treatment prior to the preparative regimen (or prior to Day 0 if no preparative regimen is being given) with a recommendation to continue treatment after Day 0: • Documented infection • Fever of unknown origin • Pulmonary nodules suspicious for fungal pneumonia • A positive PPD test requiring prophylaxis against TB • Infection requiring antimicrobial treatment continued after Day 0 *Do not report an infection comorbidity if the infection resolved prior to infusion and there was a recommendation to continue, or the recipient continued medication post-infusion as prophylaxis* Paediatric criteria The presence of one or more of the following: • History of invasive fungal infection • Infection requiring antimicrobial treatment continued after Day 0 *Do not report an infection comorbidity if the infection resolved prior to infusion and there was a recommendation to continue, or the recipient continued medication post-infusion as prophylaxis*
Inflammatory bowel disease	Any history of: • Crohn's disease or • Ulcerative colitis requiring treatment
Obesity	Body mass index (BMI) > 35.0 kg/m2 • Evaluation is based on the most recent measurement of the BMI prior to the start of the preparative regimen (or prior to Day 0 if preparative regimen was not given). Paediatric: use BMI-for-age ≥ 95% during the pre-infusion work-up period. Refer to: https://www.cdc.gov/growthcharts/ to determine the BMI-for-age if unknown .
Peptic ulcer	Any history of peptic ulcer (gastric or duodenal) confirmed by endoscopy or radiologic diagnosis and the recipient has or is receiving treatment.
Psychiatric disturbance	Any psychiatric illness requiring treatment, including regular counselling / therapy sessions, within four weeks prior to the pre-infusion work-up period. Treatment also includes the recommendation / prescription of medication and / or regular counselling / therapy sessions but the recipient is non-compliant. Examples of psychiatric disturbances include, but are not limited to, depression, anxiety, Attention-Deficit Disorder (ADD), Attention-Deficit Hyperactivity Disorder (ADHD), schizophrenia, or bipolar disorder. Do not report for recipients only receiving treatment (including counselling / therapy sessions) "as needed" or PRN
Pulmonary, * refer to the moderate	Any one or more of the following at the time of pre-infusion evaluation: • Adjusted DLCO 66-80%, using the Dinakara equation*

	• FEV1 66-80%** • Dyspnoea on slight activity attributed to pulmonary disease and not anaemia
Pulmonary, severe	Any one or more of the following at the time of pre-infusion evaluation: • Adjusted DLCO ≤ 65%, using the Dinakara equation* • FEV1 ≤ 65%** • Dyspnoea at rest attributed to pulmonary disease and not anaemia • Requires intermittent or continuous supplemental oxygen Paediatric criteria Any one or more of the following at the time of pre-infusion evaluation: • Adjusted DLCO ≤ 65%, using the Dinakara equation* • FEV1 ≤ 65%** • Dyspnoea at rest attributed to pulmonary disease and not anaemia • Requires intermediate or continuous supplemental oxygen • History of mechanical ventilation. Do not report if intubated due to premature birth for <24 hours.
Renal, moderate/severe See note below	Any one or more of the following: • Serum creatinine > 177 µmol/L • On dialysis in pre-infusion evaluation period • Prior renal transplant recipient Paediatric criteria Any one or more of the following: • Serum creatinine > 177 µmol/L • eGFR < 60 mL / min / 1.73^2 (by Bedside Schwartz calculation for < 18 years old, CKD-EPI calculation for ≥18 years old) • On dialysis in pre-infusion evaluation period • Prior renal transplant recipient
Rheumatologic	Any history of rheumatologic disease requiring treatment including: • Systemic lupus erythematosus • Rheumatoid arthritis • Sjogren' • Polymyositis • Dermatomyositis • Mixed connective tissue disease • Polymyalgia rheumatic • Polychondritis • Psoriatic arthritis • Sarcoidosis • Vasculitis syndromes
Prior malignancy	Any solid tumours, haematologic malignancies, skin malignancies that have been treated at any time point in the recipient's past history. Treatment includes surgery and/or resection. A history of any benign tumours should not be reported. If the recipient is receiving an infusion for a disease that transformed from one

	disease to another (i.e., MDS to AML, CLL to NHL), the original malignancy should not be reported as a comorbidity.

* Refer to Appendix J: Reporting Comorbidities - Forms Instruction Manual - 1

** If the PFT lists both a “control” FEV1 and “post-dilator” FEV1, the “control” FEV1 should be used to determine if a pulmonary comorbidity is present.

Note: Hepatic and renal values (AST, ALT, Total bilirubin, serum creatinine)

Assessments should include repeated values on different days between day –24 and start of preparative regimen. If only one value is available, then the second value(s) can be the most recent between days –40 to -25. Report the comorbidity if the value closest to the preparative regimen is within the criteria mentioned above.

If the liver function test or serum creatinine values closest to the start of the preparative regimen are within normal limits, the comorbidity should not be reported.

When determining the severity of the hepatic comorbidity, the value closest to the start of the preparative regimen / lymphodepleting therapy should be used.

Recipient on dialysis immediately prior to lymphodepleting therapy

- this question displays when ‘Renal moderate/severe’ is selected as a comorbidity.

Prior malignancy type

- this question displays when ‘Prior malignancy’ is selected as a comorbidity.

Please refer to the references below for more information

References:

1. CIBMTR Forms Instruction Manual, Appendix J

2. Sorror ML, Storb RF, Sandmaier BM et al. Comorbidity-Age Index: A Clinical Measure of Biologic Age Before Allogeneic Hematopoietic Cell Transplantation. J Clin Oncol 2014;32(29)

CELL THERAPY PRODUCT

The Cell Therapy Form captures product specific information for all products given to a recipient as part of a course of cell therapy.

