Data Management Guide

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CIBMTR.org

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Welcome

CIBMTR Data Management Guide

The Data Management Guide contains information on center participation and data submission to CIBMTR and serves as a resource for individuals seeking guidance about forms due, data quality, and the functions of CIBMTR research data processing.

We invite your feedback on individual sections and your suggestions on topics that you would like to see included. Feel free to contact CIBMTR Center Support with your feedback.

Manual Updates

Sections of the Data Management Guide are frequently updated. The most recent updates to the Guide can be found below. Go to the section and review the updated content.

Date	Topic	Section	Description
1/19/2024	Transplant Center Specific Analysis	International Information	Updated section to include information about eligibility requirements and application process
8/31/2023	Center Volume Data Reports	Multiple Sections	Updated and added sections to include information about timeline, datasets, status submission, and resources
8/31/2023	External Deliverables	Multiple Sections	Deleted and replaced with Center Volume Data Reports
7/28/2023	Protocols and Consent	Consent: Age of Majority	Updated and added sections to include information about reconsent pending status and updated instructions for entering a new consent for age of majority.
7/28/2023	Data Collection and Quality	Cellular Therapy	Updated multiple sections to include new TED vs CRF levels of reporting, consistent language, requirements, and information.
3/31/2023	Continuous Process Improvement Program (CPI)	Multiple Sections	Updated multiple sections for consistent language, requirements, timelines, and instructions.
3/14/2023	Continuous Process Improvement Program (CPI)	CPI Exemption Request	Updated requirements, timeline to submit requests, and CPI Exemption Request form

3/10/2023	Continuous Process Improvement Program (CPI)	Consecutive Transplant Audit	Updated instructions and requirements for steps 1, 2 (for both US and International centers), and 3 of the CTA process. Included additional sub-steps, visual aids, links to other resources, and how to solve discrepancies/queries
1/27/2023	Data Collection and Quality	NMDP Forms	Created new subpages with information on Adverse Event and Product Complaint Reporting and Genetic Mutation Reporting
7/20/2022	Primary Disease and Disease Forms Due	Non-Hodgkin Lymphoma	Updated the disease subtype options for Non-Hodgkin Lymphoma
5/25/2022	FormsNet3SM Process and Tool Instructions	Recipient Transfer Best Practices	Added Recipient Transfer Best Practices which contains answers to FAQs
5/25/2022	Data Collection and Quality	Cellular Therapy	Updated Cellular Therapy information and flow diagrams
2/10/2022	Multiple Topics	Multiple Sections	Review of sections to ensure consistent language and accurate links (e.g. CIBMTR Center Support)
11/1/2021	Form Revised Fall 2021	2814: Indication for CRID Assignment	Updated instructions with the Fall 2021 Release
9/14/21	New CPI Metrics	CPI	Added pages for CPI Exemption, New CPI Summary Reports, and International CPI Target Percentages; made updates to several pages to remove references to old 90% requirements
8/3/2020	FormsNet3SM Process and Tool Instructions	2814: Indication for CRID Assignment	Provided instructions on generating an on demand F2814 Centers should now create an on demand indication form (2814) to report a subsequent infusion when there are NO follow up forms (F2100, F2450 or F4100) available to report this information.
7/28/21	Data Collection and Quality	Primary Disease and Disease Forms Due	Updated disease inserts for each primary disease
7/28/21	FormsNet3SM Process and Tool	2804: CIBMTR Research ID	Transferred manual from Forms Instruction Manual

	Instructions	Assignment 2814: Indication for CRID Assignment 2820: Recipient Contact Information	
7/23/21	FormsNet3SM Process and Tool Instructions	Recipient Transfer Tool	Added instructions for using the NEW Recipient Transfer Tool
7/22/21		Contact Us	Updated contact information
7/22/21		Mentor Program	Removed from Guide entirely
5/12/21	Consent	Age of Majority Consent	Added instructions for reporting Age of Majority consent in FN Consent Tool
5/5/21	CPI	CTA	Add CTA Discrepancy resolution instructions
3/26/2021	CPI and CTA	Center Participation	Enhanced descriptions of Center Activity Requirements, Reporting Levels for US NonUS centers, CPI Standards, CTA Standards. Include Planned CPI Enhancements and table of Due Dates
1/6/2021	Fee Schedule	N/A	Updated Fee Schedule to include the Plasma Cell Disorder (2016/2116) forms for cellular therapy.
8/18/20	Creating Unscheduled Form	Additional Forms	Added new topic (*Creating Unscheduled Form(s)*) to **Additional Forms** section.
7/16/20	Fee Schedule	N/A	Updated Fee Schedule to include the Respiratory Virus Post-Infusion (2149) form.
2/14/20	HCT	Forms 2004, 2005, and 2006	Updated the Non-NMDP Donor, Related HLA-Mismatched/HLA-Matched, Related Syngeneic/HLA-Identical Sibling, Related Cord Blood Unit, and Unrelated Cord Blood Unit tables with correct question numbers referenced within tables. Updates match current revisions of forms released in January 2020.
12/3/	Continuous	Recipient CPI	Updated the Recipient CPI Summary Report to reflect changes to

19	Process Improvement (CPI)	Summary Report	international reporting requirements and trimester dates.
9/12/19	Correcting Historical Data	Completing Error Correction Forms	Updated the instruction for submitting error correction forms. Error correction forms should now be submitted via the ServiceNow portal.
9/9/19	Fee Schedule	N/A	Updated Fee Schedule for cellular therapy forms to reflect form groupings.
1/17/19	Continuous Process Improvement (CPI)	Forms Due Report, Summary Report, Compliance, and CPI Forms	Updated all CPI sections to reflect the inclusion of Cellular Therapy forms.
12/3/18	Continuous Process Improvement (CPI)	CPI Forms	Removed the 2500 from the list of forms excluded from CPI as these forms are currently included in CPI counts.
11/14/18	Continuous Process Improvement (CPI)	Forms Due Report, Summary Report, and CPI Forms	These sections were updated to reflect the most recent forms and reports that are involved in the CPI process.
9/6/18	Fee Schedule	N/A	Updated Fee Schedule (formerly referred to as Reimbursement Schedule) to reflect current rates
2/28/18	Data Collection and Quality	Current Form Revision	Spring release information; New forms; Forms in revision; volunteers needed; new email
2/08/18	Data Collection and Quality	Continuous Process Improvement	Changes to each sub-section: Forms Due Report; Summary Report; Non-compliance; and CPI Forms
11/15/18	Data Collection and Quality	Current Form Revision	Update to form revision schedule

For more detailed instructions on completing CIBMTR forms, access the Forms Instruction Manual.

