ABMTRR
Australasian
Bone Marrow Transplant
Recipient Registry

ABMTRR

Cell Therapy Data Collection

Guidelines

Contents

ABMTRR PROTOCOL

The details on the purpose and operations of the Australasian Bone Marrow Transplant Recipient Registry are located in the ABMTRR Protocol. This is available on the ABMTRR website at:
http://www.abmtrr.org/index.php/resources/data-management/

ABMTRR DATABASE ACCESS

REDCap is the ABMTRR web-based application for submission of cell therapy and transplant data. The system allows centres to electronically submit the required forms for the collection of cell therapy and transplant data.

ABMTRR will provide training, and training is recommended prior to logging into the system.

Login to the system is via your Username / Password. Refer to the REDCap Cell Therapy User Guide for access instructions.

If you are having trouble logging in, please contact the ABMTRR Data Manager (+61 2 9355 5694) or email abmtrr@svha.org.au

REGISTRATION REQUIREMENTS

Forms required at registration:

- **Patient Information** – also used for Transplant
- **Disease Classification** – also used for Transplant
- **Disease Specific Pre-Infusion**
- **Cell therapy Pre-infusion**
- **Cell therapy Product** - for each product
- **Cell therapy Infusion** - for each infusion of each product

Forms required at follow up

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

- **Cell therapy Follow Up**
- **Quality of Life EQ-5D**
- **Disease Specific Post Infusion**
- **New Malignancy** - if new malignancy is diagnosed (different to cell therapy indication)

Cell product not given post apheresis
Patients eligible for the commercial cell therapy products who undergo apheresis but fail to receive the cells are also required to be registered with ABMTRR. There will be a minimum data requirement.

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 and include CAR T-cells.
Cell therapy may be given following HCT to treat infection, mixed chimerism or recurrent disease and is known as donor cellular or lymphocyte infusion. Previously, these have been reported in the follow up pages of a transplant.

There will be patients receiving both transplant and cell therapy. Where there are questions in common in the Transplant and Cell Therapy Follow Up Forms, duplicate entry of data will be minimised where possible.

GENERAL GUIDELINES FOR COMPLETING FORMS

The screenshots taken from REDCap in this document may not show all available fields. Some fields are dependent on the option selected in a preceding question and do not display until the relevant option is selected.

A full list of the fields is shown in the pdf version of the forms available at:
https://www.abmtrr.org/index.php/resources/data-management/

These should be used as a guide only and may be used to assist the data collection. Please note that not all options to the questions (available in REDCap) are included on these forms.

Guide for entering date fields

Dates are entered as: dd/mm/yyyy

If the exact date is unknown, the following guidelines should be used:

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

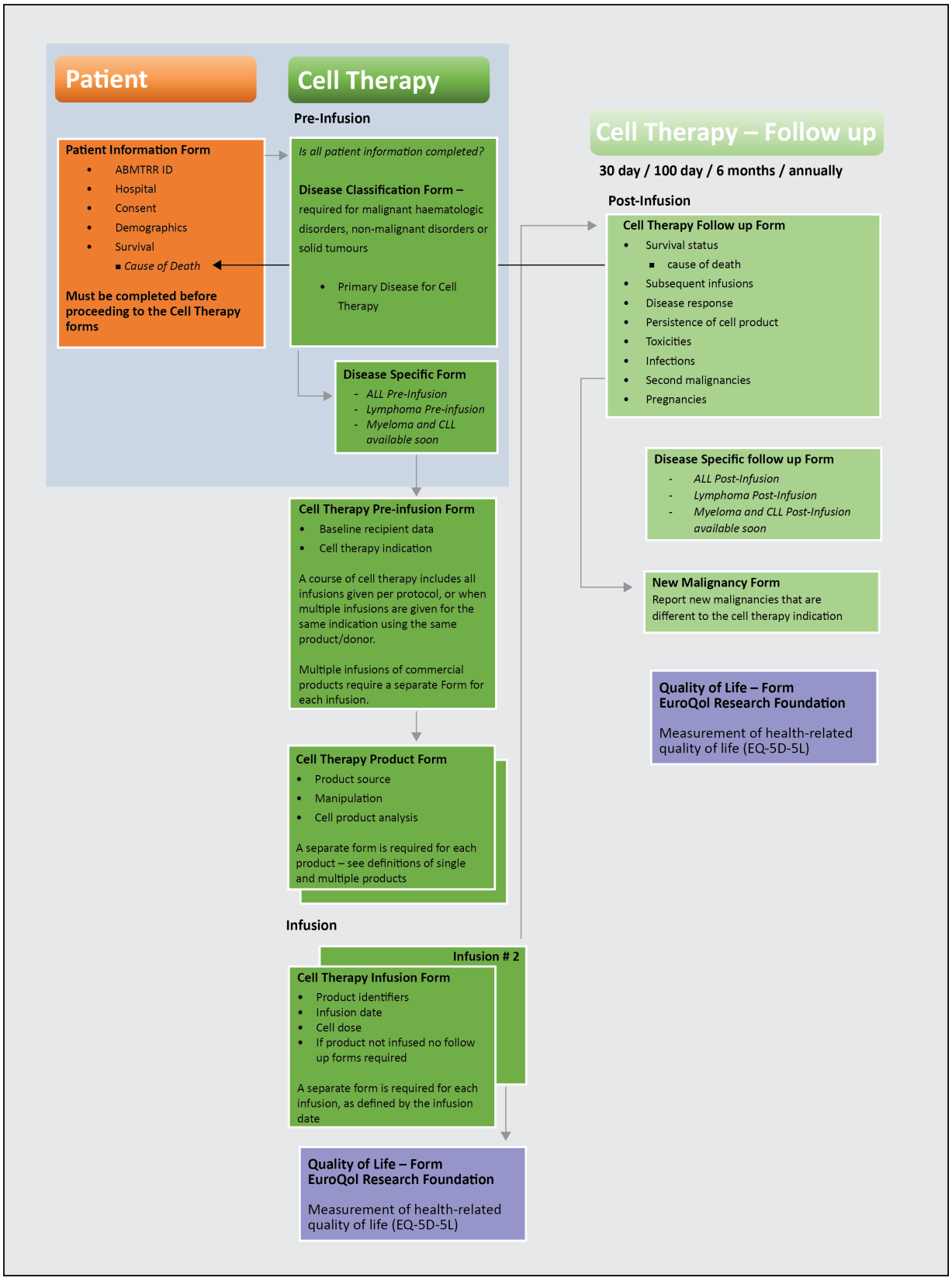
In some cases this rule may not make sense e.g. the diagnosis is in May and it is known that treatment was started on a given date in mid-May, then the diagnosis date can be entered as the 1st May.

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 ABMTRR however may be useful for confirmation of results. Alternatively, these documents can be provided at a later date if required.

For more comprehensive guidelines, please go to the CIBMTR Forms Instruction Manual at:
www.cibmtr.org/manuals/fim

FORM SUBMISSION WORKFLOW



PATIENT INFORMATION FORM

First cell therapy infusion (or transplant) for this patient?

→ Yes, create a new Patient Information Form

→ No, the patient has received a prior cell therapy infusion or transplant:

- at the same centre, then search for an existing Patient record then add the infusion and associated forms to this record.
- at a different centre, then contact ABMTRR for access to the existing Patient record.

Demographics

AID (ABMTRR ID)

This is the unique identifier that ABMTRR REDCap database assigns to the patient at the time the patient information is first entered.

*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 ABMTRR.

Patient UPN

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

Name ID

These fields are optional in the database and are only used to assist the transplant centre in identifying the recipient e.g. for follow up or queries.

This consists of the first four letters of surname and first two letters of the first name. Do not include apostrophes e.g. O'ROU enter as OROU

*Date of birth

*Sex

*Country and *Place of usual residence

Enter the country, and the State if Australian.

This should be where the patient normally resides. Do not enter a temporary accommodation the patient may be residing at during the cell therapy.

Postcode

Enter postcode for Australian and New Zealand patients.

CIBMTR ID (CRID)

This is the identifier assigned by CIBMTR (Centre for International Blood and Marrow Transplant Research) to recipients whose transplants / cell therapies are also reported to them.

EBMT ID

This is the identifier assigned by EBMT (European Society for Blood and Marrow Transplantation) to recipients whose transplants / cell therapies are also reported to them.

Other Registry ID

Enter identifiers from other registries that the patient may also be contributing data to e.g. AML Registry

Name of registry

Field appears if information is entered into the previous field

Race

Indicate the recipient's race, more than one may be indicated.

Indigenous status
This 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 ABMTRR.

Reporting of treatment and outcomes for patients receiving commercial CAR-T products is required for safety and quality purposes and for TGA reporting. Patient consent is 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 sample patient information and consent form, refer to the ABMTRR Protocol:
http://www.abmtrr.org/index.php/resources/data-management/

Survival

*Survival Status / Date of latest contact
This date is used in survival analysis 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.
Survival status will be identified as part of the follow-up process.

DOD audit, date estimated
This field will show if the Survival status = Dead. Tick this checkbox if the exact date of death is not available and 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

Cause of death

Primary cause of death

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

- Recurrence / persistence / progression of disease (HCT or cellular therapy indication)
- Acute GVHD
- Chronic GVHD
- Graft rejection or failure
- Cytokine release syndrome
- Infection, specify organism
- Pulmonary, specify
- Organ failure (not due to GVHD or infection), specify
- Malignancy, new or prior
- Haemorrhage, specify
- Vascular, specify
- Other, specify

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 postmortem 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 as relevant considered to be contributing factor.

DISEASE INFORMATION

The Disease Classification Form use the World Health Organization (WHO) disease classifications,
References: https://www.who.int/classifications, https://icd.who.int/browse11/l-m/en

Fields relating to the diagnosis are captured on two forms in REDCap to align with the CIBMTR forms:

- **Part A**: Disease Classification Forms (*CIBMTR Form 2402*)
- **Part B**: Disease Specific Forms:
    - ALL Pre-Infusion (*CIBMTR Form 2011*)
    - Lymphoma Pre-Infusion (*CIBMTR Form 2018*)
    - Myeloma and CLL Pre-Infusion (*CIBMTR Forms 2013, 2016*) to come

The ABMTRR Disease Forms pdf version contains both Part A and Part B on the same form to assist with data collection processes.

Please refer to the CIBMTR Instruction Manual website for more comprehensive guidelines and definitions.

PART A: DISEASE CLASSIFICATION FORM

The questions in this form are contained in PART A of the ALL/Lymphoma Pre-Infusion Forms pdf versions

Reporting Subsequent Infusions

If this form has been submitted for a previous transplant or cell therapy infusion, and a subsequent infusion is given for relapse or progression of the same indication, report the relapse/progression as the diagnosis (before any treatment intervention).

DIAGNOSIS

Date of diagnosis

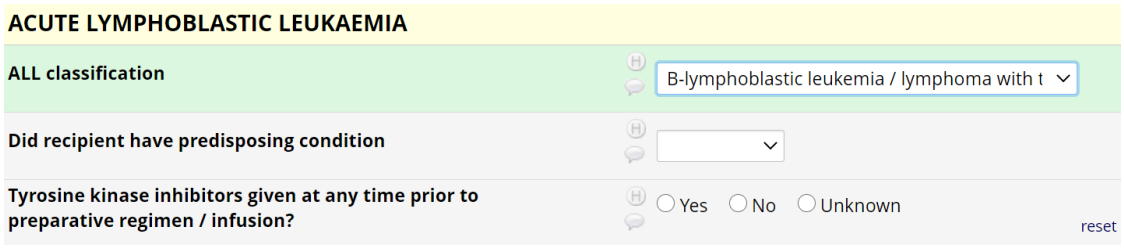
Enter the date the sample was collected e.g. bone marrow or tissue sample for biopsy. The date may be obtained from a clinician's note if laboratory results are not available. Do not report the date symptoms first appeared.

If the indication was diagnosed in utero or is a congenital disorder, report the date of birth as the date of diagnosis.

Primary Disease for HCT / Cell Therapy

A subset of associated questions will display when the **Primary Disease for HCT / Cell Therapy** is selected.

Acute Lymphoblastic Leukaemia



ALL Classification
Report cytogenetic or molecular abnormalities at diagnosis or the subtypes from the dropdown options, rather than 'ALL NOS'.

Did recipient have predisposing condition
Indicate there was a predisposing condition that may have increased the susceptibility of developing leukaemia, e.g. aplastic anaemia, Fanconi anaemia, Blooms syndrome, Down syndrome

Tyrosine kinase inhibitors given any time prior to preparative regimen/infusion
Report any of these agents that were given between diagnosis and prior to the cell therapy, e.g. imatinib

Disease Assessments
- cytogenetic (karyotyping and FISH)
- molecular assessments.

Report results at three different time points prior to the infusion, where available

- At diagnosis, must be before any treatment is started
- Between diagnosis and the latest prior to infusion
- Latest prior to the infusion, usually within 30 days of the start of preparative regimen/infusion.

CNS disease
Indicate if there was CNS disease at any time prior to the infusion.

Disease Status at Infusion
Refer to the ALL Response criteria in the CIBMTR Instruction Manual for the definitions.