If more than one product is infused, then these should be reported on a separate Cell Therapy Product Form

Examples of single and multiple products:

Single product - report on one form:

- A donor using the same collection method and mobilization cycle, and only one set of manufacturing steps are applied. The collections may be performed on different days
- The cells are processed by different methods and at the end of manufacturing are combined for a single infusion or administration

Multiple products - report on separate forms:

- Products from the same donor but obtained using different manufacturing steps and infused separately are considered different products.

Name of product

As reported in the Pre-Infusion form

1. PRODUCT SOURCE

Tissue source

Report “peripheral blood” for commercial products Kymriah, Yescarta and Tecartus.

Cell type

These are the cells harvested for use in the cell product.

Report ‘Lymphocytes (unselected)’ for commercial products Kymriah, Yescarta, Tecartus and Carvykti.

Where was product manufactured / processed

The name of the pharma/biotech company, or a cell processing lab on or off site and specify details when indicated.

If the product is from an NMDP donor used for a prior HCT, report that the product was manufactured by a “Cell processing laboratory at the same centre as the product is being infused,”

4. AUTOLOGOUS PRODUCT

If allogeneic, go directly to Cell Manipulation questions, *if applicable*

Method of product collection - e.g. BM aspirate, leukapheresis

Number of collections

Report the number of days it took to collect the necessary cells for the autologous product.

- A patient received mobilising agents and underwent a two day PBSC collection. This would be considered as two collections.
- A patient received mobilising agents and underwent a two day PBSC collection resulting with inadequate cell count. Additional mobilisation agent was added followed by another collection. This would be considered as three collections.
- Do not count any collections where the product is not used e.g. inadequate collection is discarded

5. CELL MANIPULATION

This section is not applicable for commercial products – this section shows/hides depending on the product selected in the 'Name of product' question.

Cells were selected/ modified / engineered prior to infusion?

This section should be completed if the cells were selected (positive/negative cell selection), genetically engineered or modified in any other way.

If the manipulation consists of several steps, individual steps do not need to be reported as separate manipulations, e.g. T-cell depletion as part of expansion does not need to be reported. However, if T-cell depletion and/or washing is done as separate manipulations, they should be reported.

Do not report cryopreservation or plasma removal (as part of cryopreservation) as a method of manipulation

If yes, the following questions apply:

Specify portion manipulated: Entire product | Portion of product

If portion was manipulated, then was unmanipulated portion also infused?

Was same manipulation method used on entire (all portions) product?

Method(s) used - indicate all methods

If 'Genetic manipulation' is selected, then the following fields display:

Indicate the type of genetic manipulation:

- Transfection: **if yes** –
  - Viral transduction: Lentivirus, Retrovirus
  - Non-viral transfection: Transposon, Electroporation, other
- Gene editing: if yes - Specify gene
- Cells engineered to express a non-native protein: if yes - specify inserted protein: T-cell receptor, CAR, Suicide gene
  - If CAR, specify CAR construct
  - if suicide gene, specify the suicide gene

Specify other method if none of above.

Product was manipulated to recognize a specific target/antigen

Specify target(s), e.g. viral, tumour/cancer antigen or specify other

Please refer to the CIBMTR Instruction manual for more information of the manipulation methods.

6. CELL PRODUCT ANALYSIS

This section is not applicable for commercial products – this section shows/hides depending on the product selected in the 'Name of product' question.

Transfection efficiency performed?

Relevant for genetically engineered cells only.

Transfection efficiency is calculated as a percentage of transfected cells from all cells in the sample. Methods used to determine transfection efficiency include flow cytometry, fluorometry, microscopy, real-time quantitative PCR, etc.

If yes, complete the following

- Date performed
- Transfection efficiency %
- Transfection efficiency target achieved?

Viability of cells performed?

If yes, complete the following

- Date performed
- Viability of cells %
- Method of testing cell viability: 7-AAD, Propidium iodide, Trypton blue or specify other method

If both methods of viability testing are performed, report 7-AAD results.

7. PRODUCT OUT OF SPECIFICATION

Applies to commercial products only

Products must meet predefined manufacturing specification before release for use. If the product is not produced within manufacturing specifications, indicate the reason why.

In some cases, the product may not meet a specific criteria but is still safe to administer. The infusion may go ahead with approval from the treating clinician.

Specifications for product release includes cell viability, total cell count, CD4:CD8 ratio, transduction efficiency and others.

8. PRODUCT INFUSION

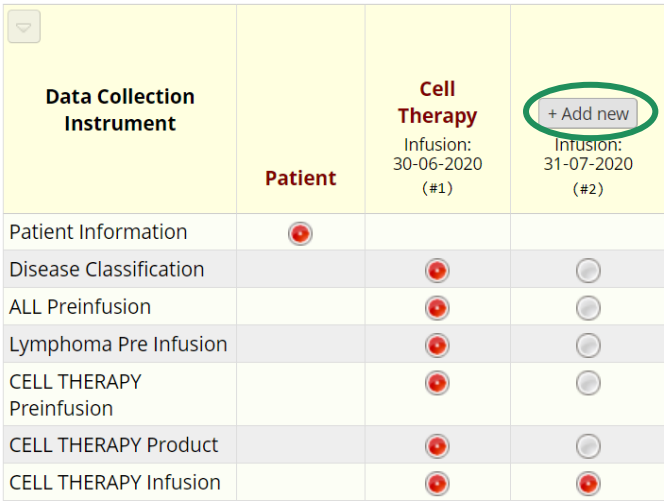
Total number of planned infusions of this product (as this course of cell therapy)

Report the number of infusions specified per protocol to be given regardless of disease assessment. This number will indicate the number of Cell Therapy Infusion forms due.

CELL THERAPY INFUSION

This form captures infusion-specific information for all infusions given to a recipient as part of a course of cell therapy.

If there is more than one infusion, as defined by event date, each infusion must be reported on a separate Cell Therapy Infusion Form. To complete a second infusion form, select the **+ Add new** button on the previous infusion event.