Last modified: Mar 07, 2024

Public Health Authority and Protected Health Information

Public Health Authority (PHA) Status

CIBMTR meets the U.S. Department of Health & Human Services HIPAA Privacy Rule's definition of a public health authority (PHA) and is authorized by law to collect the information necessary to fulfill the legislated mandate to collect data needed to assess outcomes of hematopoietic cell therapy. It is therefore not a "covered entity" under HIPAA. Additionally, transplant centers that fit the definition of covered entities may disclose certain individually identifiable health information to CIBMTR under 45 CFR 164.512 (HIPAA Privacy Rule). This allows for the disclosure of an individual's protected health information without the individual's written consent or authorization when such a disclosure is made to a PHA that is authorized by law to collect information for the purpose of preventing or controlling disease, injury, or disability.

(See: The National Institutes of Health's Protecting Personal Health Information in Research: Understanding the HIPAA Privacy Rule. Click here)

Last modified: Mar 07, 2024

PHI

Protected Health Information (PHI) and the CIBMTR Research ID (CRID)

In order to create a universal unique ID system, CIBMTR collects protected health information (PHI), including but not limited to identifiers such as name, social security number (SSN), mother's maiden name and birth information. This decision was made after careful consideration by a combination of CIBMTR staff, an external Data Advisory Group and representatives of the Health Resources and Services Administration (HRSA). Upon notification of a patient's first HCT or cellular therapy, CIBMTR will request the PHI needed to create a unique CIBMTR Research ID (CRID). A CRID must be assigned using the CIBMTR Research ID (CRID) Assignment Form (Form 2804). The CRID is a lifelong ID used across the entire C.W. Bill Young Cell Transplantation Program. Direct identifying information collected to establish the CRID will not be disclosed to investigators for research purposes.

The use of PHI to uniquely identify recipients who are registered with CIBMTR is needed for several reasons. First, CIBMTR is required by HRSA to develop a system to uniquely identify recipients for center-specific outcomes reporting. The CRID will avoid duplication of recipient records across transplant and cellular therapy programs, particularly when situations exist where sequential HCTs occur at different institutions. The CRID will facilitate knowledge of previous autologous HCTs that may not be reported by a center performing an allogeneic HCT, and therefore adjusting the expected outcome accordingly for center-specific outcome reporting. Data used to generate a CRID may be used to increase the value of the Stem Cell Therapeutic Outcomes Database (SCTOD) by acquiring matching data from other Federal government databases for government reports or research. Second, generation of a CRID is essential to determining that all allogeneic HCT recipients in the United States are reported to the SCTOD. In the event of a state law or IRB policy that supersedes federal statute, centers may opt out of providing some of these data.

The items listed below highlight the important security concerns that have been addressed with regard to the collection of the PHI.

- CIBMTR and NMDP are designated Public Health Authorities in the capacity of collecting and using data for the SCTOD and addressing HIPAA privacy regulations.

- The electronic system that collects the PHI is called FormsNet3^{SM}. The server holding the direct identifiers is secure and is separate from the outcomes database. Access to these data is highly restricted within CIBMTR. The electronic systems used for acquisition and generation of CRID numbers have undergone rigorous certification and authorization from HRSA's Office of Information Technology and comply with all United States federal regulations (21 CFR Part 11) relevant to security of electronic data in federal databases.

- Electronic transmission of the PHI from transplant centers using FormsNet3 is protected by double authentication entry requirements (login/password and SecurIDTM card) for all system users who enter the data. Electronic transmission is protected by SSL technology.

- The PHI used to create the CRID will not appear on any subsequent forms or correspondence.

Centers wishing to confirm a CRID will be able to re-enter data into one-way look-up tables, however PHI will not be displayed by the system. This security measure will prevent inappropriate revealing of PHI to unauthorized individuals.

For more information regarding the Form 2804, see the FormsNet3 Process and Tool Instructions section

Last modified: Mar 08, 2024

Protocols and Consents

Transplant centers are expected to approach all recipients for consent to participate in the Clinical Outcomes Research Database.

Centers participating in the Research Sample Repository should approach all unrelated recipients, as well as all related donor/recipient pairs at participating centers, to obtain consent to the Research Sample Repository.

Section Updates:

Date	Topic	Add/Remove/ Modify	Description
July 28, 2023	Consent: Age of Majority	Add	Added new sections for New Consent for Age of Majority and FAQ

Last modified: Jul 28, 2023

US Transplant Centers

United States Transplant Centers – Institutional Review Board (IRB) Approval:

To be compliant with United States Federal Regulations for human research subject protection, transplant centers must obtain IRB-approved informed consent from recipients to allow data submitted to the Observational Database to be used for research studies. All transplant centers must have local IRB approval for the Observational Database Research protocol. This includes all transplant centers participating as TED only and Comprehensive Report Form centers. All transplant centers that are NMDP member centers must also have local IRB approval for the Research Sample Repository protocol for unrelated recipients.

- The transplant centers participating in the Related Transplant Research Repository will submit research samples on related recipients and their donors in addition to the samples on unrelated donor recipients.

- Transplant centers that perform related donor HCTs and do not participate in the Related Transplant Research Repository will not submit research samples, and therefore do not need to obtain local IRB approval for the repository protocol.

NMDP and CIBMTR have written protocols and informed consent documents for the Observational Database and Research Sample Repository. The protocols and consent documents should be downloaded from the CIBMTR website and submitted to the transplant center's local IRB for review and approval. The protocols and consent forms must be submitted to the local IRB as written by NMDP and CIBMTR; however, the documents may be formatted according to each site's requirements. The Observational Database and Research Sample Repository protocols and consent forms can be obtained from the CIBMTR website – click here.

Upon obtaining local IRB approval, the NMDP IRB Office must receive a copy of the local IRB's approval letter, approved protocol and informed consent documents. The NMDP IRB Office tracks the IRB approval for the Observational Database and Research Repository protocols at each participating center. Sites will receive a renewal reminder approximately two months in advance of the local continuing review date. The CIBMTR Clinical research coordinators (CRCs) also send notice of the IRB expiration date to the primary data manager with the center's monthly CPI reports. Local IRB approval for these protocols must be current at all times. Failure to have current local IRB approval can impact a center's ability to meet CPI requirements for data and sample submission.

