Indication for CIBMTR Data Reporting (2814) Form

The Indication for CIBMTR Data Reporting (2814) Form collects information to initiate CIBMTR reporting on the appropriate research or data collection forms. This form must be completed for the first indication requiring the individual to register for a CIBMTR Research ID (CRID) and any subsequent infusions the recipient received.

Links to Sections of Form:

Manual Updates:
Sections of the Forms Instruction Manual are frequently updated. The most recent updates to the manual can be found below. For additional information, select the manual section and review the updated text.

If you need to reference the historical Manual Change History for this form, please reference the retired manual section on the Retired Forms Manuals webpage.

Date	Manual Section	Add/Remove/Modify	Description
7/26/2024	2814: Indication for CIBMTR data reporting	Add	Version 5 of the Indication for CIBMTR Data Reporting section of the Forms Instructions Manual released. Version 5 corresponds to revision 5 of the Form 2814.

Reporting Process

New Reporting Process

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As of July 26, 2024, a new process for reporting subsequent infusions was implemented.

The Indication for CIBMTR Data Reporting (2814) Form collects information to initiate CIBMTR reporting on the appropriate research or data collection forms. This form must be completed for the first indication requiring the individual to register for a CIBMTR Research ID (CRID) and any subsequent infusions the recipient received.

- **First infusions:** This is the first completed after the CIBMTR Research ID Assignment (2804) Form.
- **Subsequent infusions:** This form is triggered from the Post-Transplant Essential Data (2450), Post-HCT Follow-up Data (2100), or Post-Cellular Therapy Essential Data (4100) forms when a subsequent infusion is reported.

If the subsequent infusion is a cellular therapy and you will request the F4000 to be made NRQ, complete the F2814 first, to trigger the F4000 then submit a request via CIBMTR Center Support.

On-Demand reporting
There are two appropriate scenarios where centers should create an on-demand Form 2814:

1. To report a subsequent infusion when there are NO follow up forms (F2100, F2450 or F4100) available to report this information.

If follow-up forms are DUE in the forms grid, centers should NOT create a F2814, but report the subsequent infusion on the applicable follow-up form.

2. To report DLIs “on time”

To report a DLI, a prior allogeneic infusion must exist in FormsNet3SM.

For steps on how to create an on-demand form, see ‘Create an Unscheduled Form’ within the FormsNet3SM Training Guide.
The combination of answers provided in this form is used to determine the infusion type and which forms are required.

Event date
If the form is in DUE status, the event date displayed in the Recipient Forms Grid will be the date the form was created. When the form is submitted, the event date will update to the infusion date provide on the form (for HCT, gene therapy, or cellular therapy) or it will be updated to the appropriate allogeneic HCT event date for DLIs.

Determination of Infusion Type and Forms Required

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The combination of answers provided will determine the infusion type (HCT, gene therapy, cellular therapy or DLI). Review the tables below to understand how the infusion type is determined, and which forms are required.

Table 1. Reporting HCTs and Gene Therapies

	HCT (Non-GM)	Auto Rescue	HCT (GM) *New*	Gene Therapy
Question Text / Forms	2400/2402	None	2400/2402	2400/2402
Does the product(s) infused contain CD34+ cells with the intent to establish / restore hematopoiesis?	Yes	Yes	Yes	Yes
What was the primary indication for this infusion? *answered only for subsequent HCT/GT	NOT graft failure or poor graft fxn / insufficient donor chimerism	graft failure or poor graft fxn / insufficient donor chimerism	NOT graft failure or poor graft fxn / insufficient donor chimerism	[any]
Are any of the products associated with this infusion genetically modified?	No	No	Yes	Yes
Was genetic modification performed to repair or correct a genetic defect	n/a	n/a	No	Yes
Was the infusion a donor lymphocyte infusion (DLI)	n/a	n/a	n/a	n/a
Number of DLIs in this reporting period	n/a	n/a	n/a	n/a
Specify donor	n/a	Auto	n/a	n/a
Has this donor already provided cells for this recipient for a prior infusion?	n/a	n/a	n/a	n/a

Table 2. Reporting Cell Therapies

	CT (non-GM)	CT (GM)	DLI
Question Text ⬇ / Forms ➡	4000	4000	2199
Does the product(s) infused contain CD34+ cells with the intent to establish / restore hematopoiesis?	No	No	No
What was the primary indication for this infusion?	n/a	n/a	n/a
Are any of the products associated with this infusion genetically modified?	No	Yes	No
Was genetic modification performed to repair or correct a genetic defect	n/a	No	n/a
Was the infusion a donor lymphocyte infusion (DLI)	No	No	Yes
Number of DLIs in this reporting period	n/a	n/a	[number]
Specify donor	n/a	n/a	AlloR or AlloU
Has this donor already provided cells for this recipient for a prior infusion?	n/a	n/a	[answered]

Form Submission Message

When the Form 2814 is submitted, a message will display showing the infusion type.