Data Collection Instrument	Patient	Cell Therapy Infusion: 30-06-2020 (#1)	+ Add new Infusion: 31-07-2020 (#2)
Patient Information	●		
Disease Classification		●	○
ALL Preinfusion		●	○
Lymphoma Pre Infusion		●	○
CELL THERAPY Preinfusion		●	○
CELL THERAPY Product		●	○
CELL THERAPY Infusion		●	●

Name of Product

As reported on the Cell Therapy Pre-infusion Form

Product was infused: Y | N

Reason why not infused

Indicate if the product was actually infused. If not, report the reason why it did not proceed.

If the product was not infused, minimum data is required. Please refer to Section heading: Data requirements for cell products not infused under General Guidelines for Completing Forms

1. CELL PRODUCT IDENTIFIERS

Report the appropriate identifier which should be located on the product bag or shipping document.

- **Cell product ID** – Kite Connect
- **ISBT DIN number**
- **Batch number** - must be reported for Kymriah and Carvykti
- **Lot number** - must be reported for Yescarta and Tecartus (Lot number Format = 9 digits with a possible 2-digit extension)

2. INFUSION

Date of infusion - if the product was infused over multiple days, report the first date of infusion

Age at infusion - auto-calculated field

Was entire volume of product infused?

If no - indicate the fate of reserved portion, e.g. discarded, cryopreserved or specify other

Route of product infusion - For Kymriah or Yescarta, report the route as "intravenous"

3. CELL DOSES

Recipient weight and height

Report the recipient's actual or adjusted body weight (in kilograms) used to calculate the cell dose for this infusion. Do not use the lean body weight, or ideal body weight.

Total number of cells infused, not corrected for viability:

Report the total number of cells (not cells per kilogram) contained in the product administered.

Report the units separately e.g. x 10^n, i.e. specify the exponent "n".

Cell type	Number of cells		exponent
Total number of cells		x10	
Lymphocytes unselected		x10	

4. CONCOMITANT THERAPY

Recipient receive concomitant therapy?

Concomitant therapy – select all treatments that apply

When concomitant therapy given

Concomitant therapy is given to enhance the cell therapy function or decrease the toxicity.

Report if any drugs were given and if given simultaneously with the infusion or post cell therapy which is up to 24 hours after the infusion.

CELL THERAPY FOLLOW UP FORM

The follow up form should capture the information since the date of the last report and the data should be within the time period with no overlapping of preceding/subsequent follow up forms.

It is a requirement to report 15 years of follow up for genetically modified cell products. This is regardless of if a subsequent transplant or cell therapy infusion is given.

If another cell therapy infusion is given, then the follow up for the first cell therapy ceases the day before preparative therapy (or infusion if there is no preparative therapy given) of a subsequent infusion.

1. PATIENT IDENTIFICATION AND FOLLOW UP PERIOD

UPN

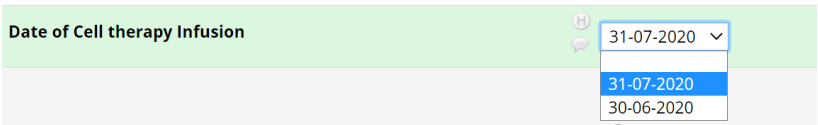
The UPN may be different from the UPN on the Patient Information form if the patient is being followed at another centre.

Hospital

The hospital responsible for follow up at the time of reporting

Date of cell therapy infusion

The date of infusion entered on the Cell Therapy Infusion Form will appear in the dropdown for selection. Ensure the correct date for this follow up is selected if this patient has received multiple infusions.



Follow Up period

- 30 day
- 100 Day
- 6 months
- Annual – 1 year; 2 year; >2 year (specify year)

Name of product (for most recent cell therapy infusion)

Select the commercial product or other product as reported on the Cell Therapy Pre-Infusion Form for which this follow up is associated with.

2. SURVIVAL

Date of actual contact to determine medical status for this report

Report the date closest to the follow up time point, guidelines below:

100 days +/- 15 days

6 months +/- 30 days

1 year +60 days, - must be 365 days or greater

2 years onwards +/- 30 days

Survival status

If survival status is 'dead', report Cause of death on the Patient Information form.

3. SUBSEQUENT CELLULAR INFUSIONS

New course of cell therapy given (unplanned) since last report?

If yes:

Reason given

- failure to respond or in response to disease assessment
- new indication

Date of cell therapy

Do not report any infusions that were planned as part of the course for which this follow up is associated with.

Complete new Cell Therapy Pre-infusion Forms and Follow up forms relating to the subsequent cell therapy.

HCT given since last report?

If yes:

Date of HCT

Reason for transplant - given for persistent/relapsed disease or other reason

4. BEST RESPONSE TO THE CELLULAR THERAPY

Skip this section if the indication is Acute Lymphoblastic Leukaemia, Lymphoma and Myeloma (including CLL when these disease specific forms become available)

5. PERIPHERAL BLOOD COUNT RECOVERY

Complete this section for 30 day, 100 day and at 6 months.

Initial neutrophil recovery

Date ANC ≥ 0.5 x10^9/L

This is the first absolute neutrophil count (ANC) recovery, defined as an ANC of ≥ 0.5 × 10^9/L for three consecutive laboratory values obtained on different days. Date of ANC recovery is the date of the first of these three days.

If the ANC never drop below ≥ 0.5 × 10^9/L after the cell infusion, select 'N/A, never below 0.5x10^9/L'.

ANC decline following initial recovery

If there are multiple declines and recovery of the ANC during a reporting period, only report the first decline and last recovery in the reporting period.

- **Subsequent ANC decline following initial recovery Yes/No**
- **Subsequent decline date**
- **Did ANC recover Yes/No**
- **ANC recovery date**

Initial platelet recovery

Date platelets ≥ 20x10^9/L

Report the date of the first of three consecutive laboratory values ≥ 20 × 10^9/L obtained on different days. If platelet transfusions were given, this date must be at least 7 days after the last transfusion date.