If the allogeneic recipient does not consent to participate in the Observational Database, the transplant center will still be required to submit TED-level data on the recipient. CIBMTR will not use the recipient's data for research studies. However, the data provided on the TED forms will be used for evaluation of the C.W. Bill Young Cell Transplantation Program, and federally required analysis such as center volumes and center-specific analysis, mandated by CIBMTR's contract to operate the Stem Cell Therapeutic Outcomes Database (SCTOD). This applies to recipients of allogeneic (related and unrelated) HCT. For autologous recipients who do not consent to participate in research, the CIBMTR requests the completion of CRID

Assignment Form 2804, the Indication for CRID Assignment Form 2814, the Pre-Transplant Essential Data Form 2400, and the Pre-TED Disease Classification Form 2402, each indicating consent to research as ‘no’. This reporting will help ensure that the epidemiological integrity of the database is maintained, and the recipient’s information will not be used in research.

NOTE:

Submit IRB approval documents to the CIBMTR Research Administration designee. For contact information, contact CIBMTR Center Support.

Last modified: Mar 05, 2024

International Centers

International Centers – Institutional Review Board (IRB) Approval

International transplant centers must follow their country's laws and regulations governing human subjects and privacy protection. The transplant center is responsible for obtaining the necessary institutional review and approval for the Observational Database.

If the recipient does not consent to participate in the Observational Database according to the laws and regulations of their country, CIBMTR requests the completion of CRID Assignment Form 2804, the Indication for CRID Assignment Form 2814, the Pre-Transplant Essential Data Form 2400, and the Pre-TED Disease Classification Form 2402, each indicating consent to research as 'no'. This reporting will help ensure that the epidemiological integrity of the database is maintained, and the recipient's information will not be used in research. This applies to recipients of allogeneic (related and unrelated) and autologous HCT.

Last modified: Mar 05, 2024

Observational Database

When a recipient consents to participate in research, their data are contained in the CIBMTR's Observational Database. The database includes recipient baseline and outcome data for related and unrelated allogeneic transplants or other cellular therapy from any cell source, and for autologous transplants or other cellular therapy. Data are also collected on unrelated donors and their donation experiences.

The primary purpose of the Observational Database is to have a comprehensive source of data that can be used to study hematopoietic cell transplantation.

Studies in which these data may be used include:

- How well recipients recover from their transplants or cellular therapy
- How recovery after transplantation or cellular therapy can be improved
- Long-term outcomes after transplantation or cellular therapy
- How access to transplantation or cellular therapy for different groups of recipients can be improved, including studies designed to inform insurance/payer policy, such as U.S. Medicare policy
- How well donors recover from collection procedures
- The application and success of transplantation in the management of marrow-toxic injuries

Consenting Requirements for Participants Enrolling onto the CMS CED Sub-Studies

There are 2 consent forms that all CMS CED Sub-Study Participants are eligible to sign: the main Research Outcomes Database Recipient consent form and the CMS Sub-Study consent form. For participants to receive CMS coverage for their transplant, ONLY the CMS Sub-Study consent form is required. Participants may choose to also sign the main Research Outcomes Database Recipient consent form.

If a CMS Sub-study Participant was only presented the Research Outcomes Database recipient consent form the following steps should be followed:

1. Approach identified patients that were not offered the opportunity to sign the CMS specific consent for CED participation:

- a. Offer these patients both the CMS Sub-study consent and the Main Research Database Consent form
- b. You site should explain to participant that they originally had consented to sharing their data with the observational database, but they should have had the option to share data solely for the purposes of the CMS CED sub studies.

2. Participant will accept or decline consent(s).

- a. If participant signs only the CMS sub study consent, this will reflect the participant's decision to use data solely for CMS CED sub study and indicates the participant does not want to be included in the Observational Research Database Protocol. This will be entered in FN3 as a withdrawal from RDB

Consent.

- b. If participants sign both the CMS sub study consent AND the Research Database Recipient consent, then the participant's data may continue to be used in the larger observational database protocol.

3. Site will retain both the original and new consent documents.

4. Site will submit a Reportable Event to their IRB of record and provide a CAPA to avoid not offering the CMS consent to future patients.

5. For additional questions reach out to DatabaseIRB@nmdp.org

Last modified: Mar 05, 2024

Research Sample Repository

The Research Sample Repository contains blood samples from unrelated recipients and/or their adult volunteer donor, or cord blood unit. Related allogeneic recipients and/or donors will participate at selected transplant centers.

The primary objective of the Research Repository is to make blood samples available for research studies related to histocompatibility and hematopoietic cell transplantation or cellular therapy.

Studies in which these data may be used include:

- Improve the understanding of tissue matching for hematopoietic cell donors and recipients
- Determine and evaluate the factors that affect transplant and cellular therapy outcome
- Study the distribution of HLA tissue types in different populations (e.g., study tissue typing differences between different racial and ethnic populations to help develop methods to improve tissue matching between donors and recipients, including testing of rare HLA types)

Last modified: Dec 20, 2017

Consent: Age of Majority

Age of Majority reconsent is a critical component of the informed consent process. CIBMTR is committed to ensuring that our participants' right to consent is provided to them once they have reached their age of majority. The following subsections are available for Age of Majority:

- Entering a New Consent for Age of Majority
- Age of Majority FAQ

Last modified: Mar 05, 2024

Entering a New Consent for Age of Majority

Age of Majority Consent for the Research Database

✻ **Age of Majority Consent definition** – each U.S. state has its own age of majority which is the legally defined age at which a person is considered an adult, with all the attendant rights and responsibilities of adulthood. The age of majority is defined by state laws, which vary by state, but is typically 18 in most states. The definition of Age of majority may be defined differently in other countries.

✻ Centers under oversight of the NMDP IRB are required to obtain Age of Majority Reconsent for participants to continue on-study. If your center uses their local IRB for this study, please confirm with your IRB if Age of Majority Reconsent is required. If your IRB has approved a waiver of Age of Majority Reconsent, please send a copy of the approval to DatabaseIRB@nmdp.org

Centers should make every attempt to contact recipients to obtain the age of majority consent. Having a process in place will ensure that consent is obtained in a timely manner. If the recipient has declined or is unable to reconsent, centers should still update the status in the Consent Tool. If you have additional questions, please consult your center's IRB specialist.

Using the Consent Tool in FormsNet3, centers should **ADD** a new record when reporting a recipient's age of majority consent.

! NOTE: If the recipient declines to be consented or the age of majority consent is not obtained, the Consent Tool will change ALLO (related and unrelated) recipients from the CRF track to the TED track.