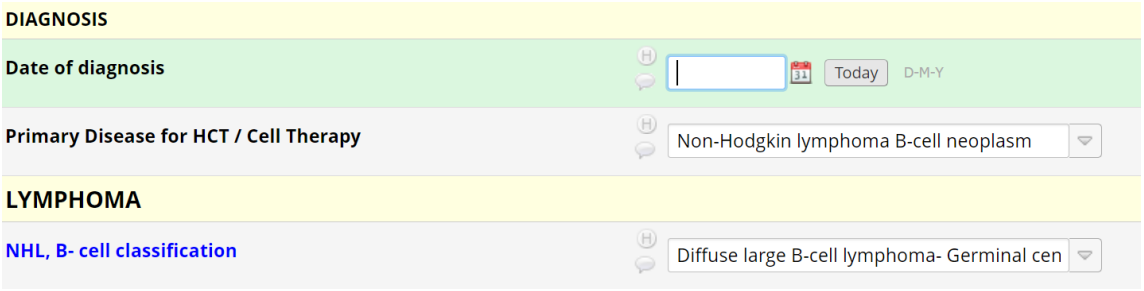
If remission was achieved, the following question(s) are relevant:

- Number of cycles of induction to achieve CR1 (incl CRi)
  Report the number of induction cycles to achieve first remission. Do not include chemotherapy given for consolidation or maintenance.
- In CR by flow cytometry
  Otherwise known as immunophenotyping or minimum residual disease testing. "Not applicable" applies when no abnormalities detected by previous flow cytometry testing or flow cytometry not performed.

If in relapse, then the following question displays
- Date of most recent relapse

Date of assessment
The date the Disease Status at Infusion assessment was performed.

Non-Hodgkin Lymphoma
Report the lymphoma histology at the time of the cell therapy infusion. If it has transformed, the prior histology is reported in the fields that follow.



The following questions will display:

DLBCL (germinal center B-cell type vs. activated B-cell type) subtype was based on

- Immunohistochemistry (e.g. Han's algorithm)
- Gene expression profile
- Unknown method

Report which method was used to identify the type of DLBCL if known

Transformed from CLL prior to infusion

This is known as a Richter's Transformation

- 17p abnormality detected

Transformed from different lymphoma (not CLL)

Report a transformation which may occur after the initial lymphoma diagnosis or can occur at the same time as the initial diagnosis.
Provide the histology and the date of original diagnosis

PET (or PET/CT) scan performed (prior to start of preparative regimen/infusion)

This is the PET scan (or combined PET/CT scan) performed after completion of any pre-infusion treatment and three months before the cell therapy.
Report if the scan showed any positive lymphoma involvement and the date performed.

Deauville (five-point) score

This score is usually found on the PET report. Report the highest score if there are multiple values.

Lymphoma Disease Status prior Infusion

Refer to the Lymphoma Response Criteria (CIBMTR Forms Instruction Manual)
Use the metabolic (PET) criteria where possible to assess the disease status. If this is not available (PET scan not available or non-PET avid disease), then the radiographic criteria can be used.

Compare the assessments at immediately prior to the cell therapy and the assessments at baseline (diagnosis or relapse/progression) to determine the disease status.

If a transformation has occurred, then count the response number (e.g. CR1, CR2) for the transformed histology only.

Total number of lines of therapy received: (between diagnosis and infusion)

Therapies/agents given during the same period with the same intent is considered one therapy line. If the patient does not achieve adequate response, they may be given different agents which would then be reported as a separate therapy line.
Report the number of therapy lines given here prior to the cell therapy.

More details of the therapy lines will be captured on the Lymphoma Pre-Infusion Form

Date disease status assessed

Depending on the criteria used to determine the disease status, this may be the date of the imaging (e.g. PET, PET/CT, MRI), bone marrow biopsy. If these were not performed within 30 days prior the cell therapy, report the latest clinical assessment of the disease status.

PART B: DISEASE SPECIFIC FORMS

ALL (ACUTE LYMPHOBLASTIC LEUKAEMIA) PRE-INFUSION

The questions in this form are contained in PART B of the pdf version of the Acute Lymphoblastic Leukaemia Pre-Infusion Form.

1. Assessments at diagnosis

If this form has been completed for a previous cell therapy infusion, then skip the diagnosis questions and go to the next section Disease Prophylaxis prior Preparative regimen/Infusion.

Please ensure that the values are reported by the units indicated

- WBC x10^9/L
- % blasts blood
- % blasts in BM
- Extramedullary disease sites - this question is not relevant if the diagnosis is precursor T-cell/B-cell lymphoblastic lymphoma/leukaemia

2. Disease prophylaxis prior preparative regimen or infusion

Indicate if CNS prophylaxis given e.g. cranial irradiation, intrathecal therapy

3. Disease treatment prior preparative regimen or infusion

Report treatment given between the ALL diagnosis and the start of preparative treatment or infusion. If no treatment was given, go directly to Section 4.

Complete this section as many times as required for multiple lines of therapy

Report each line given, as a treatment.

Therapies/agents given during the same period with the same intent e.g. induction is considered one line treatment. Additional courses of the induction therapy may be given. These are reported as an additional cycle within the same treatment line. If the patient does not achieve adequate response, they may be given different agents which would then be reported as a separate treatment line.

Do not report prior HCT here.

Selecting 'Yes' will display the associated fields:

Therapy type:

Therapy type (or purpose) is dependent on the disease status at the time:

- Induction – to achieve complete remission (CR)
- Consolidation - once achieving CR; given either as part of a protocol or to achieve a deeper response, removing any minimal residual disease.

- Maintenance – after receiving induction and consolidation, extended low dose therapy to maintain CR.
- Relapse treatment – given to achieve a further CR after disease recurrence e.g. CR2 or greater.

Intrathecal therapy: Y | N
Agents given by lumbar puncture, delivered directly to the cerebrospinal fluid to treat or prevent CNS disease.

Systemic therapy
Therapy given intravenously or orally. Do not report intrathecal therapy here.
- Dates started and ended
- Number of cycles - systemic therapy may be given in cycles with rest periods in between, then repeating weekly/fortnightly or monthly.
- Specify systemic agents

Radiation therapy
- Date started and ended
- Radiation site(s) e.g. cranial, craniospinal and any other sites

Cell therapy: Y | N
Includes effector cells, CAR T-cells

Best response to line of therapy: CR | Cri | No CR
- Date assessed

Refer to the ALL Response criteria (CIBMTR Instruction Manual)

MRD negative following this line of therapy: Y | N

This should be based on results performed within 30 days after therapy was completed for this treatment line and before a new treatment line commences.

Recipient relapsed following this line of therapy: Y | N
- Date relapsed
- Site(s) of relapse

4. Evaluations prior to start of preparative regimen or infusion

Values should be within approximately 30 days prior to preparative regimen/infusion, but after completion of any treatment. If this is not available, then report as unknown.

Please ensure that the values are reported by the units indicated
- WBC x10^9/L
- % blasts blood
- % blasts in BM
- Extramedullary disease sites

Flow cytometry performed
Report the percent of disease detected by flow cytometry in blood and bone marrow if performed.

Extramedullary disease present
Report sites of disease involvement other than in the blood or bone marrow

LYMPHOMA PRE-INFUSION

The questions in this form are contained in PART B of the pdf version of the Lymphoma Pre-Infusion Form.

If this form has been completed for a previous cell therapy infusion, then skip the diagnosis questions and go to Section 4 Disease Transformation

1. Diagnosis *(prior to any transformation)*

Lymphoma histology at diagnosis
If the diagnosis is a transformed CLL to DLBCL or Hodgkins Lymphoma, then report the DLBCL or Hodgkins here.

If the diagnosis is more than one type of lymphoma or has transformed, then report the least aggressive lymphoma here, and the most aggressive lymphoma as the transformed histology in Section 4.

Immunohistochemical stains performed
Report results if performed.

Some markers, if positive, require the percentage of cells which were positive. If the percent is documented as a range, then report the average. If documented as less than a certain percentage, then report as less one, e.g. report <10% as 9%.

Were cytogenetics performed:
Report the karyotyping and FISH results if performed

2. Laboratory values at diagnosis

Values reported here should be within 30 days of the lymphoma diagnosis reported in the prior section and performed before any treatment is given. If tests were performed outside of this period, 'Unknown' should be reported.

Please ensure that the values are reported by the units indicated

- LDH U/L and lab's upper normal limit – for all lymphoma diagnoses

The following values are only required for specific lymphoma diagnoses as indicated:

- WBC - Mantle cell, Hodgkins only
- Hb - Follicular, Hodgkins only
- Absolute lymphocyte count - Hodgkins only
- Lymphocyte % - Hodgkins only
- Serum albumin - Hodgkins only
- LDH and LDH upper limit of normal – all histologies

3. Nodal and organ involvement at diagnosis

Results reported here should be within 30 days of the lymphoma diagnosis reported in the prior section and performed before any treatment is given. If tests were performed outside of this period, 'Unknown' should be reported.

PET (or PET/CT) positive: Y | N | ND

Indicate if positive if a PET scan or combined PET/CT scan was performed

Known nodal involvement

Nodal involvement can be found by clinical assessment, biopsy or PET/CT imaging. Complete the following if there was involvement

- Total number nodal regions involved

  Report the number of nodal regions (e.g. cervical, mediastinal, para-aortic, inguinal and others) depending on lymphoma type, as follows

  - non Follicular type, options are: ☐ 1 ☐ ≥2 ☐ Unknown
  - Follicular type, options are: ☐ ≥ 5 ☐ < 5 ☐ Unknown

- Largest nodal mass

  Report the largest two dimensions in cm

Extranodal or splenic involvement

Report any involvement outside of the lymph nodes e.g. spleen, bone, GIT, skin

Stage of organ involvement

Stage	Description
I	Involvement of a single lymph node region or of a single extra-lymphatic organ or site
II	Involvement of two or more lymph node regions on same side of diaphragm, OR localized involvement of an extra-lymphatic organ or site, and one or more lymph node regions on same side of diaphragm
III	Involvement of lymph node regions on both sides of diaphragm, which may also be accompanied by localized involvement of extra-lymphatic organ or site, the spleen, or both
IV	Diffuse or disseminated involvement of one or more extra-lymphatic organs in tissues with or without associated lymph node enlargement/involvement

B symptoms present

Defined as any of these features present at diagnosis:

- unexplained fever >38C
- night sweats
- unexplained weight loss of > 10% of body weight over 6 months

ECOG score

It is advised that performance scores should be documented in the patient's notes rather than derived afterwards.

4. Disease transformation

The following three questions have also been included in Part A

Is lymphoma histology reported at diagnosis a transformation from CLL? Y | N

If yes, then skip the remaining transformation questions and go to Section 7 Disease Treatment

Transformation occurred between diagnosis and start of preparative regimen/infusion? (non CLL)

If no transformation, then go to Section 7 Disease Treatment
If yes, specify the histology at transformation

Pathology at transformation submitted to Registry

Transformation date same as diagnosis date

This question establishes if the histology information has already been captured in earlier sections

- Yes (concurrent diagnosis) - go to Section 7 Disease Treatment
- No, Date of transformation

  Complete the rest of this section and sections 5 and 6

Refer to Section 1 for guidelines to the following questions

Immunohistochemical stains performed

Were cytogenetics performed

5. Laboratory values at transformation

Values reported here should be within 30 days of the transformed lymphoma reported in the prior section and performed before any treatment is given. If tests were performed outside of this period, 'Unknown' should be reported.

Please ensure that the values are reported by the units indicated

- LDH U/L and lab's upper normal limit – for all lymphoma diagnoses

The following values are only required for specific lymphoma diagnoses as indicated:

- WBC - Mantle cell, Hodgkins only
- Hb - Follicular, Hodgkins only
- Absolute lymphocyte count - Hodgkins only
- Lymphocyte % - Hodgkins only
- Serum albumin - Hodgkins only
- LDH and LDH Upper limit of normal – all histologies

6. Nodal, organ involvement at transformation

Results reported here should be within 30 days of the transformation reported in the prior section and performed before any treatment is given. If tests were performed outside of this period, 'Unknown' should be reported.

Refer to Section 3 for the guidelines to the questions below

PET (or PET/CT) positive

Known nodal involvement

- Total number nodal regions involved
- Largest nodal mass (max dimensions)

Extranodal / splenic involvement?

Stage of organ involvement

B symptoms present 6months prior transform

ECOG score

7. Disease treatment

Report treatment given between the lymphoma diagnosis and the start of preparative treatment or infusion.

If there was a lymphoma transformation, report all treatment given starting from the original lymphoma diagnosis.

Complete this section as many times as required for each line given.

Therapies/agents given during the same period with the same intent is considered one therapy line. If the patient does not achieve adequate response, they may be given different agents which would then be reported as a separate therapy line.

If this is a subsequent infusion and the treatment lines have been previously reported with an earlier cell therapy infusion, only report treatment lines given after the prior cell therapy infusion.

Treatment was given after diagnosis: Y | N

Systemic therapy: Y | N

- Date started and stopped
- Number of cycles
- Specify regimen/agents
- This therapy line given to mobilised cells: Y | N

Intrathecal therapy: Y | N

- Indicate if given for prophylaxis or treatment of CNS disease or unknown.
- Date started and stopped
- Specify agent given

Intraocular therapy: Y | N

- Indicate if given for prophylaxis or treatment of CNS disease or unknown.
- Date started and stopped
- Specify agent given

Radiation therapy: Y | N

- Date started and stopped
- Extent of radiation field
- Radiation sites
- Radiation dose
- Technique
  E.g. Electron beam, Proton or specify other

Surgery Y | N

- Date of surgery
- Splenectomy, and other site(s)

Photopheresis: Y | N

Cell therapy: Y | N
e.g. effector cells, CAR T-cells

Refer to the CIBMTR Lymphoma Response Criteria for the definitions to disease response for the following questions:

Best response to line of therapy: (Radiographic criteria)
CR |PR | NR/SD | PD |Not done Date assessed

Best response to line of therapy: (Metabolic criteria)
CR |PR | NR/SD | PD |Not done Date assessed

This therapy given as maintenance / consolidation: Y| N
Definitions for consolidation and maintenance as follows:

- Consolidation - once achieving CR; given either as part of a protocol or to achieve a deeper response, removing any minimal residual disease.
- Maintenance – after receiving induction and consolidation, extended low dose therapy to maintain CR.