If the platelets never drop below ≥ 20 × 10^9/L after the cell infusion, select 'N/A, never below 20 x10^9/L'.

Often, platelet recovery may occur after the patient is no longer attending the centre, it may be necessary to deduce the date from available lab values (there may not be 3 consecutive days), and correspondence from the referring physician regarding any platelet transfusions and lab values.

6. DISEASE RELAPSE OR PROGRESSION

Applicable to malignant indications only.

Relapse or Progression detected since last report post infusion

Not applicable if disease specific form is available (ALL, Lymphoma and Myeloma)

If yes, report the date this was detected.

Disease relapse or progression may be detected by molecular, flow cytometry, cytogenetic, radiological, haematological or clinical.

Antigen escape

Antigen escape may occur with disease relapse and the tumour develops partial or complete loss of the tumour antigen, e.g. a recipient's disease relapses after receiving CD19 directed CAR-T cells, the T cell subset profile shows an absence of CD19 B cells i.e. the leukaemia/lymphoma cells no longer express CD19

Evidence of antigen escape

Method of detection of antigen escape

Date of antigen escape

7. CURRENT HAEMATOLOGY VALUES

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

Date latest complete blood count

Report values closest to the most recent contact date in the follow up period

WBC

Neutrophils

Lymphocytes

Haemoglobin

Haematocrit

RBC transfused ≤ 30 days prior

Platelets

Platelets transfused ≤ 7 days prior

Growth factors were given ≤ 7 days prior (or long-acting growth factors within 14 days prior)

8. NEW MALIGNANCY, LYMPHOPROLIFERATIVE OR MYELOPROLIFERATIVE DISEASE/DISORDER

If a new malignancy has been diagnosed after the date of the cell therapy, report this on the New Malignancy Form.

Do not include relapse, progression of the cell therapy indication including any new cytogenetic abnormalities or transformation of the same disease subtype.

9. PERSISTENCE OF CELLS

This section applies only to genetically modified cell products only

Tests performed to detect persistence of the cellular product

e.g., molecular (PCR), flow cytometry (immunophenotyping), immunohistochemistry

Date of sample

Cell source: BM, PB, tumour, other

Infused cells were detected

B cell aplasia was identified (flow cytometry only) – this question no longer applies

Were B cell counts monitored after infusion?

B-cell aplasia can be used as a surrogate to track persistence of the product. If the recipient has B-cell aplasia, then the product may still be present. Examples include (but not limited to) “cellular immunology report”, “lymphocyte subsets”, or “B-cell panel” of applicable tests that will show B-cell populations.

Was there B-cell recovery?

Date of initial B cell recovery

10. GRAFT VS. HOST DISEASE

Complete for allogeneic cell sources only

If the recipient also received a transplant, then report GVHD in the Transplant Follow Up Forms only

Acute GVHD

Acute GVHD developed since last report

Only report acute GVHD occurring prior to the diagnosis of chronic GVHD under Acute GVHD. This includes the organ grading and treatment relating to acute GVHD up to the date of diagnosis of chronic GVHD.

Once chronic GVHD is diagnosed, any persistent or new acute GVHD symptoms should be reported under chronic GVHD

An acute GVHD flare should be reported as a new diagnosis in a reporting period only if it appears after at least 30 days without active acute GVHD symptoms e.g. symptoms reappear after weaning immunosuppression AND there has not been any prior chronic GVHD. If acute GVHD develops within 30 days of symptoms resolving from a previous episode, this would be reported as persistent acute GVHD (which displays if ‘No’ is selected for this question).

Date of acute GvHD diagnosis

Report the earliest date of clinical diagnosis documented which may be after when symptoms first appeared.

Did acute GVHD persist since last report

This question displays if ‘Acute GVHD developed since last report’ is ‘No’.

If this question is answered ‘Yes’, then skip the following two questions (acute GVHD at diagnosis) and go to 'Maximum Overall Grade of acute GVHD’

Overall grade at diagnosis

The acute GVHD grading scale is based on clinical evidence rather than histology.

Acute GVHD grading table

Grade	Skin		Liver		Gut
I	Stage 1 or 2	AND	nil	AND	nil
II	Stage 3	OR	Stage 1	OR	Stage 1
III	-		Stage 2-3	OR	Stage 2-4
IV	Stage 4	OR	Stage 4		-

Please note: If only upper GI symptom is present in a reporting period, this is overall grade II

If acute GVHD was present but the maximum grade is unknown, select option 'present but grade not applicable'. Examples of this may involve elevated LFTs without hyperbilirubinaemia, where liver staging cannot be included in the overall grading. In these cases, only if other organs involved can be used in the overall grade.

Specify stage for each organ at diagnosis of acute GVHD

Include only symptoms attributable to GVHD in the staging and grading at the time of acute GVHD diagnosis.

Lower GI: If diarrhoea is attributed to acute GVHD but the volume is not documented, report as 'Stage 0'. The overall grade would be 'Not applicable' unless there is also Stage 4 skin/liver or an extreme decrease in performance status on the date of diagnosis/maximum grade

Liver: If bilirubin levels are normal with elevated transaminases attributed to acute GVHD, then report as 'other site' and specify. Grade would be 'Not applicable'.