Process for ADDING the Age of Majority Consent Date

Select Add New Consent

- If Q1 = **Yes**
  - Answer Q2, Q3 and Q9
  - Q9 = Site Initiated Reconsent
- If Q1 = **No**
  - Answer Q4, and Q9
  - Q9 = Withdrawn

Examples

If age of majority consent is not obtained before a form is submitted, and the form is now past due (other than the 100d), the site should use the Survival Tool to report the survival status of the recipient for that visit.

- **ALLO recipient on TED track:** if the consent has not yet been obtained, centers should continue to submit forms as required for SCTOD reporting (applies to US patients only).
- **ALLO recipient on CRF track:** if the consent has not yet been obtained but the recipient has been contacted for age of majority consent, centers should update the form status from DUE to SUR using the Survival Tool. The form will not be made DUE again once consent is obtained and reported in the Consent Tool. Data reported on the SUR form will be captured on the recipient's next follow-up form.
- **AUTO recipients (CRF or TED):** if the consent has not yet been obtained but the recipient has been contacted for age of majority consent, centers should update the form status from DUE to SUR using the Survival Tool. The form will not be made DUE again once consent is obtained and reported in the Consent Tool. Data reported on the SUR form will be captured on the recipient's next follow-up form.

Last modified: Nov 20, 2023

Age of Majority FAQ

When is reconsent required?

Age of majority reconsent will be continuously required for all participants enrolled to the CIBMTR Research Outcomes Database Protocol under minor consent. Centers under the oversight of the NMDP IRB are required to follow the NMDP IRB's guidelines which require this at age of majority. If your center is under oversight of your local IRB, the center must follow their guidance. If your local IRB has approved a waiver of consent, send the waiver to DatabaseIRB@nmdp.org to maintain a record of this waiver.

When was this change implemented?

As of July 28, 2023, CIBMTR began identifying recipients turning 18 at US centers and updating their consent status to *Reconsent Pending*. This process is completed monthly.

What about patients who reached Age of Majority prior to July 2023?

The NMDP IRB has granted a waiver of data use on these participants until August 17, 2024. CIBMTR will continue utilizing data for research regardless of Age of Majority reconsent status until that date. Note, participants who were appropriately approached with reconsent after age of majority, and declined, will NOT have data used for research.

Centers should begin making attempts to reconsent these patients at their next follow up visit or sooner. After August 17, 2024 CIBMTR will provide further communication regarding disposition for any participants that have not yet been reconsented.

This decision by the NMDP IRB applies to centers under the NMDP IRB and centers under the oversight of their local IRB. For centers under the oversight of their local IRB, a local determination may be substituted for the NMDP IRB's decision. This documentation must be provided to DatabaseIRB@nmdp.org

Why was this change implemented?

Age of Majority reconsent is a critical component of the informed consent process. CIBMTR is committed to ensuring that our participants' right to consent is provided to them once they have reached their age of majority.

What are transplant centers expected to do?

Centers are expected to monitor recipients who were consented using a minor consent (i.e., < 18 years old). Once a recipient reaches the age of majority, the center will be required to reconsent the recipient using the current version of the study informed consent forms.

What should centers do if reconsent cannot be obtained?

If the recipient cannot be reached for reconsent via in-person or remote consent, the reconsent status can be updated accordingly and the recipient will be exited from the study. Data required for reporting purposes will be collected on the appropriate track, based on the infusion.

How long should centers try to obtain reconsent?

The *Reconsent Pending* status will automatically protect a recipient's data from being used for research. We understand that follow-up schedules can vary. We expect recipients will be reconsented at their next follow-up visit.

What will happen to the submitted data if reconsent cannot be obtained?

Data that has already been submitted will remain in the database but will not be available for use in research.

What will happen to the forms if reconsent cannot be obtained? Will forms still come due?

If reconsent cannot be obtained, the consent status should be updated to **No** or **Not approached** (review instructions below on when to use these options) within the consent tool. FormsNet3^{SM} will update the recipient's track accordingly once the update has been submitted within the consent tool.

Can centers still complete and submit data while trying to obtain reconsent?

Centers can still be complete and submit data while reconsent is trying to be obtained; however, the data submitted will not be used for research when the consent status is *Reconsent Pending*.

Can centers still complete and submit data if reconsent cannot be obtained?

Centers can continue to complete and submit data, however, without reconsent, the data will not be used for research.

Who should the center contact with questions regarding Age of Majority?

Submit any questions through CIBMTR Center Support (FormsNet3 > Consent Tool)

Recipient Contacted for Reconsent but No Response
When the recipient has been contacted for reconsent but the center has not yet heard from the recipient, the consent status should be reported as **No.** To determine how long centers should wait before updating the consent status to **No** is dependent upon the center IRB's guidelines. Transplant centers who use the NMDP IRB can use the following rule: *After two*

*attempts made with no response, update the consent status to **No**.*

When should each option in the consent tool be used for the reconsent status?

Select **Yes** if the recipient has been approached and signed a new consent form, indicating they agree to participate in the Research Database.

Select **No** in the following scenarios:

- The recipient has been approached with a new consent form but declined to participate in the Research Database
- The center contacted the recipient with the new consent form but the recipient did not respond

Select **Not approached** if the recipient is unable to be located or contacted for reconsent and no further attempts will be made.

Can remote consent be used to obtain Age of Majority reconsent?

Yes. CIBMTR understands that it may not be feasible to reconsent all patients in-person. Therefore, we encourage sites to utilize remote consent if that is an available option at your center.

- For centers under NMDP IRB, remote consents must be done in compliance with Section 10 of the NMDP IRB SOP S00045 General Consenting Requirements.
- For centers under Local IRB, remote consents must be conducted in compliance with your local institutional guidelines.

Last modified: Mar 05, 2024

Fee Schedule

Fee Schedule for Forms Completion

CIBMTR pays transplant centers for all completed Comprehensive Report Forms and Cellular Therapy Forms. Reporting of TED level data is not compensated, with the exception of the Form 2006 when requested for recipients on the TED track. Once a form is designated as "CMP" in the FormsNet application, the transplant center will be paid during the next payout time-point.

> ! Effective January 1, 2013, Comprehensive Report Forms will be paid only if completed within one calendar year of the form due date.