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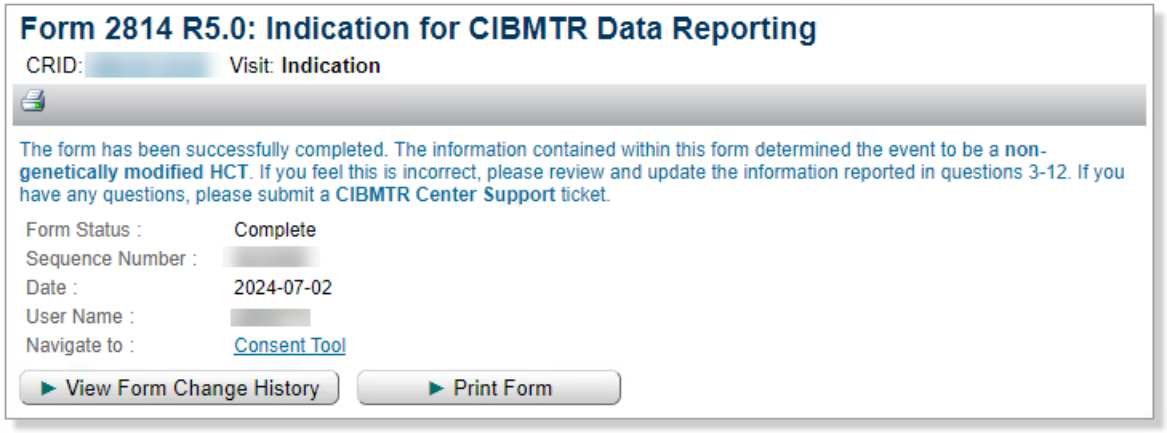
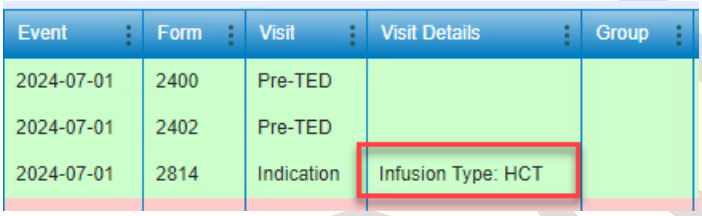


The infusion type will also display in the Recipient Forms Grid in the Visit Details column.



Editing the F2814
This form can be edited until the Pre-TED (2400) and Disease Classification (2402) Forms or Pre-CTED (4000) Form is completed and submitted.

If the infusion type displayed on the form completion page or in the Visit Details column of the Recipient forms grid is incorrect, go back and edit the form. Refer to Table 1 and 2 to understand how the infusion type is determined

If any changes to the form need to be made after these forms are submitted, contact CIBMTR Center Support.

Q1-2: Indication

Questions 1 - 2: Specify the indication for CIBMTR data reporting

Indicate whether the individual will be receiving an **Infusion** (e.g., hematopoietic cellular transplant (HCT), gene therapy, cellular therapy), **Marrow toxic injury**, or **Non-cellular therapy** (e.g., chemotherapy, immunotherapy, etc.).

For more information on infusion types, review Appendix D.

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Marrow toxic injury should only be reported by Radiation Injury Treatment Network (RITN) centers in the event of mass casualty incident resulting in marrow toxic injury. Do not report marrow toxic injury for individuals receiving pre-infusion radiation therapy or for accidental, isolated exposures to radiation. If the indication is **Marrow toxic injury**, specify the date of the marrow toxic injury (i.e., radiation event).

If completing this form for a patient at a RITN center and are uncertain if the patient's data should be reported using the marrow toxic injury indication, submit a CIBMTR Center Support ticket or email RITN@nmdp.org.

Non-cellular Therapy

There are currently no active studies for this option. If you feel this option is correct, submit a CIBMTR Center Support ticket

Non-cellular therapy may include vaccine or immunomodulatory trials; report non-cellular therapy when the patient is enrolled on a trial or protocol requiring data submission to CIBMTR.

Section Updates

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (if applicable)

Q3-12 Infusion

Determining Infusion Types and Forms Selection

The combination of answers provided in the following questions will be used to determine the infusion type and which forms are required.