GVHD Staging table

Stage	Skin	Liver	Gut
1	Rash on <25% of skin[1]	Bilirubin 34-50 µmol/L [2]	Diarrhoea > 500 ml/day[3] or persistent nausea[4] *Paediatric*: 280-555 ml/m^2/day or 10-19.9 mL/kg/day
2	Rash on 25-50% of skin	Bilirubin 51-102 µmol/L	Diarrhoea >1000 ml/day *Paediatric*: 556-833 ml/m^2/day or 20-30 mL/kg/day
3	Rash on >50% of skin	Bilirubin 103-255 µmol/L	Diarrhoea >1500 ml/day *Paediatric*: >833 ml/m^2/day or > 30 mL/kg/day
4	Generalized erythroderma with bullous formation	Bilirubin >> 255 µmol/L	Severe abdominal pain with or without ileus

Przepiorka et al, Bone Marrow Transplant 1995; 15(6):825-8

1 Use "Rule of Nines" (Percent Body Surfaces table) or burn chart to determine extent of rash.

2 Range given as total bilirubin. Downgrade one stage if an additional cause of elevated bilirubin has been documented.

3 Volume of diarrhoea applies to adults. For paediatric patients, the volume of diarrhoea should be based on body surface area. Downgrade one stage if an additional cause of diarrhoea has been documented.

4 Persistent nausea with or without histologic evidence of GVHD in the stomach or duodenum.

5 Criteria for grading given as minimum degree of organ involvement required to confer that grade.

6 Grade IV may also include lesser organ involvement with an extreme decrease in performance status

Maximum Overall Grade of acute GVHD

Report the maximum grade since last report.

If chronic GVHD develops in this reporting period, then report the maximum grade of acute GVHD prior to the onset of chronic GVHD.

Date of maximum overall grade of acute GVHD

If there were multiple instances where GVHD reached the same maximum grade, report the earliest date.

Chronic GVHD

Chronic GvHD developed since last report

Chronic GVHD which occurs 30 days after symptoms have resolved from a previous diagnosis of chronic GVHD should also be reported here as it would be considered a new diagnosis.

Persistent chronic GVHD or a flare occurring within 30 days of a previous diagnosis is reported under 'Chronic GVHD persisted since date of last report' question.

Date of chronic GvHD diagnosis

Report the date of the clinical diagnosis which may not be the same as when symptoms first appear.

If more than one episode occurs in the same reporting period, then report the earliest date of onset.

Chronic GVHD persisted since last report?

This question displays if 'Chronic GVHD developed since last report' is answered 'No'.

Do not report quiescent or inactive chronic GVHD, or a prior history of GVHD.

Specify maximum grade since last report

Report the maximum chronic GVHD involvement, based on clinical grade, as documented by the clinician i.e. based on the best clinical judgment.

Maximum grade of chronic GVHD during this period (NIH criteria)

Category	Number of affected organs or sites	Maximum severity score in affected organs or sites
Mild	1 – 2 organs (excluding lung)	1
Moderate	3 or more organs	1
	Any organ	2 (or lung score of 1)
Severe	Any organ	3 (or lung score 2 or 3)

Maximum grade is based on the following NIH Consensus Criteria 2014:

www.ncbi.nlm.nih.gov/pmc/articles/PMC4329079

Extent of chronic GVHD

Report the extent of chronic GvHD during this reporting period using following criteria (Sullivan KM, Blood 1981: 57:267)

Limited:	Localised skin involvement resembling localised scleroderma with or without liver involvement. No other organ involvement
Extensive:	Generalised skin and/or other organ involvement

Date of maximum grade of chronic GVHD

If there were multiple instances of the GVHD reaching the same maximum grade, report the earliest date.

Immunosuppressive agents

Currently taking systemic steroids

(Do not report steroids for adrenal insufficiency or a steroid taper of ≤10 mg/day for adults, <0.1 mg/kg/day for children)

Do not report non-systemic steroids e.g., topical creams, ointments, inhaled or ingested treatments that are not absorbed and circulated into the body.

Currently taking non-steroidal immunosuppressive agents (including PUVA) for GVHD

11. TOXICITIES – CYTOKINE RELEASE SYNDROME

Ref: Lee DW et al, ASTCT Consensus Grading for Cytokine Release Syndrome and Neurologic Toxicity Associated with Immune Effector Cells. Biol Blood Marrow Transplant 2019 Apr;25(4):625-638

Cytokine Release Syndrome (CRS)

Date of diagnosis

Therapy given - e.g. Corticosteroids, Siltuximab, Tocilizumab, specify other

Doses of tocilizumab

CRS Symptoms

Report symptoms and their date of onset. If there were multiple instances, report the first episode.

Fevers ≥ 38° C

Date of onset

Hypotension requiring treatment

Date of onset

Treatment given e.g. IV fluids, vasopressors and number given, specify other

Hypotension was controlled with therapy

Hypoxia requiring minimal supplemental oxygen (FiO2 <40%) e.g. low-flow nasal cannula or blow-by device

Date of onset

Hypoxia requiring more than minimal supplemental oxygen (FiO2 ≥40%) e.g. high-flow nasal cannula, facemask, opti-flow, non-rebreather or Venturi mask (do not include use of CPAP/BiPAP for sleep apnoea)

Date of onset

Positive pressure ventilatory support required e.g. CPAP, BiPAP, intubation, mechanical ventilation

Date of onset

Cytokine release syndrome resolved?

Date resolved

Features were related to HLH/MAS

Date onset

HLH/MAS therapy

Splenomegaly

Confirmed by biopsy

Lowest fibrogen level and date

Highest triglyceride level and date

Date MAS/HLH- toxicities resolve

12. TOXICITIES – NEUROTOXICITY

Neurotoxicity

Please report any new or continuing incidence of neurotoxicity in the reporting period.