Forms are paid at the following rate:

Data Transmission Agreement / Master Healthcare Data and Sample Submission Agreement Fee Schedule

Form #	Description	Payment	TIN[1]
Product Insert			
Form 2006	HSCT Infusion	$25*	CIBMTR
Form 2003	Gene Therapy Product	$25*	CIBMTR
* Form 2006 and 2003 may be paid when requested by CIBMTR for those recipients not on the CRF track. No center will be paid twice for the same form.			
Comprehensive Report Forms			
Form 2000+	Recipient Baseline Form, plus disease specific inserts	$135	CIBMTR
Form 2004+	Infectious Disease Markers (related donor only)		
Form 2005+	Confirmation of HLA Typing (related donor only)		
Form 2006+	HSCT Infusion Form		
+ These four forms will be paid as a unit when all required forms are received.			
Form 2100	100 Days Post-HSCT Data, **plus** any required inserts	$110	CIBMTR
Form 2100	Six Months to Two Years Post-HSCT Data, **plus** any required inserts	$85	CIBMTR
Form 2100	Yearly Follow-Up for Greater than Two Years Post-HSCT Data,	$65	CIBMTR

	plus any required inserts		
Form 2149	Respiratory Virus Post-Infusion Form	$20*	CIBMTR
Form 2900	Recipient Death Data	$15	CIBMTR
* Effective January 1, 2023			
Gene Therapy Infusions			
Form 2000+	Recipient Baseline Form, **plus** disease specific inserts	$135	CIBMTR
Form 2003+	Gene Therapy Product Form		
+ These two forms will be paid as a unit when all required forms are received.			
Form 2100	100 Days Post-HSCT Data, **plus** any required inserts	$110	CIBMTR
Form 2100	Six Months to Two Years Post-HSCT Data, **plus** any required inserts	$85	CIBMTR
Form 2100	Yearly Follow-Up for Greater than Two Years Post-HSCT Data, **plus** any required inserts	$65	CIBMTR
Form 2149	Respiratory Virus Post-Infusion Form	$20*	CIBMTR
Form 2900	Recipient Death Data	$15	CIBMTR
* Effective January 1, 2023			
Cellular Therapy Essential Data (CTED) Forms			
Form 4000*	Pre-Cellular Therapy Essential Data Form	$150	CIBMTR
Form 4001*	Pre-Cellular Therapy Baseline Data		
Form 4003*	Cellular Therapy Product Form		
Form 4006*	Cellular Therapy Infusion Form		
Form 2402*	Disease Classification Form		
* These five forms will be paid as a unit when all required forms are received. Not all cellular therapies require a F2402 or F2005.			
Form 4003+	Cellular Therapy Product Form	$10	CIBMTR
Form 4006 R1/2+	Cellular Therapy Infusion Form	$25	CIBMTR
Form 4006 R3+	Cellular Therapy Infusion Form	$15	CIBMTR

[+]Paid separately when associated with a Pre-TED F2400.			
Form 4100[*]	Post Cellular Therapy Essential Data Form	$120	CIBMTR
Form 4101[*]	Post-Cellular Therapy Follow-Up		
[*] These two forms will be paid as a unit when both forms are received. Not all cellular therapies require a F4101.			
Form 2011 / 2013 / 2016 / 2018	Disease-Specific Pre-Treatment Insert for ALL, CLL. PCD or LYM	$80	CIBMTR
Form 2111 / 2113 / 2116 / 2118	Disease-Specific Post Disease Insert for ALL, CLL, PCD or LYM	$80	CIBMTR
Form 3500	Subsequent Neoplasms	$25	CIBMTR
Form 3501	Pregnancy	$25	CIBMTR
Form 2900	Recipient Death Data	$15	CIBMTR
Repository Forms			
N/A	Repository Sample Received – Related Donor Transplant	$35	TC
N/A	Repository Sample Received – Unrelated Donor Transplant	$10	TC
Form F00227	Repository Excuse Code – Related Transplant	$10	TC
Form F00227	Repository Excuse Code – Unrelated Transplant	$5	TC

[1] Payment is made to the Tax Identification Number (TIN) for the TC# or CIBMTR# as provided by the Center.

Study Forms

A copy of the studies fee schedule can be accessed on the CIBMTR Portal > Training & eLearnings > Studies Fee Schedule.

Last modified: Mar 05, 2024

Access to CIBMTR Systems

There are several systems that you will need to use when interacting with CIBMTR. This section describes how to get access to each.

Systems

Network Partner Portal instructions for Primary Data Managers for user maintenance
CIBMTR Center Support
FormsNet3
CIBMTR Portal

When users log in for the very first time, there are additional instructions.
New User First Login Instructions

Section Updates:

Date	Topic	Add/Remove/Modify	Description

Last modified: Jul 26, 2021

Network Partner Portal

> ! This information is specific to the Primary Data Manager or Medical Director role.

To get someone access to CIBMTR systems (FormsNet3, the CIBMTR Portal, and CIBMTR Center Support) the Primary Data Manager will need to add an account in the Network Partner Portal.
If that person will be a FormsNet3 users, they must also be given a role within that application. The center's primary data manager* or medical director can add the person to the center staff at https://nmdp.service-now.com/partner/. This is generally done using "Create New User".

Some users may already have NMDP accounts. If the user already exists, you will get an error message indicating that the email is already in the system. You must add a new center association by choosing "Modify User" and then "Add an existing user…" The person can be found in the system using their email address, associated with the new center as applicable, and given a role.

The account will be configured based on the role given to the person in the Network Partner Portal. All users have access to CIBMTR Center Support, CIBMTR Portal Application(s), and may also have access to FormsNet3.
Please refer to the Network Partner Portal Role Reference Guide.

The account takes about an hour and a half to process and applications will be available within two business days or less.

Last modified: Mar 08, 2024

User Updates

Creating a New User

1. From the **Select Your Center** field, choose the center from the dropdown the new user will be associated with.
2. In the **Select New User's Role** field, select the appropriate job role for your new user. Next to each role is a short description of the job role; when you select a specific job role, a more in-depth description will display.

✻ NOTE: Based on the job role and center type you select, access to NMDP applications will be assigned automatically.

If the new user is being added as an NMDP contact, additional fields will appear. Complete all required fields (indicated with a red asterisk) on the page and press the **Submit** button on the bottom left.

! NOTE: If a user already has an active account with NMDP, you will be prompted to submit a Modify User request instead of a Create New User request. This helps eliminate duplicate accounts for individuals.

Removing a User from your Center(s):

Submit this as soon as you are aware of the change.

1. Enter the name of the user in the Select Existing User field.
2. Select the center(s) in the Select Center(s) to Remove User From field.

✻ NOTE: If you want to remove the user from all centers you manage, check the Remove User From All My Centers box. A pop-up box will appear asking you to confirm the changes.