Question 3: Does the product(s) infused contain CD34+ cells with the intent to establish / restore hematopoiesis?

The intent of this question is to separate HCT/CD34+ boosts/gene therapy infusions from cellular therapy (e.g., genetically modified or non-genetically modified, or DLI) infusions. This question is answered for all infusion types.

Co-infusions

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Co-infusions are considered part of the HCT protocol and should not be considered for this question. Co-infusion products will be captured on the Pre-TED (2400) Form for this infusion. See Appendix D for more information.

The intent of CD34+ products is generally to restore hematopoiesis by replacing or repopulating the recipient marrow.

Specify if the product(s) infused contain CD34+ cells *and* the intent is to establish and / or restore hematopoiesis. If you are unclear of the intent of the CD34+ cells, confirm the intent with the physician.

For more information on infusion types, review Appendix D.

What was the primary indication for this infusion?
This question only applies to subsequent HCT/gene therapy infusions and will not be enabled if this is the first infusion reported to CIBMTR.

Questions 4-5: What was the primary indication for this infusion?

The intent of this question is to determine whether a new Pre-TED is required for the subsequent infusion. This question is answered for subsequent HCT and gene therapy infusions only.

Indicate the reason for the subsequent infusion (check only one).

- **Graft failure:** Additional stem cells are required because the ANC did not recover following HCT (primary graft failure), or hematopoietic recovery indefinitely declined after the initial hematopoietic recovery or hematopoietic recovery (secondary graft failure)
  - **Autologous infusion**: If autologous cells are infused for this reason, this is considered an autologous rescue; in this case, reporting will continue under the prior HCT date, and a new Pre-TED form is not required.
  - **Allogeneic infusion**: If allogeneic cells are infused, this would be considered a subsequent HCT, and a new Pre-TED is required, and reporting would start over.
- **Poor graft function / insufficient donor chimerism**: Additional stem cells are required because hematopoietic recovery was deemed insufficient or too slow for survival following previous high-dose therapy and HCT.
  - If autologous cells are infused for this reason, this is considered an autologous rescue; in this case, reporting will continue under the prior HCT date, and a new Pre-TED form is not required. If allogeneic cells are infused, this would be considered a subsequent HCT, and a new Pre-TED is required, and reporting would start over.

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  - In the case of a stable, mixed donor chimerism, the infusion of additional cells (usually lymphocytes and not mobilized stem cells) is typically classified as a DCI. Verify with the transplant physician that the cells given should be reported as a subsequent transplant and that stable, mixed chimerism is the reason for the transplant. However, in the case of declining chimerism – when the percentage of donor cells is sequentially decreasing on several studies, indicating possible impending graft failure – additional stem cells are required. Usually, the donor chimerism has fallen below 30-50%.
- **Persistent primary disease:** Additional stem cells are required because of the persistent presence of disease pre- and post-infusion (i.e., clinical / hematologic complete remission was never achieved following the previous infusion, clinical / hematologic complete remission was achieved but disease persisted by other methods of assessments (molecular, flow cytometry, cytogenetics)).
- **Recurrent primary disease:** Additional stem cells are required because of relapse of the primary disease by any method of assessment (i.e., clinical / hematologic complete remission was achieved pre or post-infusion, but the disease relapsed following the previous infusion, clinical / hematologic and molecular complete remission was achieved pre- or post-infusion, but the disease relapsed by molecular assessments following the previous infusion).
- **Planned subsequent HCT, per protocol:** Additional stem cells are given as defined by the protocol for a subsequent transplant / infusion. This infusion is not based upon recovery, disease status, or any other assessment.
- **New malignancy (including PTLD and EBV lymphoma):** Additional stem cells are required because the recipient developed a new malignancy. This does not include a transformation or progression of the original malignancy for which the recipient was transplanted (i.e., MDS progressed to AML). If New malignancy is selected, also complete the New Malignancy, Lymphoproliferative or Myeloproliferative Disorder section of the appropriate follow-up form.
- **Other:** If additional stem cells are given for a reason other than the options listed, select Other and specify.

Question 6: Are any of the products associated with this infusion genetically modified?

The intent of this question is to separate genetically modified products from non-genetically modified products to determine the follow up schedule. This question is answered for all infusion types.

A genetically modified product consists of cells genetically modified outside the body after pheresis (i.e., product collection). Genetically modified products include any product where the cells are manipulated via either:

- Gene transfer: a process by which copies of a gene are inserted into living cells in order to induce synthesis of the gene's product; or

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- Transduction: a process by which foreign DNA is introduced into a cell by a virus or viral vector

CART-T and Gene Therapy Products
CAR-T and gene therapy products are genetically modified based on manufacturing process.