Neurotoxicity developed or continuing since the last report

Neurotoxicity date onset

Lowest ICE Score

ICE Score

Orientation: orientation to year, month, city, hospital	4 points
Naming: ability to name 3 objects (e.g. point to clock, pen, button)	3 points
Following commands: ability to follow simple commands (e.g. "Show me 2 fingers" or "Close your eyes and stick out your tongue")	1 point
Writing: ability to write a standard sentence (e.g. "Our national bird is the bald eagle")	1 point
Attention: ability to count backwards from 100 by 10	1 point

CAPD assessment for children 12 years or less

- Cornell Assessment of Paediatric Delirium tool

Encephalopathy Assessment for Children Age <12 Years Using the CAPD

Answer the following based on interactions with the child over the course of the shift					
	Never, 4	Rarely, 3	Sometimes, 2	Often, 1	Always, 0
1. Does the child make eye contact with the caregiver?					
2. Are the child's actions purposeful?					
3. Is the child aware of his/her surroundings?					
4. Does the child communicate needs and wants?					
	Never, 0	Rarely, 1	Sometimes, 2	Often, 3	Always, 4
5. Is the child restless?					
6. Is the child inconsolable?					
7. Is the child underactive; very little movement while awake?					
8. Does it take the child a long time to respond to interactions?					

(Adapted from Traube et al [36]; reproduced with permission.)
For patients age 1-2 years, the following serve as guidelines to the corresponding questions:
1. Holds gaze, prefers primary parent, looks at speaker.
2. Reaches and manipulates objects, tries to change position, if mobile may try to get up.
3. Prefers primary parent, upset when separated from preferred caregivers. Comforted by familiar objects (ie, blanket or stuffed animal).
4. Uses single words or signs.
5. No sustained calm state.
6. Not soothed by usual comforting actions, eg, singing, holding, talking, and reading.
7. Little if any play, efforts to sit up, pull up, and if mobile crawl or walk around.
8. Not following simple directions. If verbal, not engaging in simple dialog with words or jargon.

Assessments

Depressed level of consciousness - specify most severe level

Dysphasia / aphasia - report speech impairment, with aphasia being grade 3 dysphagia

Seizure – type and severity

Grade 3 - Any clinical seizure focal or generalized that resolves rapidly; or Non-convulsive seizures on EEG that resolve with intervention.

Grade 4 - Life-threatening prolonged seizure (>5 min); or Repetitive clinical or electrical seizures without return to baseline in between)

Hemiparesis / paraparesis / other motor deficit

Cerebral oedema - specify the type: focal/local oedema or diffuse cerebral oedema/clinical concern

Hallucinations

Tremors

Cerebral vascular accident (stroke) – date onset and type

Leukoencephalopathy

Other neurological symptoms

Did neurotoxicity resolve

Date resolved

Therapy given for neurotoxicity – select from list of therapies

References:

- Common Terminology Criteria for Adverse Events (CTCAE) v5.0
- ASTCT Consensus Grading For Cytokine Release Syndrome And Neurologic Toxicity Associated With Immune Effector Cells. Biology Of Blood And Marrow Transplantation, Volume 25, Issue 4, April 2019, Pages 625-638

13. OTHER TOXICITIES

Hypogammaglobinemia

- Dates of onset and resolution where relevant

Requiring immunoglobulin replacement therapy

- Dates of therapy commencement and ceasing where relevant.

Tumour lysis syndrome

- Dates of onset and resolution
- Grade – the most severe grade

Other toxicities

- Description and dates of onset / resolution

14. GRADE 3 AND 4 ORGAN TOXICITY

*** Complete for 30 day, 100 and 6 month follow up only ***

Report organ toxicities defined by the CTCAE criteria:

- Grade 3 toxicity - severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self-care Activities of Daily Living.
- Grade 4 toxicity - life-threatening consequences and urgent intervention required

Organ involved

Dates of onset and resolution - where relevant

Examples:

Organ / System	Symptom or Event
Cardiovascular	Cardiac arrhythmia, capillary leak syndrome, hypotension, new or worsening heart failure, left ventricular systolic dysfunction, myocardial infarction, pericardial effusion, pericarditis, restrictive cardiomyopathy, hypertension, thromboembolic event
Gastrointestinal	Abdominal pain, constipation, diarrhea, dyspepsia, gastroenteritis, intestinal obstruction, nausea, vomiting, oral mucositis
Liver	Increases in Alkaline phosphatase, ALT/AST, bilirubin. Hepatitis viral, liver failure
Kidneys	Cystitis noninfective, chronic kidney disease, acute kidney injury
Musculoskeletal	Arthralgia, muscle weakness, generalized or specific area (not due to neuropathy), myalgia
Other	Anorexia, peripheral oedema, dysgeusia (taste alternation)

15. MAXIMUM LAB RESULTS SINCE LAST REPORT

Report the maximum results and date of the sample collection of the following if available

Interleukin-6

Soluble interleukin-2 receptor α (sIL2RA or soluble CD25)

Total serum ferritin

C-reactive protein

16. INFECTION

Report any clinically significant infections that have occurred in this period. 'Clinically significant' is defined here as infections requiring treatment.

Do NOT report the following:

- Culture-negative neutropenic fever without clear source;
- Upper respiratory infections which are presumed viral, but no virus identified;
- Candida detected in oral or stool samples (includes oral thrush);
- Toenail fungus;
- Yeast infection in the groin, vagina, or under the breasts;
- Surveillance cultures in which normal flora is present and the recipient is asymptomatic;
- Infections persisting from a prior reporting period (including infections which have progressed to new sites since the last report); or
- Infections recurring within the periods specified in the table below (considered to be part of the same infection)

Recurring infection definitions –
Use the table below to determine if the infection within the indicated periods would be considered part of the same infection. If they occur beyond the period specified, then report as a separate infection.

Bacteria	Virus	Fungal
≤ 7 Days • Any bacteria **≤ 30 Days** • Clostridium difficile **≤ 365 Days** • Helicobacter pylori	**≤ 14 Days** • Adenovirus • Enterovirus • Herpes zoster • Influenza • Parainfluenza • Rhinovirus • Respiratory syncytial • Varicella zoster **≤ 30 Days** • Human Herpes Virus - 6 **≤ 60 Days** • Cytomegalovirus • Epstein-Barr virus • Herpes simplex • Polyomavirus	**≤ 14 Days** • Any yeasts **≤ 90 Days** • Any molds

Ref: CIBMTR Forms Instruction Manual

Organism

Report the organism as identified in a report or clinical documentation.