Relapse/progression occurred after this therapy line
If yes, report the date relapse/progression

8. DLBCL - complete if CR not achieved after 1st line therapy

Complete this section if the indication for cell therapy is Diffuse Large B Cell Lymphoma (DLBCL), or has transformed into DLBCL

If CR was achieved after the first line of therapy, skip this section and go to Section 9

Assessments provided should be performed after completion of the first treatment line, but before commencement of second treatment line. If a second treatment line is not given, then report the assessments prior to preparative therapy/infusion, using the most recent if assessed more than once.

LDH
Provide LDH value in the units indicated and the lab's upper normal limit of LDH

Refer to Section 3 for the guidelines to the questions below

Stage of organ involvement

ECOG score

Extranodal or splenic involvement:

9. Disease assessment at last evaluation prior to preparative regimen / infusion

Results reported here should be within approximately 30 days prior to starting preparative therapy/infusion, but after the latest treatment line if applicable. If tests were performed outside of this period, 'Unknown' should be reported.

Were cytogenetics performed
Refer to section 3 for the guidelines

Laboratory values
Provide values for the lymphoma types specified only

- Hb – Follicular and Hodgkins
- Absolute lymphocyte count – Hodgkins only

Minimal residual disease
Report if any of the following assessments were positive for detecting minimal residual disease.

- Flow cytometry
- PCR
- NGS, 3rd gen (Next Generation Sequencing)

If positive:

- Date of sample
- Sample source - e.g. blood, bone marrow

Pathology report(s) submitted to Registry: Y | N

Refer to Section 3 for the guidelines to the questions below

Known nodal involvement
Total number nodal regions involved - report for Follicular only

- Largest nodal mass (max dimensions)

Extranodal / splenic involvement

CELL THERAPY PRE-INFUSION

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

1. Patient identification

UPN

This question is required as the UPN may be different from the UPN on the Patient Information form.

Hospital

This is the hospital responsible for follow up at the time of reporting, which should match the user's associated centre.

Referral centre and doctor

Enter the referring centre and/or clinician

2. Cell Therapy

Participating cellular therapy clinical trial?

This includes pharmaceutical company/ corporate sponsored or investigator driven studies. List all studies if participating in more than one.

If yes - select the type of sponsor eg. Corporate/Industry, Investigator initiated, Other. Then specify the name of the sponsor and the study identification number, if applicable.
Refer to: ANZCTR, ClinicalTrials.gov Identification Number or use other official reference number.
ANZCTR will have the prefix 'ACTRN' followed by 16-digit number. ClinicalTrials.gov will have prefix 'NCT'. The prefixes must be included.

If no – **not participating in a trial, select from the following reason(s):**

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

Product funding (Commercial products only):

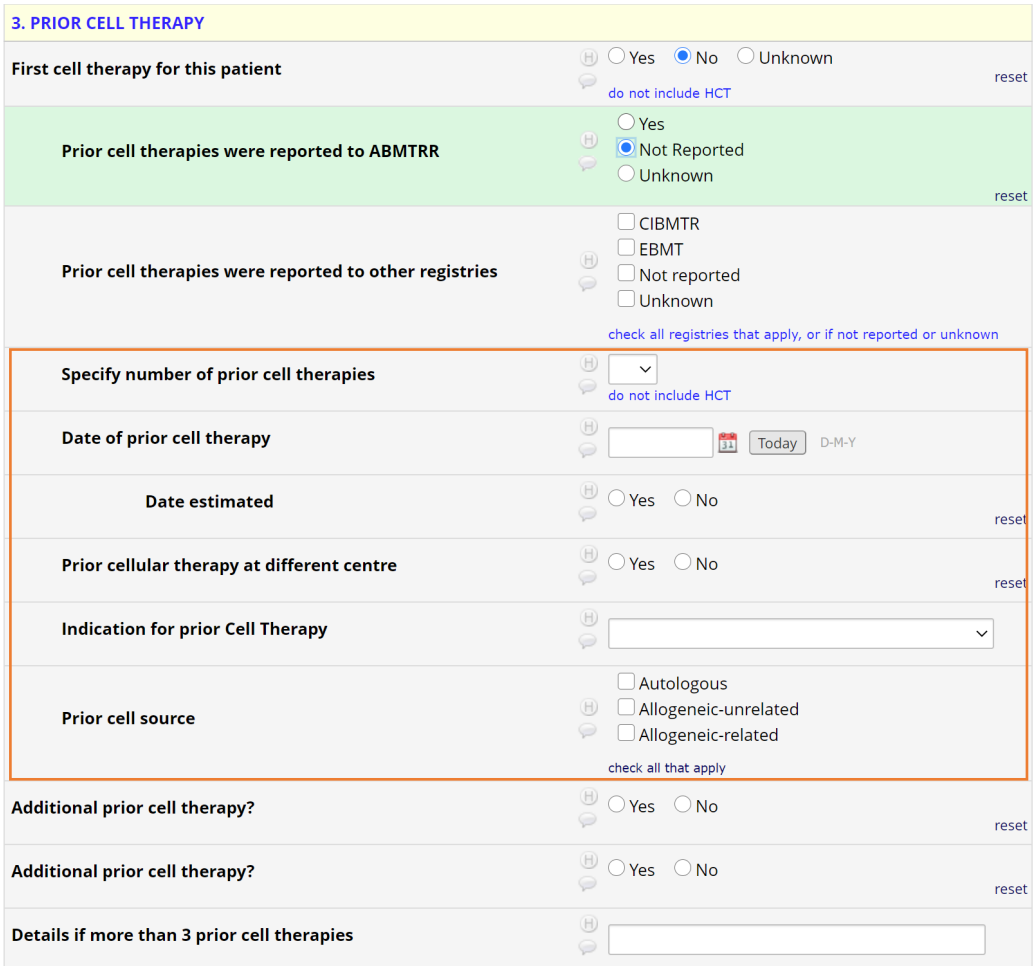
Select from the following:

- Clinical Trial
- MBS (Medicare Benefits Scheme)
- MTOP (Medical Treatment Overseas Program)
- Self-funded

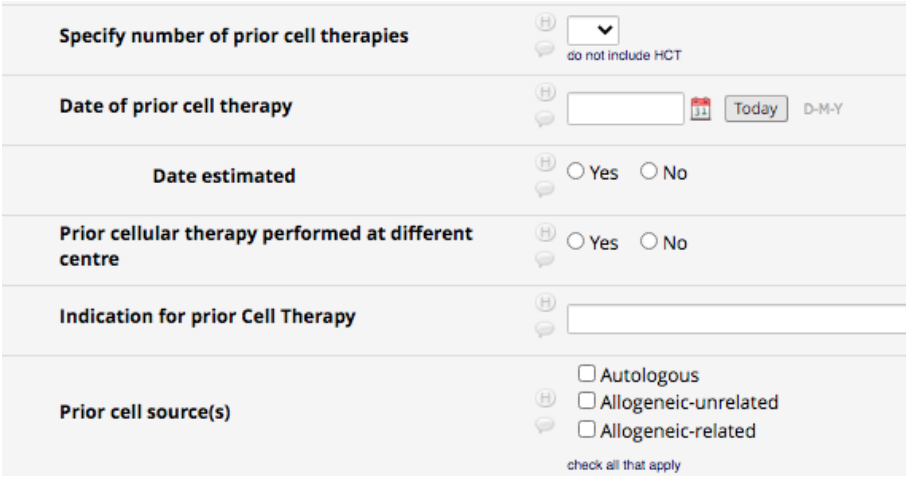
3. Prior Cell Therapy

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 these have not been reported to ABMTRR, then the fields to capture the details for the prior infusion/s will display.



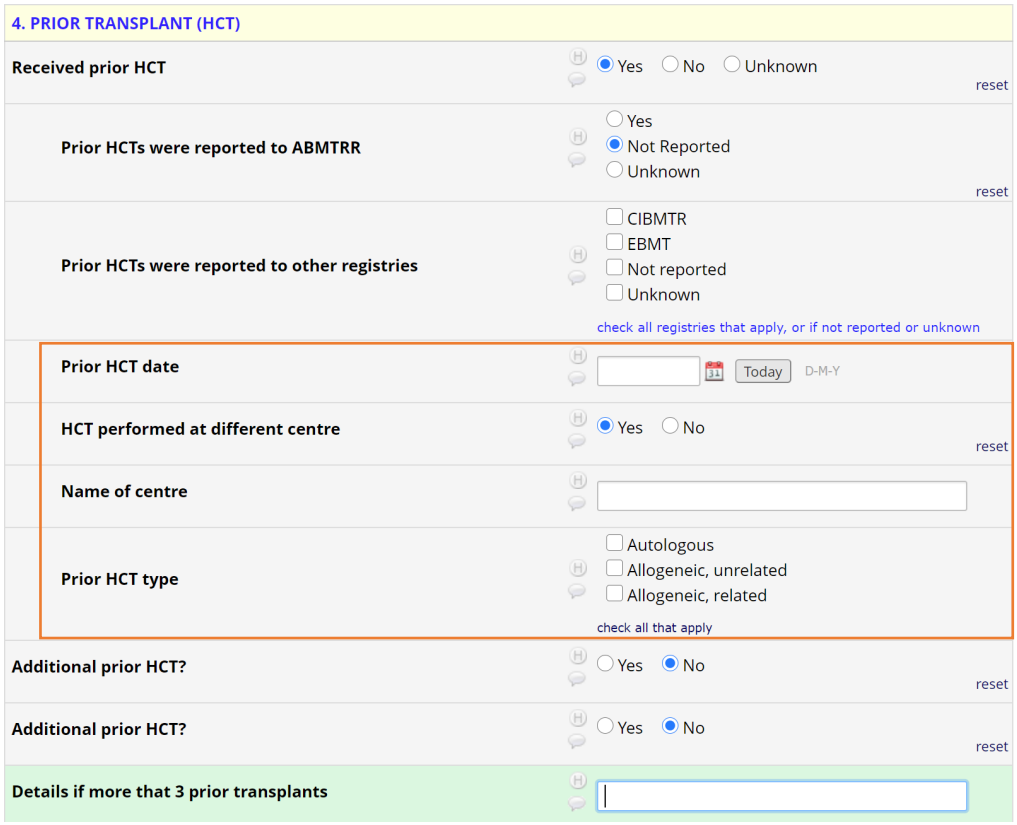
Each infusion is reported separately. Complete the following for each prior cell therapy:



4. Prior Transplant (HCT)

Received prior HCT

If the recipient has received a transplant at any centre, and it has not been reported to ABMTRR (or not known if this has been reported), then the fields to capture the details for the prior infusion/s will display.



5. Product Identification

Product genetically modified?

If more than one product is being infused, indicate if any of these products were genetically modified.

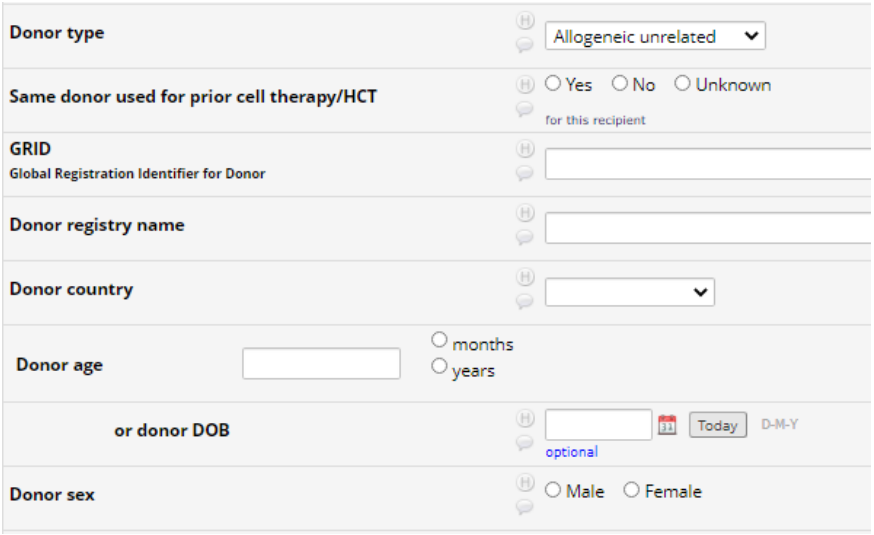
This includes manipulation such as gene editing or insertion of different genes to alter its expression, e.g. CAR T-cells are genetically modified T-cells directed towards specific tumour targets.