Last modified: Mar 05, 2024

New User First Login Instructions

New User's First Login to CIBMTR Systems

When a new user account is created, the person will be able to log into CIBMTR systems approximately 90 minutes after the account request is completed. Not all applications will be available at that time. Reference the section for each system for availability timeline. When the account is created, the **requestor** will receive a notification with the username and a separate email with a system-generated temporary password. After that email is received, the account is processing. It is necessary for the new user to **wait one hour** after receiving the username to log in.

What if I do not get the username and/or password?

If you do not receive the username for a new FormsNet3 user, the username can be found in the Security Toolset on the Admin tab in FormsNet3. For users who will not have access to FormsNet3, there is not a place to look up the username. You must request the username by submitting a ticket via CIBMTR Center Support.

If the requestor does not receive a password for the new user, or if the requestor is not available, it is possible to use the self-service password reset from the login screen of any application by clicking on *"Need help signing in?"* and *"Forgot password"* . The user should put in their *username* when prompted and they will receive a link to set a password by email to the email address listed in the original account request.

Once the password is established, it will be possible to log into CIBMTR Center Support (https://nmdp.service-now.com/csm) and/or FormsNet3 (https://formsnet3.nmdp.org).

The CIBMTR Portal will be available within the following two business days.

Multifactor Authentication

Upon the first login, the user will be prompted to set up multifactor authentication using Okta Verify or RSA (uncommon).
Users must select Okta Verify and follow the on-screen prompts to set up the account on their mobile device or tablet. The Okta Verify app can be found in the Apple App Store or on Google Play.

> There are two Okta-related apps. You must choose the one with the blue circle in the white square.

If for some reason the user is unable to use Okta Verify on their mobile device, the user must contact the NMDP Service Desk at 800-526-7809 ×3411 (or 1-763-406-3411 outside the U.S.) to discuss an alternate multifactor authentication option. The Service Desk is also able to assist in resolving issues with Okta Verify

setup.

The new user or one of their colleagues may request assistance by putting in a ticket via CIBMTR Center Support. Select CIBMTR Center Maintenance and the provide the application the user is trying to access. You may also find an instruction sheet attached for getting a password and Okta Verify setup within the Knowledge Base in CIBMTR Center Support. Search for ‘New User Access to CIBMTR Systems.

Last modified: Mar 05, 2024

Network Partner Portal Role Reference Guide

Center Type	Role Name	Description of New Role	Software
RC	Primary Data Manager	Access to FormsNet3, CIBMTR Portal, CIBMTR Center Support and the Network Partner Portal. Individual responsible for managing activities to meet NMDP and CIBMTR requirements. This is the main person NMDP and CIBMTR will contact for operational questions. You are required to identify one primary data manager for each research center. Only one primary data manager is allowed for each center.	• FormsNet3 • CIBMTR Portal • Network Partner Portal
RC	Medical Director	Physician responsible for overseeing clinical activities to ensure center meets NMDP and CIBMTR requirements. This is the medical director CIBMTR will contact for clinical questions. Access to FormsNet3, CIBMTR Portal, ServiceNow and Network Partner Portal. Serves as backup to primary data manager for creating, modifying, and deleting center users. Each center is allowed only one medical director.	• FormsNet3 • CIBMTR Portal • Network Partner Portal
RC	Data Manager	A member of your staff who will be using FormsNet3 and the CIBMTR Portal. Person has access to ServiceNow and is added to your center's list with CIBMTR.	• FormsNet3 • CIBMTR Portal
RC	Center Administrator	The administrator of the data management staff who may be using FormsNet3 and the CIBMTR Portal. A user in this role has access to ServiceNow and is added to your center's list with CIBMTR.	• FormsNet3 • CIBMTR Portal
RC	FACT-JACIE Quality Manager	A user in this role can access FormsNet3, the CIBMTR Portal, ServiceNow, and is added to your center's list with CIBMTR.	• FormsNet3 • CIBMTR Portal
RC	Staff Physician	Physician at your center that is not the Medical Director. This role does not have access to FormsNet3. A user in this role has access to the CIBMTR Portal, ServiceNow, and is added to your center's list with CIBMTR.	• CIBMTR Portal
RC	Financial Staff	Financial Staff only. This role does not have access to FormsNet3. A user in this role can access backup documentation for payments in the CIBMTR Portal, have access to ServiceNow, and is added to your center's list with CIBMTR.	• CIBMTR Portal
RC	Staff	Other staff involved with your center activities. Not a FormsNet3 user. Person has access to the CIBMTR Portal and ServiceNow and is added to your center's list with CIBMTR.	• CIBMTR Portal

Last modified: May 17, 2021

CIBMTR Center Support

Center Support delivers a transparent, flexible, and service-oriented experience for Centers.

CIBMTR Center Support allows CIBMTR Data Operations to:

- unify multiple processes and tools into one consistent and integrated system
- simplify our Centers experience while expanding support options
- increase internal efficiency and resolve issues more quickly, and drive continuous service improvement with better data and metrics

All questions and requests should be directed to Center Support.

Center Support link:

https://nmdp.service-now.com/csm

Once an account is established, all questions and requests should be submitted via CIBMTR Center Support. They will be routed to the appropriate teammates for a response. Questions and requests submitted in other ways, by email, for example, may not be responded to in a timely manner as the team is prioritizing questions and requests that come in via CIBMTR Center Support.

Last modified: Mar 08, 2024

FormsNet3

Obtaining Access

For a FormsNet3 user, once the account is created, the person must also be assigned an application user role in FormsNet3. Without a role, the user will not be associated with a center and will be unable to access the Recipient tab in the FormsNet3 application. A new staff member will be viewable in FormsNet3 approximately an hour and a half after the new account request is submitted.

To give someone a role, the primary data manager should find the username in the dropdown in the Security Toolset on the Admin tab in the FormsNet3 application. The username is the first letter of the person's first name and up to seven letters of their last name (sometimes followed by a number.)

In order to have a center association in FormsNet3, it is necessary that the center's primary contact assign an application user role in FormsNet3's Security Toolset. The Security Toolset is found on the Admin tab in FormsNet3.

If no one at the center appears to have access to the Admin tab in FormsNet3, please put a ticket in ServiceNow for assistance.

For the Recipient tab,

Assign the role FN3_REC_DATA_MANAGER unless the person is taking over as the Primary Data Manager.
The Primary Data Manager should be assigned FN3_REC_PRIMARY_DATA_MANAGER.
Per CIBMTR policy, only one person should have the role of Primary Data Manager.

For the Donor tab,

Assign the role FN3_DNR_[Center Type]_COORDINATOR unless the person is taking over as the primary coordinator or is the medical director.
The primary coordinator should be assigned FN3_DNR_[Center Type]_PRIMARY_COORDINATOR.
The medical director should be assigned FN3_DNR_[Center Type]_Center_MD
There are also VIEW ONLY roles for each center type.