If a fungal infection is suspected but not identified, enter this as 'suspected fungal infection'

Similarly, if a bacterial or viral infection is suspected and treated, but not confirmed, select Suspected bacterial/viral infection.

Site

An infection may occur in more than one site at the same or at different times.

Report all sites if the same organism is identified at multiple sites and within the recurrence interval ie. same infection, as indicated by the table above. If it is the same organism but outside the time periods, report as a new infection.

Note: Blood as the site of infection includes blood from a central IV line, catheter tip, or from a direct needle stick (peripheral draw). Infections in the bone marrow is also reported as blood.

Date of Diagnosis

This is the collection date for the positive microbiology culture or laboratory report.

For suspected fungal infections, enter the date of a radiological test or the date treatment was started.

If there are multiple sites of infection, report the collection date of the earliest positive report.

17. HOSPITALISATIONS

Report the total number of days admitted into hospital and ICU, and the reasons for the admissions.

Only count the number of days that fall within the reporting period. If the admission continues into the next reporting period, then include those days in the next follow up and check those days are not counted twice.

18. High-cost medication use

Report high-cost treatment such as for monoclonal antibodies and other biological agents. Only report the agents if these have not been reported in earlier sections e.g. tocilizimab in the treatment of CRS.

19. Pregnancy status

Answer this section for appropriately aged recipients

Recipient or female partner pregnant during reporting period

Specify outcome of the pregnancy

Any congenital abnormalities

Delivery date

NEW MALIGNANCY FORM

Visit the CIBMTR Forms Instruction Manual for comprehensive guidelines.
Form 3500: Subsequent Neoplasms

Do not report relapse, progression of the malignant disease that the cell therapy was treating or the transformation of the same disease subtype.

Date of cell therapy infusion

The date of infusion entered on the Cell Therapy Infusion Form will appear in the dropdown for selection. Ensure the correct date for this follow up is selected if this patient has received multiple infusions.

Follow Up period

30 day, 100 day, 6 months, annual

New Malignancy diagnosis

Date of diagnosis

New malignancy is donor/cell product derived

Documentation submitted to registry

Documentation to confirm the origin e.g. VNTR, cytogenetics, FISH

Pathology or autopsy report submitted to registry

Pathology of the new malignancy

Post-transplant lymphoproliferative disorder

If the new malignancy is a post-transplant lymphoproliferative disorder, then the following fields will display:

EBV reactivation present in blood

Method diagnosed:

Quantitative or Qualitative PCR of blood or specify other method

If quantitative PCR method was used then:

- **EBV viral load at diagnosis (copies/ml)**
- **Quantitative PCR of blood repeated after diagnosis**
- **Highest EBV viral load of blood (copies/ml)**

Was there lymphomatous involvement (mass)

Site(s) involved

Was PTLD confirmed by biopsy

If yes, attach PTLD biopsy report

QUALITY OF LIFE FORM

EQ-5D Quality of Life (EuroQoL) forms are available as an electronic form in REDCap and as a paper form, consisting of five multiple choice questions and one sliding scale question.

Two forms are available, depending on age range EQ-5D-Y and EQ-5D-5L from EuroQol Research Foundation. The EQ-5D-Y contains the same five questions and sliding scale question as the EQ-5D form with adjustments to the wording to be more child-friendly.

Collection of the QoL should occur at the following timepoints:

- At infusion
- 30 day / 100 day / 6 month / annual follow ups

Data entry of patient responses can be entered into the REDCap forms.

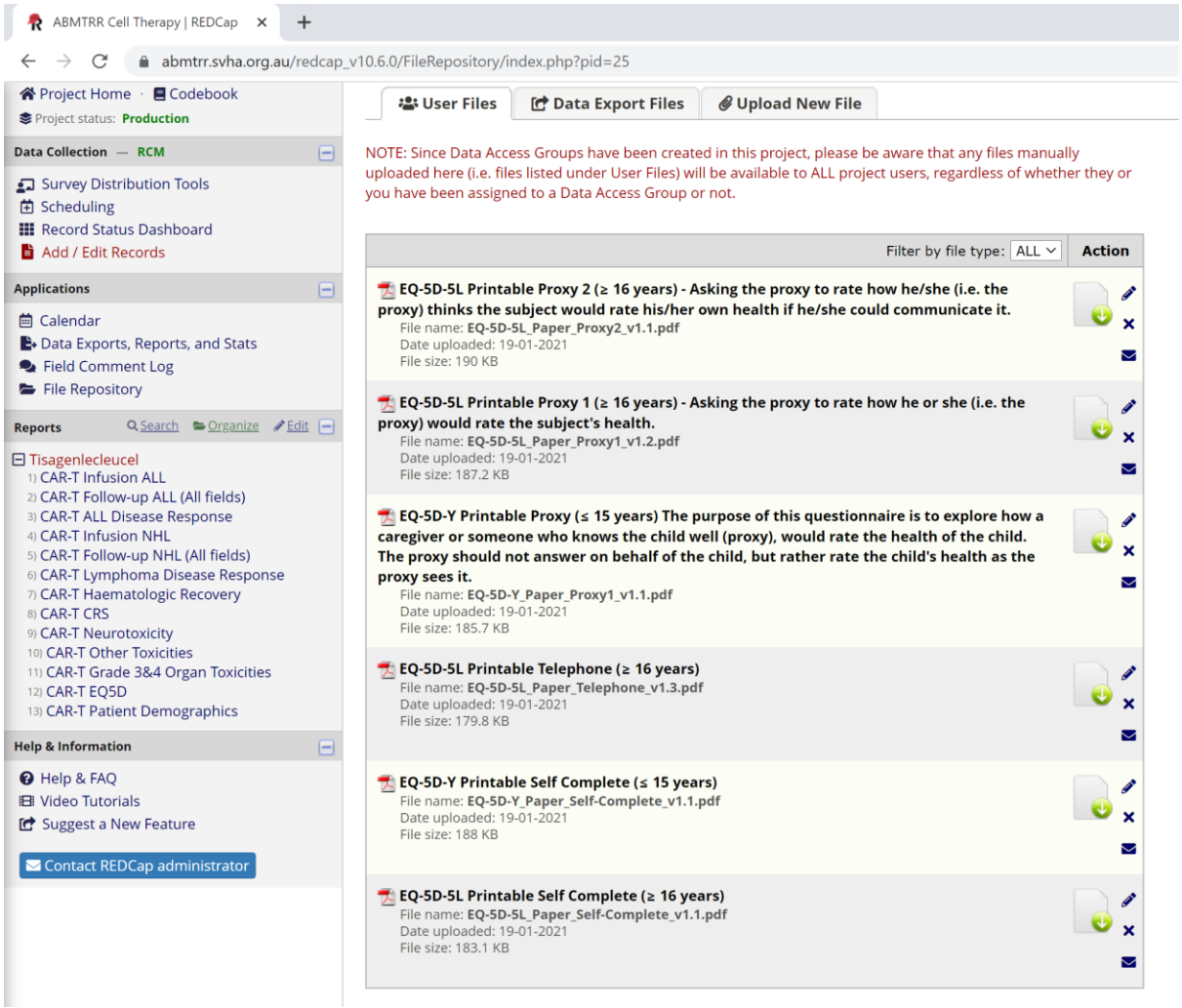
EuroQol Research Foundation recommended age range form versions:

Age range	Recommendation
0-3 years	**No EQ-5D-Y version is available for this age range**
4-7 years	**For children aged 4-7 years, a proxy version should be used** No self-reported EQ-5D-Y is available for this age range at present
8-11 years	**Use EQ-5D-Y** The EQ-5D-Y is more understandable for children in this age range than an adult version of the EQ-5D.
12-15 years	**Both the EQ-5D-Y and adult EQ-5D versions can be used** An overlapping area. Generally, EQ-5D-Y is recommended. However, depending on study design, it might also be appropriate to use one of the EQ-5D adult versions. For example, if a study includes both adult respondents and respondents between the ages of 12 and 15, the study team might prefer to use just one version of EQ-5D across the whole study population
16 years and older	**Use an adult version (EQ-5D-3L or EQ-5D-5L)** A possible exception would be a study that only includes children up to age 18. In this case, it may be preferable to use EQ-5D-Y across the full age range to avoid using two different versions of EQ-5D

Paper forms (Self-reported / Proxy/ Telephone) can be accessed and downloaded from the ANZTCT Registry Cell Therapy REDCap Project:

On the left side of the screen REDCap screen, under Applications click the ‘File Repository’ option.

Under the User Files Tab > Click the download button to download and print the forms you require.



Please note that the ANZTCT REDCap database cannot email these directly to the patient.
The ‘Send email invitation?’ question is displayed at the top of the forms as a requirement by EuroQol, however it cannot be utilised.

EQ-5D-5L (≥ 16 YEARS)

Date of QoL completion: ____ /_____ /_____

Mobility

- ❑ I have no problems with walking around
- ❑ I have slight problems with walking around
- ❑ I have moderate problems with walking around
- ❑ I have severe problems with walking around
- ❑ I am unable to walk around

Personal Care

- ❑ I have no problems with washing or dressing myself
- ❑ I have slight problems with washing or dressing myself
- ❑ I have moderate problems with washing or dressing myself
- ❑ I have severe problems with washing or dressing myself
- ❑ I am unable to wash or dress myself

Usual activities *(e.g. work, study, housework, family or leisure activities)*

- ❑ I have no problems doing my usual activities
- ❑ I have slight problems doing my usual activities
- ❑ I have moderate problems doing my usual activities
- ❑ I have severe problems doing my usual activities
- ❑ I am unable to do my usual activities

Pain/discomfort

- ❑ I have no pain or discomfort
- ❑ I have slight pain or discomfort
- ❑ I have moderate pain or discomfort
- ❑ I have severe pain or discomfort
- ❑ I have extreme pain or discomfort

Anxiety/depression

- ❑ I am not anxious or depressed
- ❑ I am slightly anxious or depressed
- ❑ I am moderately anxious or depressed
- ❑ I am severely anxious or depressed
- ❑ I am extremely anxious or depressed

We would like to know how good or bad your health is TODAY

Use slider to set a response between 0 (worst health) and 100 (best health)

EQ-5D-Y (≤ 15 YEARS)

Date of QoL completion: ____ /_____ /_____

Mobility *(walking about)*

- ❑ I have no problems with walking about
- ❑ I have some problems with walking about
- ❑ I have a lot problems with walking about

Looking after myself

- ❑ I have no problems washing or dressing myself
- ❑ I have some problems washing or dressing myself
- ❑ I have a lot of problems washing or dressing myself

Doing usual activities (for example, going to school, hobbies, sports, playing, doing things with family or friends)

- ❑ I have no problems doing my usual activities
- ❑ I have some problems doing my usual activities
- ❑ I have a lot of problems doing my usual activities

Having pain or discomfort

- ❑ I have no pain or discomfort
- ❑ I have some pain or discomfort
- ❑ I have a lot of pain or discomfort

Feeling worried, sad or unhappy

- ❑ I am not worried, sad or unhappy
- ❑ I am a bit worried, sad or unhappy
- ❑ I am very worried, sad or unhappy

We would like to know how good or bad your health is TODAY.

This line is numbered from 0 to 100.

100 means the best health you can imagine.

0 means the worst health you can imagine.

Please click on the line to show how good or bad your health is TODAY.