Donor type

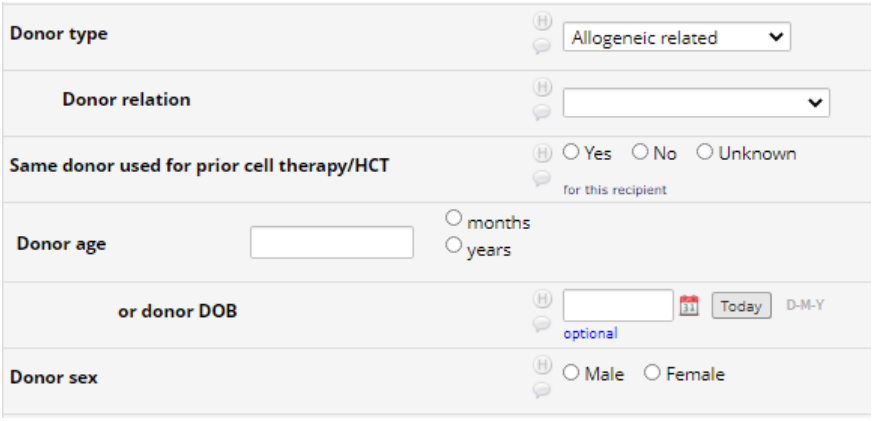
Options: Autologous, Allogeneic related, Allogeneic unrelated, Autologous cord blood
If more than one donor is used for this cell infusion, additional fields will display to capture the details of the second donor further down in this section.

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

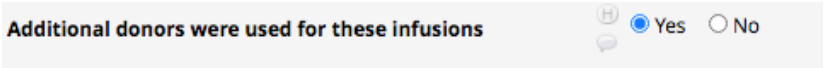
Donor is Allogeneic unrelated



Donor is Allogeneic related



If more than one donor was used for this course of cell therapy, ticking yes on the field below will display the additional questions required.



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 Cell Therapy Products forms required. A new Cell Therapy Product Form is required for each product. Refer to Cell Therapy Product Form section for instructions.

A single product example(s):

- A donor using the same collection method and mobilization 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.

Name of Product
This will be the name of the commercial product or select 'other product' for non- commercial products e.g. DLI

Date of product request
This is the date that the patient is determined eligible for cell therapy.

Date manufacturing started

Date receipt of product
Report the date the product arrives at the centre where the infusion is planned.

Additional donors were used for these infusions
If yes is selected, then additional fields will display to capture the details of the second donor and product.

- Donor type and associated fields
- Specify number of products
- Name of Product
- Date of product request
- Date manufacturing started
- Date receipt of product

Planned setting of infusion
Report if the infusion is planned to be given as an inpatient or outpatient.

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, regardless 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
- autologous or allogeneic:

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

Considered as a donor lymphocyte infusion
An infusion is classified as a "DLI" when:

- cell type is lymphocytes and infused after a transplant.
- the cell source is often from the same donor used in the transplant.
- indications include suboptimal donor chimerism, immune reconstitution, GVHD treatment, prevent or treat disease relapse; NOT to restore haematopoiesis

Indication for cell therapy

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

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 - no associated questions, go to the next section (no additional consent is required from the patient)

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

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

- infection prophylaxis - **specify organism**

Report the diagnosis and diagnosis date for the following indications:

- Cardiovascular
- Musculoskeletal
- Neurologic
- Ocular
- Pulmonary
- Infection
- Other – select if indication does not fit into any of the above categories

Date of diagnosis

Applies to indications other than malignant haematologic disorders, non-malignant disorders and solid tumours.
Enter the date the sample was collected e.g. bone marrow or tissue sample for biopsy. If the indication is infection, this would be the date of the sample providing the first positive microbiology culture. The date may be obtained from a clinician's note if laboratory results are not available. Do not report the date symptoms first appeared.

If the indication was diagnosed in utero or is a congenital disorder, report the date of birth as the date of diagnosis.

For malignant haematologic disorders, non-malignant disorders and solid tumours, the date of diagnosis is reported on the Disease Classification Form

8. Disease assessment prior to cell therapy

These questions apply to malignant diseases with relapsed, persistent or progressive disease only.

Bridging therapy was given

If yes, date started

Bridging therapy is any 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.

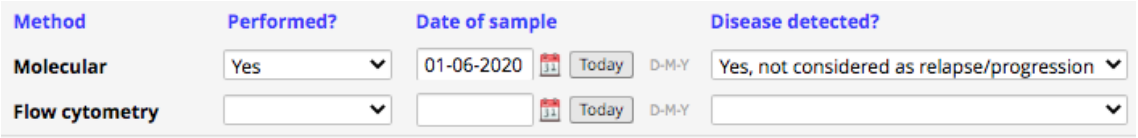
Disease Assessments

The assessments must reflect the most recent testing prior to the start of preparative regimen / or infusion (if no preparative regimen given).

Indicate if the disease was assessed by the following methods:

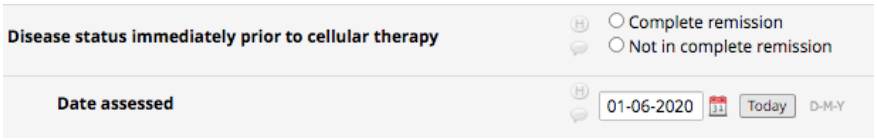
- Molecular
- Flow cytometry (Immunophenotyping)
- Cytogenetic – karyotyping or FISH
- Radiological
- Clinical or haematological

Within each method performed, indicate the date assessed and if disease was detected.



Disease status immediately prior to cellular therapy

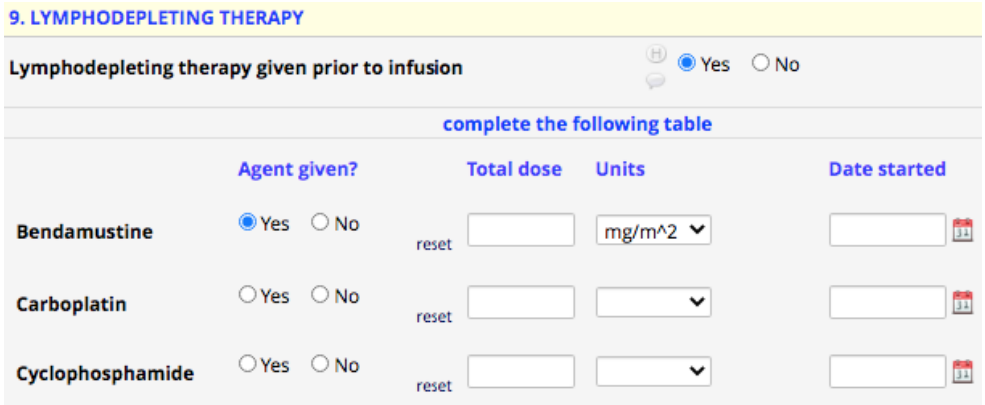
Indicate if the disease is in complete remission or not.



9. Lymphodepleting Therapy

Indicate if lymphodepleting therapy was given.
Note: Report bridging therapy on the disease specific form rather than in this section.

- Report the agent, the total dose, and the date started of each agent given. Report the actual dose given rather than the prescribed or daily dose.
- If a test dose of a drug is given, ensure the date started is the date of the first therapeutic dose.



10. Patient Assessment

Karnofsky/Lansky score prior cell therapy

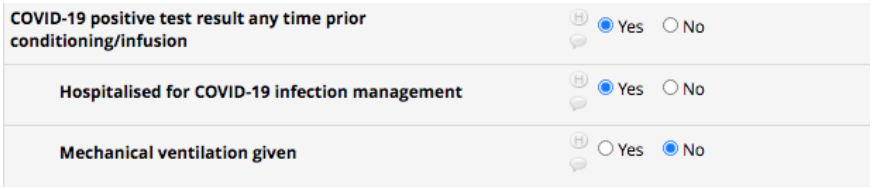
The patient performance status should be assessed within 30 days prior to the cellular infusion.

	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

COVID-19

Report COVID-19 diagnosis here if this was prior to starting lymphodepleting therapy/infusion. If diagnosed after the commencement of lymphodepleting therapy/infusion, then report in the Cell Therapy Post Infusion Form.

If there was a positive result, then specify if the patient required hospitalisation and whether mechanical ventilation was given.



Comorbidities (HCT CI Score)

Complete for malignant haematological disorder or solid tumour indications.

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

Comorbidity	Definition and/or criteria
Arrhythmia	Any history of: • Atrial fibrillation • Atrial flutter • Sick sinus syndrome • Ventricular arrhythmias requiring treatment
Cardiac	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, or • Any history of congestive heart failure, or • LVEF ≤ 50% (or a shortening fraction (SF) of < 26% for paediatric cases) on most recent evaluation prior to the start of the preparative regimen
Cerebrovascular disease	Any history of: • Transient ischemic attack • Cerebrovascular accident/stroke • Subarachnoid, subdural, epidural, or intraparenchymal haemorrhage
Diabetes	Current (within 4 weeks prior) 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 most recent echocardiogram: • At least a moderate or severe degree of valve stenosis or insufficiency as determined by echo, (mitral, aortic, tricuspid or pulmonary); • Prosthetic mitral or aortic valve; • Symptomatic mitral valve prolapse
Hepatic, mild See note below	Any of the following: • Chronic hepatitis • Any history of Hepatitis B or Hepatitis C • Bilirubin >ULN to 1.5 x ULN (upper limit of normal) • AST or ALT >ULN to 2.5 x ULN
Hepatic, moderate/severe See note below	Any of the following: • Liver cirrhosis • Bilirubin > 1.5 x ULN (upper limit of normal) • AST or ALT > 2.5 x ULN
Infection	One or more of the following requiring continuation of therapeutic antimicrobial/antifungal treatment after Day 0: • Documented infection, • Fever of unknown origin, • Pulmonary nodules suspicious for fungal pneumonia • A positive PPD test requiring prophylaxis against TB
Inflammatory bowel disease	Any history of: • Crohn's disease or ulcerative colitis requiring treatment
Obesity	During pre-infusion work-up period: Adults BMI > 35 kg/m2 Paeds BMI-for-age ≥ 95% - if only the BMI is known, refer to: https://www.cdc.gov/growthcharts/.
Peptic ulcer	Any history of peptic ulcer (gastric or duodenal) confirmed by endoscopy or radiologic diagnosis and the patient has or is receiving treatment.

Comorbidity	Definition and/or criteria
Psychiatric disturbance	Any psychiatric illness requiring treatment within four weeks prior to pre-infusion work-up period. Examples include depression, anxiety, ADD, ADHD, schizophrenia, or bipolar disorder.
Pulmonary, moderate	Any of the following at the time of pre-transplant evaluation: • Adjusted DLCO 66-80% • FEV1 66-80% • Dyspnoea on slight activity attributed to pulmonary disease and not anaemia
Pulmonary, severe	Any of the following at the time of pre-transplant evaluation: • Adjusted DLCO ≤ 65% • FEV1 ≤ 65% • Dyspnoea at rest attributed to pulmonary disease and not anaemia • Requires intermediate or continuous supplemental oxygen
Renal, moderate/severe See note below	Any of the following: • Serum creatinine > 177 µmol/L • On dialysis during the 4 weeks prior to cell therapy • Prior renal transplantation
Rheumatologic	Any history of rheumatologic disease requiring treatment including: • Systemic lupus erythematosus • Rheumatoid arthritis • Sjogren' • Polymyositis • Dermatomyositis • Mixed connective tissue disease • Polymyalgia rheumatic • Polychondritis • Sarcoidosis • Vasculitis syndromes Do not include degenerative joint disease or osteoarthritis
Prior malignancy	Any solid or haematological malignancy treated in the past history excluding the primary disease for cell therapy. If the cell therapy indication is a transformation, do not include the original diagnosis here.
Other co-morbid condition	Other co-morbid condition with significant potential impact to recipient's transplant outcome or overall survival; examples would be those co-morbid conditions which do not fit in the above options but require modifications to the recipient's transplant plan or course.

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.

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)

Recipient on dialysis immediately prior to lymphodepleting therapy

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

Prior malignancy (haematologic or non-melanoma skin cancer) other than cellular therapy indication

Report the malignancy type.

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.