Maintaining Access

If your password was set to expire and you did not change it prior to the expiration date, you can use the self-service password reset or contact the Service Desk.

The NMDP Service Desk can be reached in the U.S. at 800-526-7809 ×3411 or (or 1-763-406-3411 outside the U.S.). Representatives are available 24 hours a day, 7 days a week.

Last modified: Mar 08, 2024

CIBMTR Portal

Obtaining Access

Access to the CIBMTR Portal will also be set up based on the submission of the account creation request in the Network Partner Portal. The Primary Data Manager is the person responsible for creating an account for the individual CIBMTR Portal users in the Network Partner Portal. Centers are responsible for maintaining the user accounts of eligible individuals. When someone has access, they will have access until such time as their account is deleted from the Network Partner Portal.

Access to each portal application is governed by the role assigned (see Network Partner Portal Role Reference Guide) It may take up to two business days for the user to be fully activated.

To expedite the setup, please put in a request via CIBMTR Center Support. Include the information that the account was already created in the Network Partner Portal.

> If you are not sure who the primary data manager at your center is, please submit a request via CIBMTR Center Support, or have a colleague submit a ticket on your behalf to request the information.

Maintaining Access

Each user must keep their password current by changing it at a minimum every 60 days. Accounts not accessed for over 60 days will be disabled and can only be re-enabled by NMDP Service Desk. Users contacting the Customer Service Center through ServiceNow can request that their account be re-enabled.

Special Access

All people wishing to have access to the Network Partner Portal must have an account in the Network Partner Portal. If you need additional access beyond the standard access for your role, please submit a ticket through CIBMTR Center Support. Special permission will be requested from your medical director.

- Survival Calculator
  - Reserved for physicians at CIBMTR centers and CIBMTR center administrators
- DBtC/eDBtC (Data Back to Centers/enhanced Data Back to Centers)
  - Reserved for medical directors, IRB PI, center administrators, primary contacts and data managers
- Center Volumes Data Report
  - Reserved for medical directors, IRB PI, center administrators, primary contacts and data managers
  - Only the medical director and primary contact have “write” access
- CPA (Center Performance Analytics)
  - Reserved for medical directors, IRB PI, center administrators, primary contacts and data managers

Last modified: Mar 06, 2024

Self-Service Password Reset

If you forgot your password, or it doesn't seem to be working, you can reset the password from the login screen.

1. Click on "Need help signing in?"
2. Click on "Forgot password?"
3. Enter your username

If it doesn't seem to be working, double check your username to be sure it is spelled correctly and reattempt.

The email will go to the email associated with your account in the Network Partner Portal.

Your Primary Data Manager can log into the Network Partner Portal to check or change the email address that we have associated with your account.

Last modified: Mar 06, 2024

Center Participation

Center Status Level Assignment

The Stem Cell Therapeutic Outcomes Database (SCTOD) is part of the C.W. Bill Young Cell Transplantation Program (Program), authorized by the Stem Cell Therapeutic and Research Act of 2005 (Public Law 109-129) and reauthorized by the Stem Cell Therapeutic and Research Reauthorization Act of 2010 (Public Law 111-264), and the Stem Cell Therapeutic and Research Reauthorization Act of 2015 (Public Law 114-104).
As the contract holder, the Center for International Blood and Marrow Transplant Research (CIBMTR) is required to collect data for all allogeneic (related and unrelated) hematopoietic cell transplants (HCTs) performed in the United States, and for all HCTs utilizing a product procured through the Program, but performed outside of the United States.

The CIBMTR has established processes to assess and close any gaps that exist in data reporting to the SCTOD. To determine a member center's participation level, the CIBMTR has established the following statuses. These participation statuses determine if a center is required to comply with the CIBMTR Continuous Process Improvement program (CPI).

Active Status

A center that has registered and submitted forms for new patients during the most recent 24-month period to the CIBMTR. Active centers must have established reporting levels for each infusion type and are subject to all Continuous Process Improvement (CPI) requirements. An Active status allows for center staff to participate in CIBMTR leadership roles.

Follow-Up Status

A center that has submitted forms during the most recent 24-month period but has not registered any new patients during that same time. Follow-up centers are subject to some requirements of the CPI program. A Follow-up status allows for center staff to participate in CIBMTR leadership roles.

Inactive Status

A center that has not submitted forms or registered new patients within the last 24-month period. Inactive centers are not subject to any CPI requirements. An Inactive status prohibits center staff from participating in CIBMTR leadership roles.

Date	Topic	Add/Remove/Modify	Description

Last modified: Jan 29, 2024

Determining Reporting Levels: US Centers

For US centers, the Center Participation Status with NMDP and CIBMTR programs will determine the allowable reporting levels and the subsequent data collection forms the transplant center will be required to submit to the CIBMTR. This designation will inform the CPI Program of the center's selected level of participation.

Infusion Types

Allogeneic (Unrelated and Related) Infusions

All allogeneic (related and unrelated) HCTs performed in the US require a minimum of Transplant Essential Data (**TED**) level data submission, even if the recipient declines consent to the observational research database. If a recipient is participating in a clinical trial, Comprehensive Report Form (**CRF**) level data submission may be required (e.g. select BMT CTN trials, RCI BMT, etc.). In these cases, consent is included with the study protocol and that criteria will be used to select which reporting track will be required.

Autologous Infusions

Reporting autologous infusion data to CIBMTR is required for BMT-CTN member centers. For those centers not participating with BMT-CTN, reporting autologous infusions is voluntary. A site may elect to report all autologous infusions to CIBMTR, or may choose to not report any infusions. However, if the site elects to report autologous infusions, they must report all autologous infusions performed.

Data Collection Forms

- **Transplant Essential Data Forms (TED)**: data are used for evaluation of the Stem Cell Therapeutic Outcomes Database (SCTOD) program operations, including federally required research such as analyses of center-specific outcomes and evaluation of optimal registry and cord blood bank size.
- **Comprehensive Report Forms (CRF)**: data are included in research studies, though TED-level data may occasionally be used. These forms collect more detailed data including disease assessments at each follow up visit, expanded Acute and Chronic GVHD data, engraftment data, etc.