Donor Lymphocyte Infusion (DLI)
By the definition used by CIBMTR, DLIs cannot be genetically modified.

Indicate if the product(s) associated with the infusion was genetically modified. If more than one product is being infused, indicate if *any* of the products are genetically modified.

Question 7: Was genetic modification performed to repair or correct a genetic defect?

The intent of this question is to determine if the infusion is a gene therapy. This question is answered for HCT or gene therapy infusions.

There are two general approaches to gene therapy:

1. Gene addition: Correct copies of genes are inserted into the DNA of the stem cells using a vector system.
2. Gene editing: defective DNA sequences at a specific location are removed or replaced with the correct sequence.

Indicate if genetic modification was performed to repair or correct a genetic defect.
For more information on gene therapy, review Appendix D.

Question 8: Was the infusion a donor lymphocyte infusion (DLI)?

The intent of this question is to determine if the if the cellular therapy is a Donor Lymphocyte Infusion (DLI).

Donor lymphocyte infusions (DLI) are considered a type of cellular therapy. These infusions are *not* intended to promote hematopoiesis. If the recipient received additional cells due to engraftment issues, or if they received an infusion of unmanipulated CD34+ cellular product (stimulated peripheral blood stem cells, bone marrow, or cord blood), this question should not be answered.

An infusion is a donor lymphocyte infusion when all the following criteria are met:

- The intent of the infusion is something other than to restore hematopoiesis
- The infusion must be post-Allogenic HCT, often by the same donor as the HCT
- The product must be a lymphocyte product
- The product cannot be genetically modified

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Indicate if the infusion was a DLI (i.e., met the criteria listed above).

For more information on DLIs, review 2199 Donor Lymphocyte Infusion manual.

Question 9: Number of DLIs in this reporting period:

Report the number of Donor Lymphocyte Infusions (DLI) the recipient received in the current reporting period. This question is used to make the correct number of Donor Lymphocyte Infusion (2199) Forms come due.

Question 10: Specify donor

This question is answered for subsequent HCT and DLIs.

Indicate the donor type for this infusion.

- **Autologous**: The product has cells collected from the recipient for his / her own use. This option cannot be selected for DLIs.
- **Allogeneic, unrelated**: An unrelated donor who shares no known ancestry with the recipient. Include adoptive parents / children or stepparents / children.
- **Allogeneic, related**: A related donor, a blood-related relative. This includes monozygotic (identical twins), non-monozygotic (dizygotic, fraternal, non-identical) twins, siblings, parents, aunts, uncles, children, cousins, half-siblings, etc.

Question 11: Has this donor already provided cells for this recipient for a prior infusion?

Donor Lymphocyte Infusions
If this question is being answered for a DLI, the answer should be **Yes.**

The intent of this question is to determine if the same donor was used for a prior infusion.

Indicate if the current donor for this infusion was used for any prior infusions for this recipient. If this is the recipient's first infusion, select **No**.

Question 12: Date of infusion:

This question is answered for all infusion types except for autologous rescues and DLIs.

Intrauterine transplants

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For intrauterine transplants, report the date of birth as the date of transplant to avoid error from occurring in FormsNet3SM.

Report the planned date of transplant. An approximate date is fine to report if the date is not yet on the hospital schedule. When or if the approximated or planned date of infusion changes, the form should be updated in FormsNet3SM, as this data field is used to populate the date of infusion on the recipient's other data collection forms. If the recipient has a previous infusion already reported to CIBMTR, review previous transplant follow-up forms and ensure the subsequent infusion is correctly reported on the follow-up forms, which will prompt appropriate follow-up forms to come due; a new or additional Indication for CIBMTR Data Reporting (2814) Form is not required.

Section Updates

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (if applicable)

Q13-15 Non-Cellular Therapy

Non-cellular Therapy
There are currently no active studies for this option. If you feel this option is correct, submit a CIBMTR Center Support ticket

Questions 13-14: Specify the disease / study for which non-cellular therapy was given

Indicate the disease or study for why the non-cellular therapy was given.

If the recipient is participating in the BMT CTN 17-02 study, select **BMT CTN**.

If the recipient is receiving the non-cellular therapy as treatment for disease, specify the disease.

If the recipient is enrolled in a study or receiving therapy for a disease that is not on the form, specify the disease or study.

Question 15: Enrollment date (date of consent)

Report the date of consent for enrollment on the non-cellular therapy protocol.

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Section Updates

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (if applicable)

DRAFT

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