1. Product Source

Name of product
As reported in the Pre-Infusion form

Date of cell product collection
e.g. the date that apheresis was performed

Tissue source
Report from which tissue source the cells for processing are derived from for the cell product.
Report “peripheral blood” for commercial products Kymriah® and Yescarta®

Cell type
The type of cells harvested for use in the cell product.
Report ‘Lymphocytes (unselected)’ for commercial products Kymriah® and Yescarta®

Where was product manufactured / processed
Indicate where the product was manufactured. Select 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,”

2. Autologous Product
(If allogeneic, go directly to Cell Manipulation questions, *if applicable*)

Method of product collection
E.g. BM aspirate, leucopheresis, byoptic sample

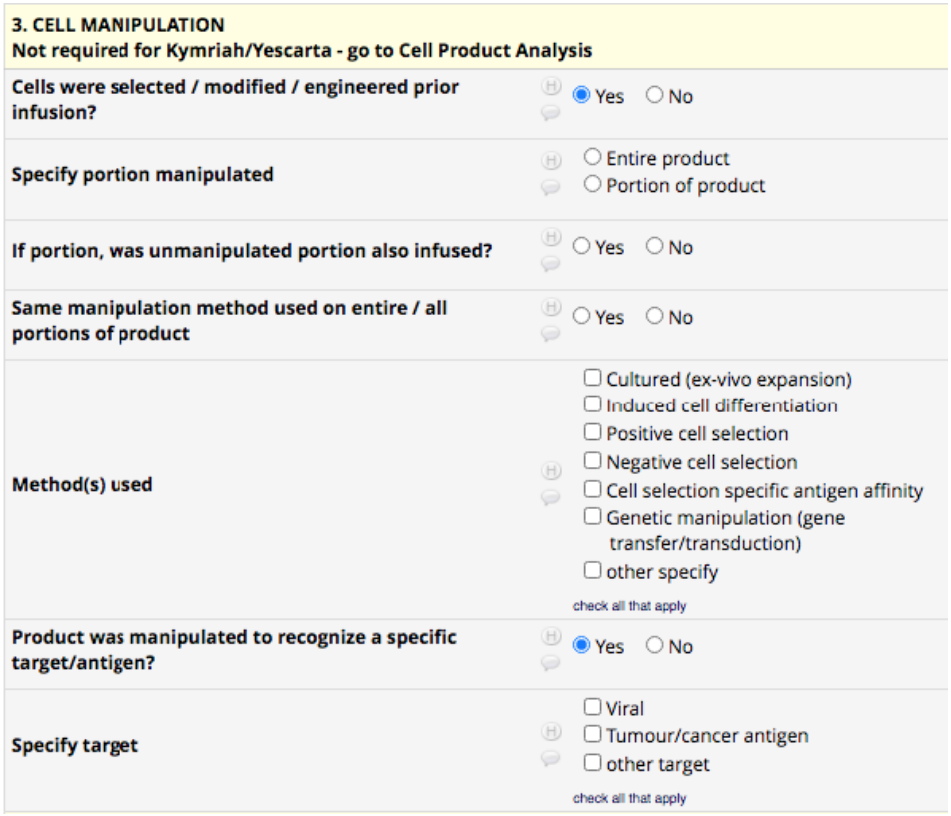
Number of collections
Report the number of days it took to collect the necessary cells for the autologous product.

- A patient received mobilising agents and undergoes a two day PBSC collection. This would be considered as two collections.
- A patient received mobilising agents and undergoes 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 and is discarded

3. Cell Manipulation

Not applicable for Kymriah/Yescarta (this section is hidden if the 'Name of product' (at top of this form) is 'Kymriah' or 'Yescarta)



3. CELL MANIPULATION Not required for Kymriah/Yescarta - go to Cell Product Analysis	
Cells were selected / modified / engineered prior infusion?	(●) Yes ( ) No
Specify portion manipulated	( ) Entire product ( ) Portion of product
If portion, was unmanipulated portion also infused?	( ) Yes ( ) No
Same manipulation method used on entire / all portions of product	( ) Yes ( ) No
Method(s) used	☐ Cultured (ex-vivo expansion) ☐ Induced cell differentiation ☐ Positive cell selection ☐ Negative cell selection ☐ Cell selection specific antigen affinity ☐ Genetic manipulation (gene transfer/transduction) ☐ other specify check all that apply
Product was manipulated to recognize a specific target/antigen?	(●) Yes ( ) No
Specify target	☐ Viral ☐ Tumour/cancer antigen ☐ other target check all that apply

Were cells 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 are 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:

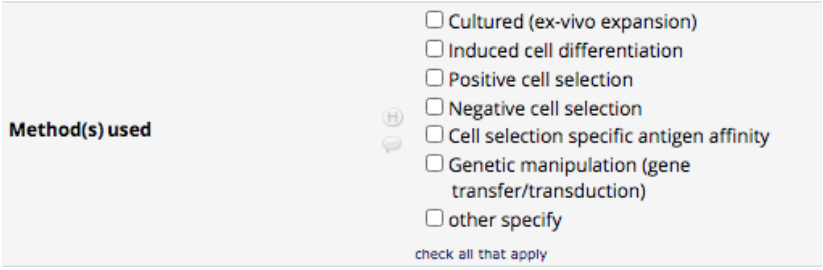
Specify portion manipulated: Entire product | Portion of product

- If this is a DLI/DCI where the product is a portion reserved from the transplant, this should be reported as an entire product.

If portion was manipulated, then was unmanipulated portion also infused? Y | N

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

Method(s) used - indicate all methods:

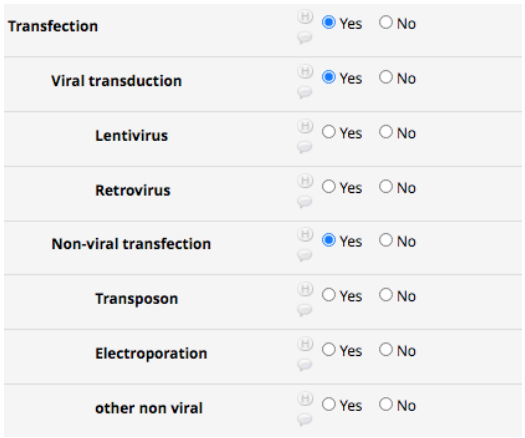


Please refer to the CIBMTR Instruction manual for more information of the manipulation methods - https://www.cibmtr.org/manuals/fim/1/en/topic/4003q27-58

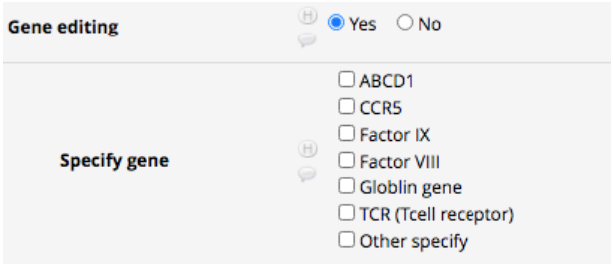
If 'Genetic manipulation' is selected, then the following fields display:

Indicate the type of genetic manipulation:

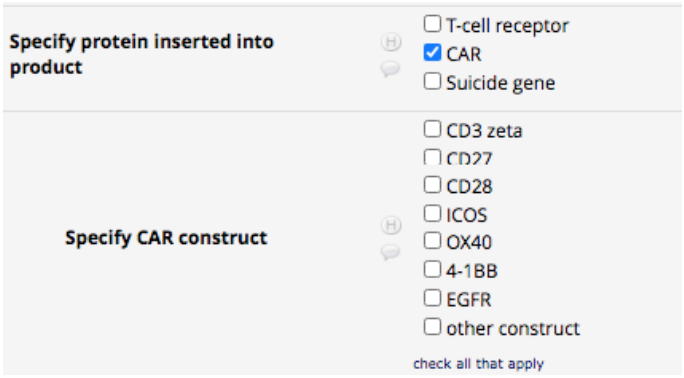
- Transfection: **if yes** –
  - Viral transduction: Lentivirus, Retrovirus
  - Non-viral transfection: Transposon, Electroporation, other



- 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



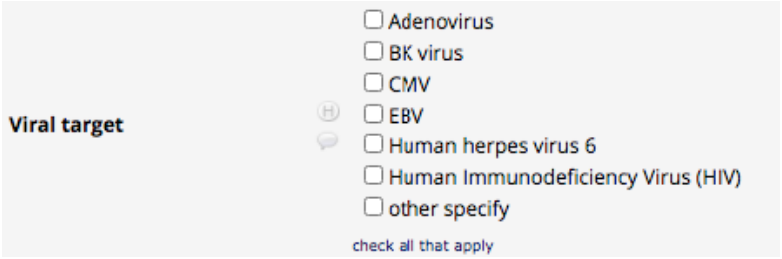
    - if suicide gene, specify the suicide gene

Specify other method if none of above.

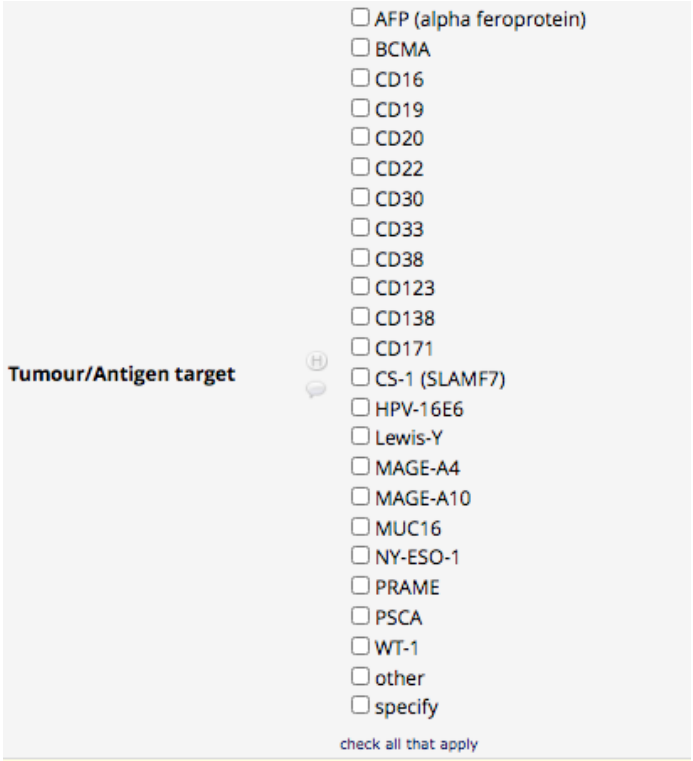
Product was manipulated to recognize a specific target/antigen

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

Viral targets:



Tumour/cancer antigens



4. Cell Product Analysis

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.

5. Product out of specification (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.
Specifications for product release includes cell viability, total cell count, CD4:CD8 ratio is not achieved, transduction efficiency and others.

6. 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

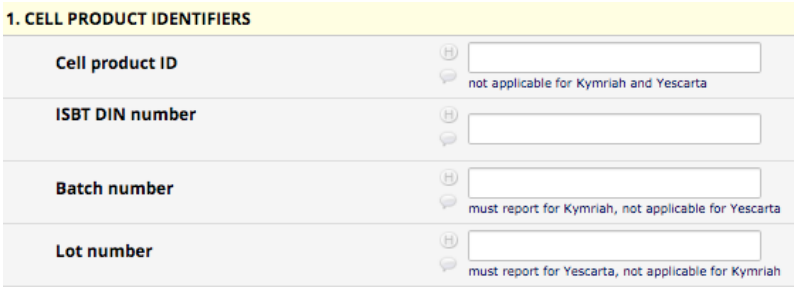
Indicate if the product was actually infused. If not, report the reason why it did not proceed.
If the product was not infused, complete Section 1 Cell Product Identifiers only and skip the reminder of the form. No further forms are required.

1. Cell Product identifiers

Report the appropriate identifier which should be located on the product bag or shipping document, e.g. Cell product ID/Batch Number/Lot number

Please note, for commercial products:

- the batch number must be reported for Kymriah
- the lot number must be reported for Yescarta



1. CELL PRODUCT IDENTIFIERS

Cell product ID	not applicable for Kymriah and Yescarta
ISBT DIN number	
Batch number	must report for Kymriah, not applicable for Yescarta
Lot number	must report for Yescarta, not applicable for Kymriah

2. Infusion

Date of infusion
If the product was infused over multiple days, report the first date of infusion.

Age at infusion
This is an 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
Specify the route e.g. intravenous, intraperitoneal, intra-organ (specify the site)
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”.

Report total number of cells in the product given (not cells per kg and not corrected for viability)

Cell type	Number of cells		exponent
Total number of cells		x10	
Lymphocytes unselected		x10	
CD4+ lymphocytes		x10	
CD8+ lymphocytes		x10	
Natural killer cells (NK cells)		x10	
Dendritic cells /tumour cell hybridomas		x10	
Mesenchymal stromal stem cells (MSCs)		x10	
Unspecified mononuclear cells		x10	
Endothelial progenitor cells		x10	
Human umbilical cord perivascular cells		x10	
Cardiac progenitor cells		x10	
Islet cells		x10	
Oliodendrocytes		x10	
Other, specify		x10	

Please refer to the CIBMTR Instruction manual for more information of the cell types.
https://www.cibmtr.org/manuals/fim/1/en/topic/4006q1-45

4. Concomitant therapy

Concomitant therapy is given to enhance the cell therapy function.
If the recipient has both a transplant and cell therapy, report treatment only relating to the cell therapy infusion on this form i.e. do not include the transplant conditioning therapy.

Recipient receive concomitant therapy?

If yes, report all drugs given, e.g. Atezolizumab, Durvalumab, GM-CSF, IL-2, Lenalidomide

When concomitant therapy given

Indicate if the therapy was given simultaneously with the infusion or post cell therapy which is up to 24 hours after the infusion. This question applies to the therapy as a whole, not to each individual drug.

CELL THERAPY FOLLOW UP FORM

The follow up form should capture the information since the date of the last report.

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. However, if the product is not genetically modified, then the follow up ceases the day before preparative therapy (or infusion if there is no preparative therapy given) of a subsequent infusion.

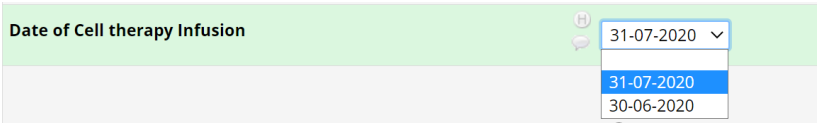
Patients having received both cell therapy and transplant will require follow up forms for the transplant and cell therapy to be completed. The follow up times for these forms will be based on the cell therapy infusion date. Where there are questions in common, duplicate entry of data will be minimised where possible.

1. Patient Identification and follow up period

UPN
This question is required as the UPN may be different from the UPN on the Patient Information form.

Hospital
This is the hospital responsible for follow up at the time of reporting, which should match the user's associated centre.

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: Alive / Dead

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

Also complete a new Cell Therapy Pre-infusion
This includes the accompanying Cell Therapy Product and Infusion forms and Follow up forms relating to the subsequent cell therapy.

HCT given since last report?
If yes:

Date of HCT
Also complete a new HCT (Transplant) form

4. Best response to the cellular therapy

Skip this section if the indication is ALL, CLL, Lymphoma or Myeloma, (this information will be reported in the disease specific follow up form)
Also skip this section if cell therapy is given for GVHD prophylaxis post-transplant, prevention of disease relapse, and infection prophylaxis

This is the best response achieved from the planned cell therapy course. Do not report the response to HCT if also given.

This question is relevant to both malignant and non-malignant indications.

For malignant diseases, applicable responses would be:
- complete response
- partial response
- no response
- disease progression
- unknown

For recipients with continued complete response (in CR at the time of infusion), please report CR for best response.

For non-malignant disorders, applicable responses would be:
- complete response
- partial response
- no response
- unknown

Cardiovascular, musculoskeletal, neurologic, ocular and pulmonary disorders, applicable responses would be:
- normalization of organ function
- partial normalization of organ function
- no response
- worsening of organ function

- unknown

If the indication is infection, the applicable responses would be:

- complete response
- partial response
- no response
- unknown

Guidelines to Best Response to Cellular Therapy can be found on the CIBMTR website:
https://www.cibmtr.org/manuals/fim/1/en/topic/4100q15-16

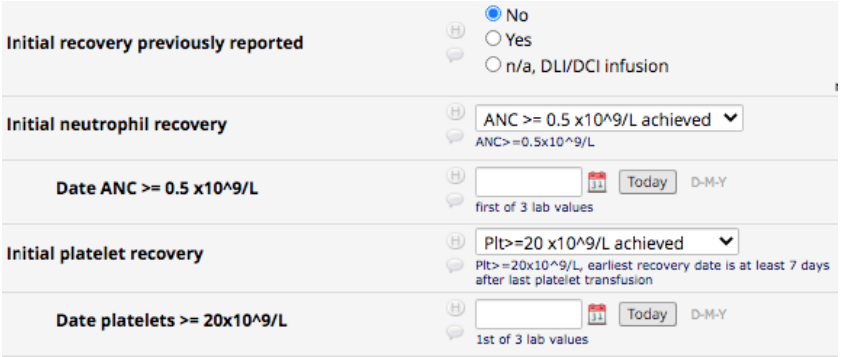
Date of best response or previously reported

Report the date of the best response if this is the first follow up where this is achieved.

5. Peripheral Blood Count Recovery

Complete this section for 30 day, 100 day, 6 month, 1 and 2 year follow up

If the recovery dates have not been previously reported, then these fields below will show when relevant.



Initial neutrophil recovery

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'.

Initial platelet recovery

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

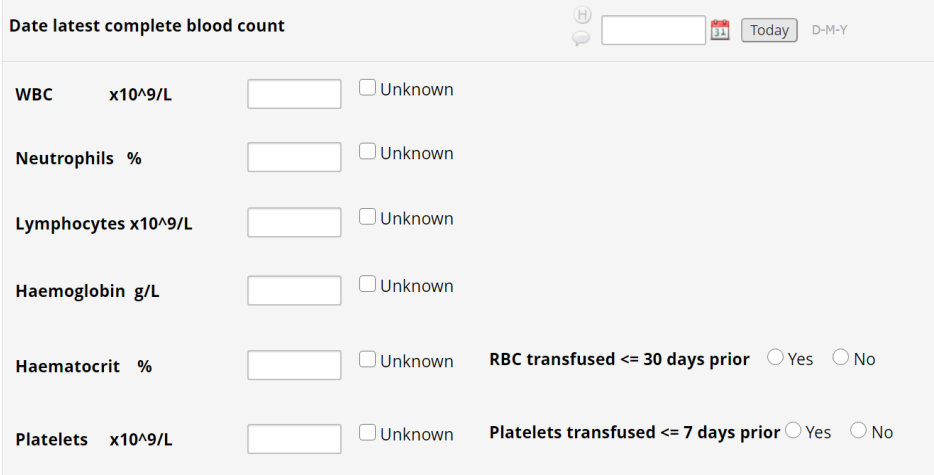
Applicable to malignant indications only.
Skip this section if disease specific form is available (ALL, Lymphoma available now, Myeloma and CLL coming soon)

Relapse or Progression detected since last report post infusion
If yes, report the date this was detected.
Disease relapse or progression may be detected by molecular, flow cytometry, cytogenetic, radiological, haematological or clinical.

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 for the parameters below



8. New malignancy, lymphoproliferative or myeloproliferative disease/disorder

If a new malignancy has been diagnosed after the date of the cell therapy, report this using 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

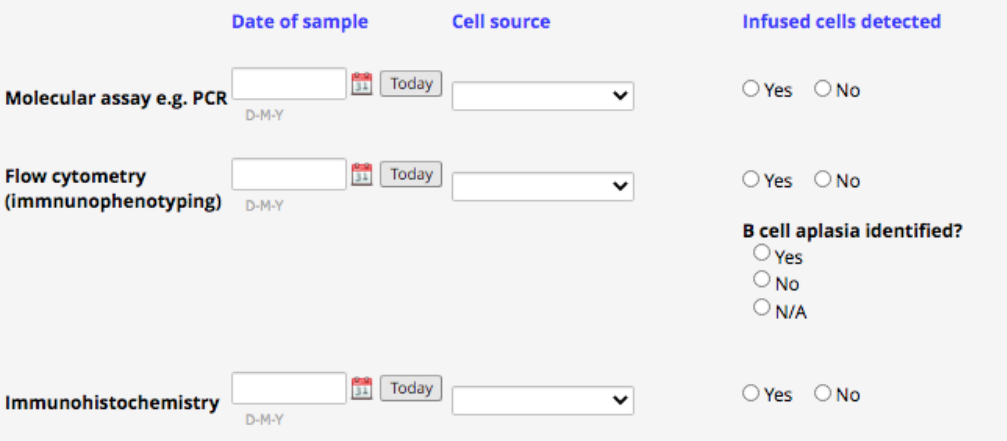
This section applies only to genetically modified cell products only

Tests performed to detect persistence of the cellular product during this period?
Detected by following methods:

- molecular (PCR)
- flow cytometry (immunophenotyping)
- immunohistochemistry
- other method, specify

With each detection method, report

- Date of sample
- Cell source: BM, PB, tumour, other
- Infused cells were detected
- B cell aplasia was identified with flow cytometry.



10. Graft vs. Host Disease

Complete for allogeneic cell sources only

If the recipient also received a transplant and Transplant Follow Up Forms are also completed concurrently with the Cell Therapy Follow Up, then report GVHD in the Transplant Follow Up Forms only (i.e. skip this section)

Acute GVHD

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 in REDCap).

Acute GVHD developed since last report

This is the first incidence or subsequent separate incidence since last report.
Refer to guidelines at the top of this section.

Date of acute GvHD diagnosis

Report the earliest date of clinical diagnosis documented which may be after the date that symptoms first appeared. If this is unclear, then this should be clarified and documented by the clinician.

Did acute GVHD persist since last report

This question displays if 'Acute GVHD developed since last report' is answered 'No'.
Refer to guidelines at the top of this section.
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

Indicate the overall grade of acute GVHD at the time of diagnosis. The acute GVHD grading scale is based on clinical evidence rather than histology. Do not report the severity based on 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
Determine the maximum grade of acute GVHD in this reporting period and the date this occurred. It may be the same date and maximum grade at diagnosis of acute GVHD.
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

- Skin
- Lower GI
- Upper GI
- Liver
- Other sites

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.
Refer to the grading table in the 'Overall grade at diagnosis' question.

Date of maximum overall grade of acute GVHD

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

Chronic GVHD

Chronic GvHD developed since last report

Report a new diagnosis of chronic GVHD in this reporting period.
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. There should be some documentation of the clinical diagnosis.
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. Refer to table below.
Ref: www.ncbi.nlm.nih.gov/pmc/articles/PMC4329079

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

Indicate if any are given at the report time point. This is for both prevention and treatment of GVHD.

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)
Non-systemic steroids should not be reported. This includes treatment used for their local effects such as 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?

e.g. ATG, Cyclosporine, cyclophosphamide, extra-corporeal photopheresis, Tacrolimus, methotrexate, mycophenolate, tocilizumab and others.

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)

Haemophagocytic Lymphohistiocytosis (HLH) / Macrophage Activation Syndrome (MAS) can be a feature of CRS and should be reported here including its treatment.
If CRS did occur in this reporting period, answer the following questions

Date of diagnosis

Therapy given

e.g. Corticosteroids, Siltuximab, Tocilizumab, specify other

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
- Features were related to HLH/MAS
- Cytokine release syndrome resolve?
    - If yes, then the Date resolved is required

12. Toxicities – Neurotoxicity

Neurotoxicity

Report if neurotoxicity developed or is continuing in this reporting period. the date diagnosed and symptoms, reporting the highest grade in this reporting period.

ICE Score

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

CAPD Assessment

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.

References:

1. Common Terminology Criteria for Adverse Events (CTCAE) v5.0
2. 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

Assessments

- Lowest ICE score – report the lowest ICE score which will indicate the worst level of cognition.
- CARTOX10 neurologic assessment - this is optional. In most cases, the ICE score is used.
- CAPD score for children (12 years and less) Cornell Assessment of Paediatric Delirium tool
- Depressed level of consciousness - specify most severe level
- Dysphasia / aphasia - report speech impairment, with aphasia being grade 3 dysphagia
- Seizure
    - Seizure type e.g. complex partial, generalized tonic clonic, non-convulsive status epilepticus and others
    - 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
- Hallucinations
- Tremors
- Cerebral vascular accident (stroke)
    - Date of onset
    - CVA type: haemorrhagic, ischaemic
- Leukoencephalopathy
- Other neurological symptoms
- Did neurotoxicity resolve
    - Date resolved

- Therapy given for neurotoxicity e.g. anti-epileptics, corticosteroids, specify other

13. Other toxicities

Hypogammaglobinemia

- Dates of onset and resolution where relevant
- Requiring immunoglobulin replacement therapy and the dates therapy commenced and stopped where relevant.

Tumour lysis syndrome

- Dates of onset and resolution
- Grade – the most severe grade as follows:
    - 3 Present
    - 4 life threatening consequences, urgent intervention indicated
    - 5 death

Other toxicities

- Dates of onset / resolution and specify the toxicity(ies)
- Additional other toxicities can be entered into the additional text box, including onset dates

14. Grade 3 or 4 organ toxicity?

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

Grade 3 toxicities are applicable to Kymriah only.
Grade 4 toxicities are applicable for all cell therapy products.

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 known

- Interleukin-6
- Interferon gamma IFN-γ
- 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;
- Suspected (unconfirmed) viral or bacterial infections;
- 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 (by organism type) occurring 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

If a fungal infection is suspected (e.g. radiology assessments), but no organism is isolated, this should be reported.

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'

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 the same organism but outside the time periods, report as a new infection.
Note: Blood as the site of infection includes blood or serum obtained 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.

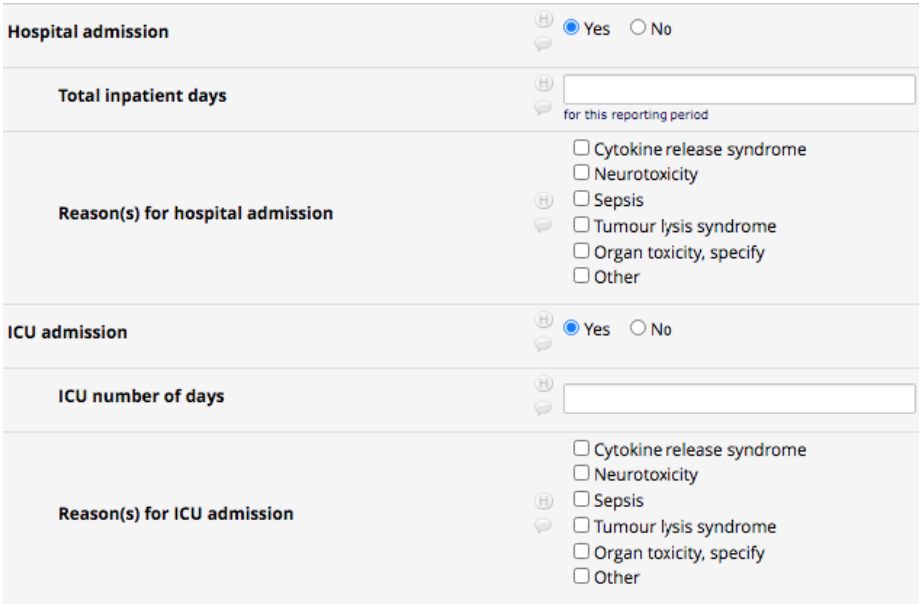
Date of Diagnosis

Guidelines for following scenarios:

- 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 number of days admitted into hospital and ICU if any, and the reasons for the admissions.



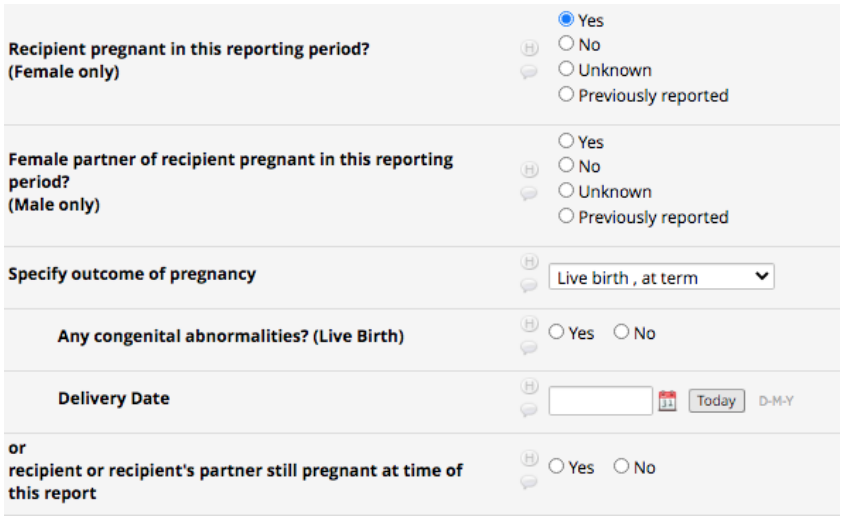
18. High cost medication use

Report very 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. Functional Status

Recipient or female partner pregnant during reporting period

Report if a pregnancy occurred at any time during the reporting period.
The following questions will display



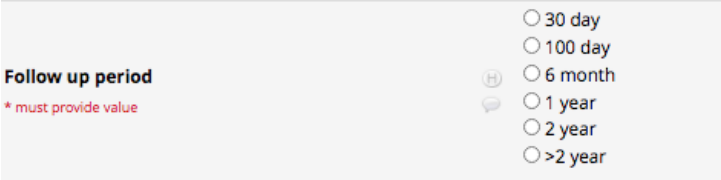
DISEASE SPECIFIC FOLLOW UP FORM POST INFUSION

A summary of the data fields is available under Cell Therapy Forms on the ABMTRR website
https://www.abmtrr.org/index.php/resources/data-management/

ALL POST INFUSION FORM

(Acute Lymphoblastic Leukaemia)

Select the follow up period for this report



Go to CIBMTR Form Instruction Manual for comprehensive guidelines at:
https://www.cibmtr.org/manuals/fim/1/en/topic/2111

1. Best response to HCT or Cellular Therapy

Do not include the response to therapy given for relapses / persistent / progressive disease

If recipient has received a cell therapy then a transplant and this form is being completed for the cell therapy infusion, then the best response achieved will be prior starting preparative regimen for the subsequent HCT (or infusion if no preparative regimen is given).
Similarly, if recipient has received a transplant and then cell therapy then the best response to the HCT will be reported on the Transplant Follow Up Form, which will be the best response prior to commencing lymphodepleting therapy/infusion for the cell therapy where relevant.

If in Continued CR or Date of best response previously reported, go directly to Post Infusion Therapy section

Best response to HCT or Cellular therapy

- Continued complete remission
- Complete remission
- No complete remission
- Previously reported

CR definition: – all of the following response criteria without progression for at least four weeks:

- <5% blasts in the bone marrow,
- no blasts with Auer rods,
- no extramedullary disease (e.g., CNS or soft tissue involvement)

Date of best response

Report the earliest date that the best response was first documented e.g. date of bone marrow/biopsy sample. If this is not available, the date of review if the response was assessed clinically may be used

Tests performed at time of best response

These assessments should be performed within a certain time frame of the Date of best response (previous question).
This time frame is dependent on which follow up period is being reported.

30 and 100 day, 6 month Follow Up: +/- 15 days of Date of best response
Annual Follow Up: +/- 30 days of Date of best response

If the samples are not within these time periods, then they may be considered as 'not done'.

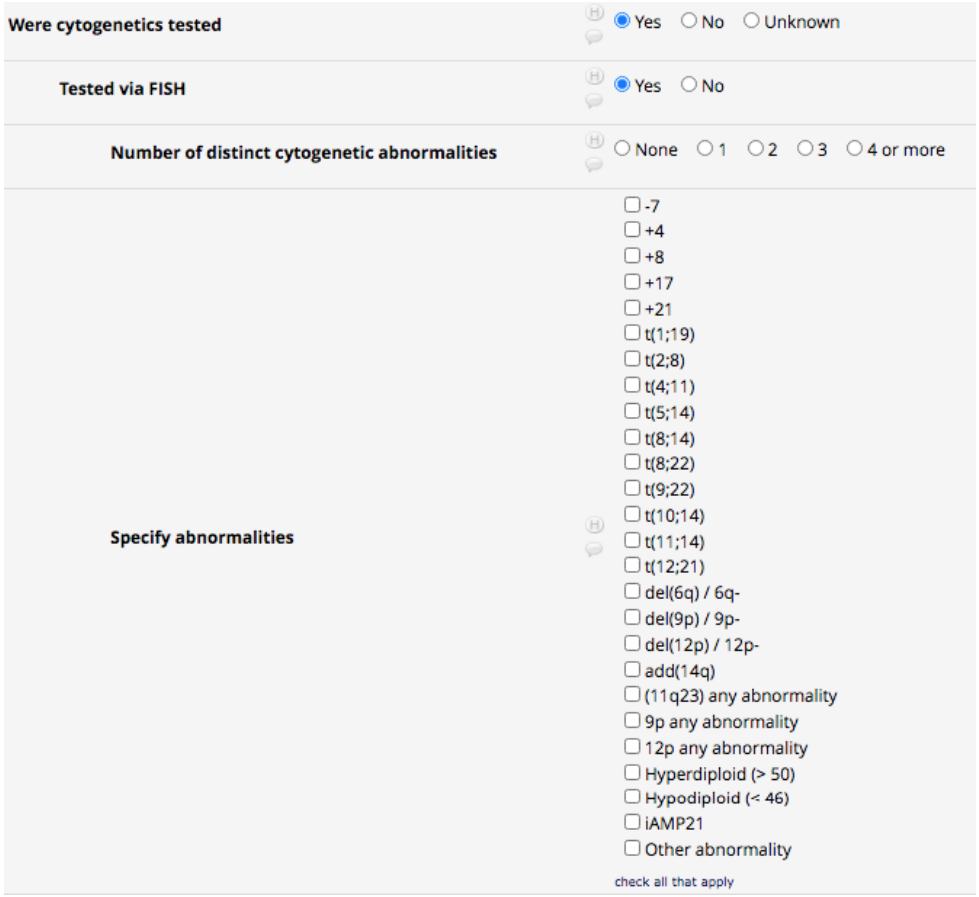
These questions will display if this is the first time reporting the best response to cell therapy

Tests performed at time of best response	
Molecular testing performed?	○ Yes ○ No ○ Unknown eg. PCR, NGS
Flow cytometry performed	○ Yes ○ No ○ Unknown
Were cytogenetics tested	○ Yes ○ No ○ Unknown
Disease status by another method	○ Yes ○ No

Report the test results as shown below

Molecular testing performed?	◉ Yes ○ No ○ Unknown eg. PCR, NGS
BCR / ABL	○ Positive ○ Negative ○ Not done
TEL-AML / AML1	○ Positive ○ Negative ○ Not done
Specify other molecular marker	
Other molecular marker	○ Positive ○ Negative ○ Not done

Flow cytometry performed	◉ Yes ○ No ○ Unknown
Disease detected in blood	◉ Yes ○ No ○ Not done
Date of blood sample	Today D-M-Y
Percent disease detected in blood	
Disease detected in bone marrow	◉ Yes ○ No ○ Not done
Date of BM sample	Today D-M-Y
Percent disease detected in BM	

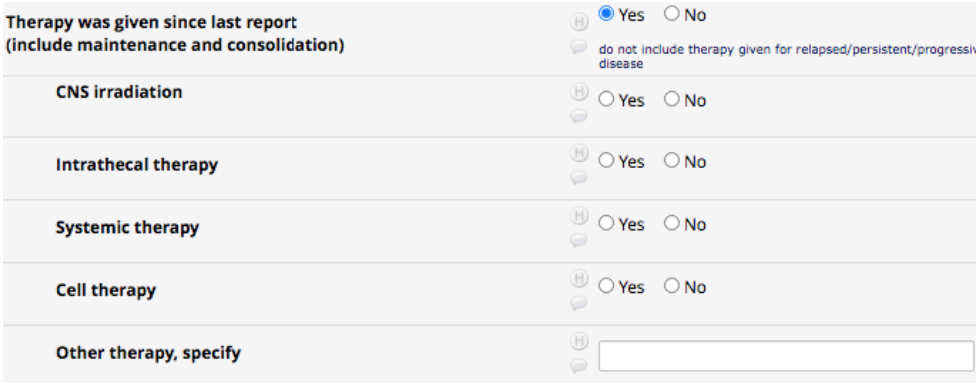


Similar questions will appear if karyotyping is performed.

2. Post infusion therapy

Therapy given since last report

Report therapy given as prophylaxis, maintenance or consolidation. This is usually planned as part of the cell therapy protocol.
Therapy given for relapse/progression or persistent disease (including treatment for minimal residual disease) is reported in Section 4



CNS irradiation

Indicate the site: cranial, craniospinal

Systemic therapy

- Date Maintenance therapy started
- Specify systemic agents – given by injection or orally includes chemotherapy, immunotherapy, targeted therapies.

Cell therapy

Report cell therapy if given for reasons other than for relapsed/persistent disease post infusion.
Do not include HCT here.

Other therapy

Specify any other therapy given, not for relapsed/persistent disease post infusion

3. Disease Detection Since Last Report

Disease was detected by any assessment method

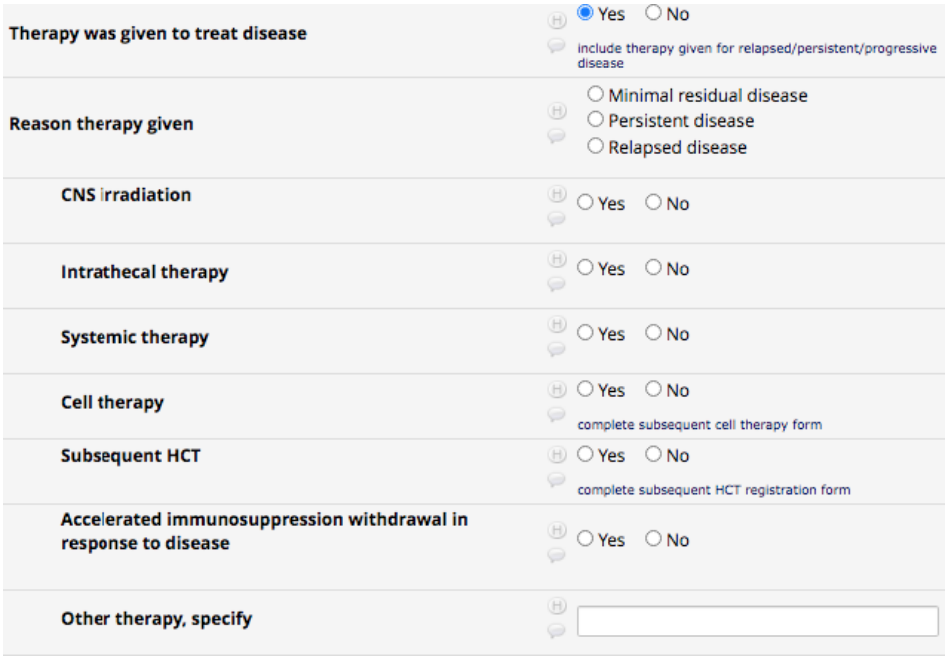
If disease has relapsed, or persistent or minimal residual disease is present in this reporting period, select 'Yes'.
The following fields will display.

Disease was detected by any assessment method	(●) Yes ( ) No
Molecular testing	( ) Yes ( ) No ( ) Unknown eg. PCR, NGS
Flow cytometry	( ) Yes ( ) No ( ) Unknown
Cytogenetic testing	( ) Yes ( ) No ( ) Unknown
Clinical/haematological assessment	( ) Yes ( ) No
Disease detected by other assessment	( ) Yes ( ) No

Report the earliest date of disease detection for each method performed.
Refer to these fields in Section 1 for more information (under 'Tests performed at time of best response')

4. Therapy given to treat relapsed, persistent or minimal residual disease

Report if any treatment has been given post-infusion for minimal residual disease, persistent disease, or relapse since the date of last report
If multiple lines of therapy were given in this reporting period, duplicate sections are available to capture each therapy line.
Selecting **Yes** will show these associated fields for completion.



Reason therapy given

Report the scenario that applies

- **Minimal Residual Disease:** Recipient is in haematologic CR, but has evidence of disease detectable by more sensitive assessments e.g. molecular, flow cytometry or cytogenetics.
- **Persistent Disease:** The recipient was in primary induction failure or relapse at the time of infusion and has not achieved a haematologic CR post-infusion.
- **Relapsed Disease:** The recipient was either in CR at the time of infusion or had achieved a CR post-infusion, relapsing post infusion.

CNS irradiation

Systemic therapy

- **Date first started**
  If the systemic therapy was commenced in a prior reporting period, select 'previously reported'
- **Systemic agents given**
  Select from agents from the list

Cell therapy / Subsequent HCT

If 'Yes' to either of these, an additional cell therapy or transplant form is required.

Accelerated withdrawal of immunosuppression in response to disease

Indicate if the immunosuppression was withdrawn to promote graft versus leukaemia effect.

Other therapy

Report any other treatment that may be given not included in the fields above.

5. Disease Evaluation for this reporting period

This section is intended to capture further assessments if the disease status has changed since the assessments in Section 3 (Disease Detection since last report).

Latest disease status is same as reported in Section 3, without subsequent treatment (as reflected by the assessments reported in Section 3)

Yes – go directly to Section 6

Choose this option if:

- disease was detected in this reporting period and no therapy was given between dates in section 3 and the latest date of contact for this report
- disease was detected and reported in section 3, treatment was given but no assessments performed before the latest date of contact.

No – complete this section

Choose this option if:

- disease was not detected during this reporting period. Enter assessment results here as no results were entered in section 3
- disease was detected and reported in Section 3, treatment was given and disease was re-assessed.

Then complete the results for the assessment methods performed:

Molecular testing	○ Yes ○ No ○ Unknown eg. PCR, NGS
Flow cytometry	○ Yes ○ No ○ Unknown
Cytogenetic testing	○ Yes ○ No ○ Unknown
Clinical/haematological assessment	○ Yes ○ No
Disease detected by other assessment	○ Yes ○ No

N/A, disease not assessed – end of form

Only choose this option if there were no assessments performed, including clinical assessments.

Refer to these fields in Section 1 for more information (under 'Tests performed at time of best response')

6. Current disease status

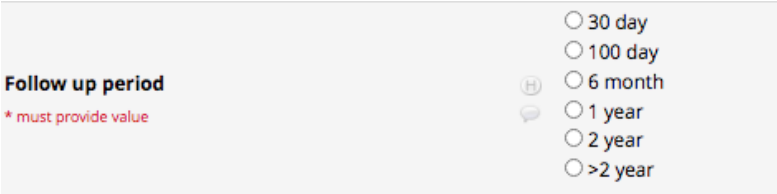
This is the haematologic disease status according to the ALL Response Criteria at the latest disease assessment in this reporting period.
Refer to the CIBMTR Forms Instruction Manual for the ALL Response Criteria.

Date assessed

This date should be the approximately within 30 days from the date of contact.

LYMPHOMA POST INFUSION FORM

Select the follow up period for this report



Go to CIBMTR Form Instruction Manual for comprehensive guidelines at:
https://www.cibmtr.org/manuals/fim/1/en/topic/2118

1. Best response to cell infusion since last report

Best response by CT (radiologic) criteria since last report

Best response by PET (metabolic) criteria since last report

Best response includes the response to therapy given for post cell infusion maintenance, consolidation or persistent disease, but does not include response to any therapy given for disease relapse or progression post-infusion.
To determine the best response, compare the post-infusion disease status to the status immediately prior to the preparative regiment or infusion, regardless of time since the cell infusion. If a recipient already achieved their best response in a previous reporting period, confirm the best response and indicate that the date was previously reported.

If the recipient has received both cell therapy and a transplant, report the best response achieved to cell therapy on this form, which will be the best response prior to commencing preparative regimen/infusion for the HCT where relevant.
Similarly, best response to the HCT will be reported on the Transplant Follow Up Form, which will be the best response prior to commencing lymphodepleting therapy/infusion for the cell therapy where relevant.

Refer to the LYM response criteria for the definitions
https://www.cibmtr.org/manuals/fim/1/en/topic/lymphoma-response-criteria

These assessments should be performed within a certain time frame of the Date of best response (previous question).
This time frame is dependent on which follow up period is being reported.
30 and 100 day, 6 month Follow Up: +/- 15 days of Date of best response
Annual Follow Up: +/- 30 days of Date of best response

If the samples are not within these time periods, then they may be considered as ‘not done’.

Date assessed
Report the earliest date that the best disease status achieved was obtained or tick the ‘previously reported’ checkbox if this is not the first follow up reporting this date.

Minimal Residual Disease assessed at time of best response
If the response to the above questions are ‘Continued CR’ or ‘Not assessed’, skip these questions and go to Section 2.

If any of these assessments were performed, then also report:

- Sample Source
- Date sample collected

Minimal residual disease (MRD) assessed at time of best response	◉ Yes ○ No ○ Unknown ○ NA, best response previously reported
Flow Cytometry	○ Positive ○ Negative ○ Not done
PCR	○ Positive ○ Negative ○ Not done
Next generation sequencing	○ Positive ○ Negative ○ Not done NGS, 3rd gen
Pathology report submitted to Registry	○ Yes ○ No

2. Post HCT / Infusion Therapy

Report therapy given for maintenance, consolidation, and persistent disease (including MRD) since last report. Do NOT include therapy for relapse or progressive disease.
If multiple lines of therapy were given for in this reporting period, duplicate sections are available for reporting each line.

Therapy given since last report e.g. maintenance, consolidation and persistent disease therapy	◉ Yes ○ No Do NOT include therapy for relapse or progressive disease
Report an additional therapy line if treatment is changed in this reporting period	
Therapy line 1	
Systemic therapy	○ Yes ○ No
Radiation therapy	○ Yes ○ No
Cellular therapy (e.g. CAR-T)	○ Yes - complete cell therapy forms ○ No
Other therapy	○ Yes ○ No

Systemic therapy

If given, then the following fields will show.

Systemic therapy	◉ Yes ○ No
Date started known	
Date stopped known	
Specify therapy	☐ Brentuximab vendotin ☐ Ibrutinib (Imbruvica) ☐ Lenalidomide (Revlimid) ☐ Nivolumab ☐ Pembrolizumab ☐ Rituximab (Rituxan, MabThera) ☐ Other systemic therapy
Reason systemic therapy stopped	
Therapy part of clinical trial	◉ Yes ○ No ○ Unknown
Clinical Trial ID	

Cell therapy

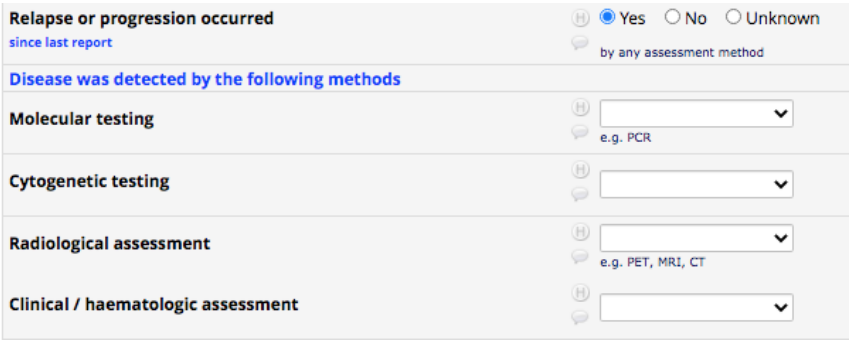
If cell therapy was given as part of the line of therapy, then addition Cell therapy Pre-Infusion Forms (and the associated forms) are required to be completed.

Other therapy

Specify any therapy not reported above

3. Disease Relapse or Progression since last report

If relapse or progression occurred, by any assessment method, selecting 'Yes' will display the following questions

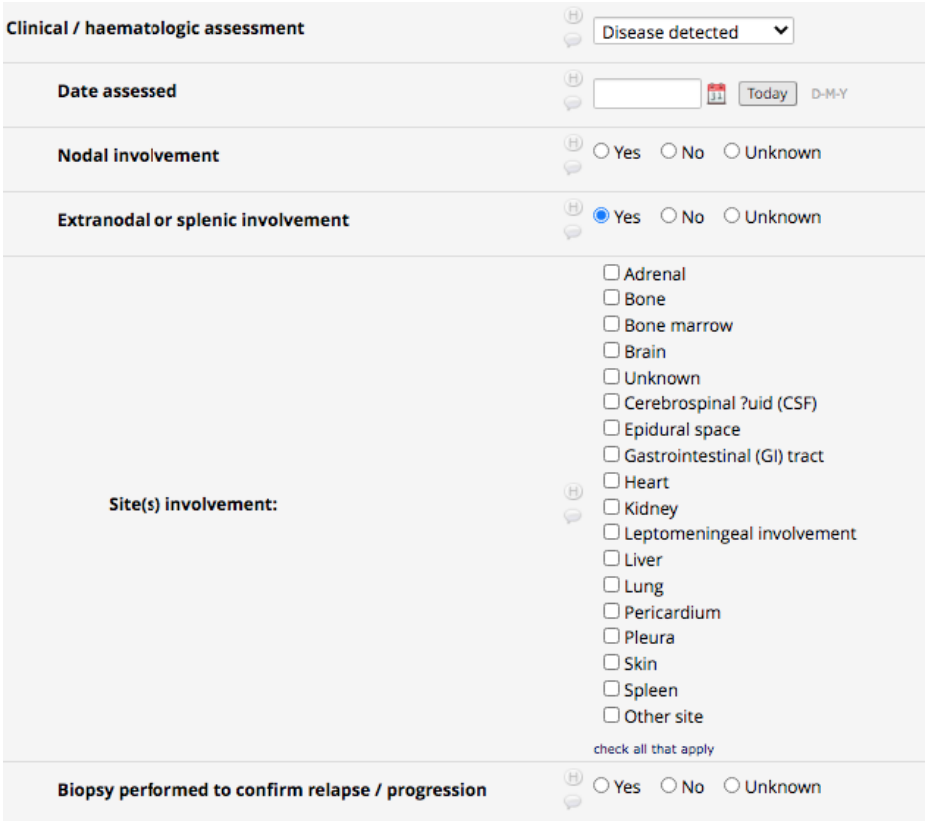


Under each assessment method:

- Molecular
- Cytogenetics – FISH and Karyotyping
- Radiological
- Clinical/Haematologic

Indicate if disease was detected and the date assessed.

Additional fields display if disease was detected by Clinical /Haematologic assessment



4. Therapy for Relapse or Progression

Therapy given for relapsed, progressive or minimal residual disease

Report any treatment was given for relapsed or disease progression.
Treatment may also be given for minimal residual disease (MRD), but only report this if the MRD is new. Do not include here if it was existing at the time of cell therapy as this is reported in Section 2.

If multiple lines of therapy were given for relapse or progression in this reporting period, duplicate sections are available for reporting each line.

Reason therapy given

Report the scenario that applies

- **Relapsed Disease**: The recipient was either in CR at the time of infusion or had achieved a CR post-infusion, then relapsed post infusion.
- **Progressive Disease**: Disease progressed following a period of stable disease or after achieving a partial remission.
- **Minimal Residual Disease**: Recipient is in haematologic CR, but has evidence of disease relapse detectable by more sensitive assessments e.g. molecular, flow cytometry or cytogenetics.

Systemic therapy

- Dates started and stopped
- Specify agents given
  Select agents from the list
- Therapy part of clinical trial
  Report the Clinical Trial ID

Intrathecal therapy

- Dates started and stopped

Intraocular therapy

- Dates started and stopped

If multiple intraocular therapies are given as part of a single line, report each therapy as a separate line.

Radiation therapy

Cell therapy

If cell therapy was given for disease relapse/progression/MRD, complete new Cell Therapy Pre-infusion Forms (and the associated forms)

Specify other therapy

Best response to line of therapy by CT (radiologic) criteria

- Date assessed

Best response to line of therapy by PET (metabolic) criteria

- Date assessed

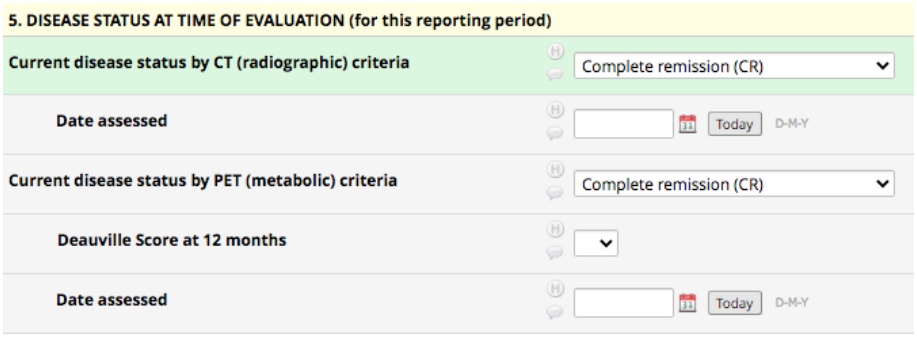
Refer to the CIBMTR LYM response criteria for the definitions
https://www.cibmtr.org/manuals/fim/1/en/topic/lymphoma-response-criteria

5. Disease Status at Time of Evaluation for this reporting period

Current disease status

Disease specific assessments (CT or PET scans) do not need to be repeated at each reporting period to report the current disease status.
Once a particular disease status is achieved, this disease status can continue to be reported again until there is evidence of relapse or progression.

Deauville Score is captured prior to the infusion on the Disease Classification form and at 12 months post infusion. This is a five-point score obtained from the PET report.



NEW MALIGNANCY FORM

Go to the CIBMTR Forms Instruction Manual for comprehensive guidelines.
Form 3500: Subsequent Neoplasms
https://www.cibmtr.org/manuals/fim/1/en/topic/3500

Do not include 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 – 1 year; 2 year; >2 year (specify year)

New Malignancy diagnosis

Date of diagnosis

New malignancy is donor/cell product derived

Report if the new malignancy originated from the donor product

- Attach documentation
  documentation to confirm the origin e.g. VNTR, cytogenetics, FISH

Pathology or autopsy report submitted to registry

Indicate if a pathology report of the new malignancy diagnosis has been submitted e.g. pathology report, autopsy.

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 PCR of blood, 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

Select sites from a list

Was PTLD confirmed by biopsy

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.

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

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.