Determining Reporting Levels

For each infusion type performed at the center, the Medical Director will be required to designate the reporting level (at the time of Member Center Set-Up) as defined below:

Allogeneic – Related Infusion: Reporting Level Options (must select one)

- TED Only Center (will NOT be assigned to the CRF track for any recipient)
- CRF Eligible – Data reporting track assigned based on Research Algorithm
- Do not perform Infusion type

Allogeneic – Unrelated Infusion: Reporting Level Options (must select one)

- TED Only Center (will NOT be assigned to the CRF track for any recipient)
- CRF Eligible – Data reporting track assigned based on Research Algorithm
- Do not perform Infusion type

Autologous Infusion: Reporting Level Options (must select one)

- TED Only Center (will NOT be assigned to the CRF track for any recipient)
- CRF Eligible- Data reporting track assigned based on Research Algorithm
- Perform Infusions, but do not report to CIBMTR
- Do not perform infusion type

Additional Clarifications

TED Only

Center reports all infusions of this type to CIBMTR, all cases assigned to TED follow-up track only.

- Forms include forms 2814, 2400, 2402, 2004, 2005, 2006, 2450, plus select event-based forms (F2900 Recipient Death; F3500 Subsequent Neoplasms)
- Data may be used for research studies if patient consents to research participation
- Forms completed are not reimbursed, except for a few select forms (see Fee Schedule)

CRF Eligible

Center reports all infusions of this type to CIBMTR.

- Research algorithm assigns subset of all transplant recipients to CRF track
- Determined by variables such as consent, type of transplant, age, disease, etc.
- If not assigned to CRF track, recipient data will be reported on TED forms
- Forms completed are reimbursed – (see Fee Schedule)

Do Not Perform

This option should be selected if the site does not perform this infusion type.

Perform, Do Not Report

This option should be selected if the center performs this infusion type, but does not report the data to CIBMTR.

Research Algorithm

CIBMTR developed a weighted-randomization selection algorithm for CRF centers that determines which set of forms (TED versus CRF) is required for each HCT recipient. The algorithm randomly selects an epidemiologic sample of recipients for whom a CRF is to be requested. The algorithm includes, but is not limited to, type of HCT, age of the recipient, disease, etc. It gives higher weights to patients receiving HCT for rare indications, to very young and very old patients, and novel treatment approaches. It aims to provide representative, adequately sized subsets of patients for studies requiring detailed data. The algorithm is periodically reviewed to assess the burden of data submission for centers. If a recipient consents to participate in research, the algorithm determines the HCT follow-up data submission level: Post-TED forms or the CRFs. If an allogeneic recipient does not consent to participate in research, then the algorithm is not used, and HCT follow-up data must be submitted on the Post-TED form.

Last modified: Mar 06, 2024

Determining Reporting Levels: International Centers

For international centers, the Center Participation Status with NMDP and CIBMTR programs will determine the allowable reporting levels and the subsequent data collection forms the transplant center will be required to submit to the CIBMTR. This designation will inform the CPI Program of the center's selected level of participation.

Infusion Types

Allogeneic (Unrelated and Related) Infusions

All allogeneic HCTs performed using products collected in the U.S. require a minimum of Transplant Essential Data (**TED**) level data submission. If a recipient is participating in a clinical trial, Comprehensive Report Form (**CRF**) level data submission may be required (e.g. select BMT CTN trials, RCI BMT, etc.). In these cases, consent is included with the study protocol and that criteria will be used to select which reporting track will be required.

Autologous Infusions

Reporting autologous infusion data to CIBMTR is voluntary. A site may elect to report all autologous infusions to CIBMTR, or may choose to not report any infusions. However, if the site elects to report autologous infusions, they must report all autologous infusions performed.

Data Collection Forms

- **Transplant Essential Data Forms (TED)**: data are used for evaluation of the Stem Cell Therapeutic Outcomes Database (SCTOD) program operations, including federally required research such as analyses of center-specific outcomes and evaluation of optimal registry and cord blood bank size.
- **Comprehensive Report Forms (CRF)**: data are included in research studies, though TED-level data may occasionally be used. These forms collect more detailed data including disease assessments at each follow up visit, expanded Acute and Chronic GVHD data, engraftment data, etc.

Determining Reporting Levels

For each infusion type performed at the center, the Medical Director will be required to designate the CIBMTR reporting level (at the time of Member Center Set-Up) as defined below:

Allogeneic – Related Infusion: Reporting Level Options (must select one)

- TED Only Center (will NOT be assigned to the CRF track for any recipient)
- CRF Eligible – Data reporting track assigned based on Research Algorithm

- Perform Infusions, but do not report to CIBMTR
- Do not perform Infusion type

Allogeneic – Unrelated Infusion: Reporting Level Options (must select one)

- NMDP-Facilitated Infusions – If center is receiving products from NMDP, those infusions must be reported to CIBMTR
- TED Only Center (will NOT be assigned to the CRF track for any recipient)
- CRF Eligible – Data reporting track assigned based on Research Algorithm
- Perform Infusions, but do not report to CIBMTR
- Do not perform Infusion type

Autologous Infusion: Reporting Level Options (must select one)

- TED Only Center (will NOT be assigned to the CRF track for any recipient)
- CRF Eligible- Data reporting track assigned based on Research Algorithm
- Perform Infusions, but do not report to CIBMTR
- Do not perform infusion type

Additional Clarifications

TED Only

Center reports all infusions of this type to CIBMTR, all cases assigned to TED follow-up track only.

- Forms include forms 2814, 2400, 2402, 2004, 2005, 2006, 2450, 2900, plus select event-based forms (e.g., F2149 to report COVID infection)
- Data may be used for research studies if patient consents to research participation
- Forms completed are not reimbursed, except for a few select forms (see Fee Schedule)

CRF Eligible

Center reports all infusions of this type to CIBMTR.

- Research algorithm assigns subset of all transplant recipients to CRF track
- Determined by variables such as consent, type of transplant, age, disease, etc.
- If not assigned to CRF track, recipient data will be reported on TED forms
- Forms completed are reimbursed – (see Fee Schedule)

Do Not Perform

This option should be selected if the site does not perform this infusion type.

Perform, Do Not Report

This option should be selected if the center performs this infusion type, but does not report the data to CIBMTR.

Research Algorithm

CIBMTR developed a weighted-randomization selection algorithm for CRF centers that determines which set of forms (TED versus CRF) is required for each HCT recipient. The algorithm randomly selects an epidemiologic sample of recipients for whom a CRF is to be requested. The algorithm includes, but is not limited to, type of HCT, age of the recipient, disease, etc. It gives higher weights to patients receiving HCT for rare indications, to very young and very old patients, and novel treatment approaches. It aims to provide representative, adequately sized subsets of patients for studies requiring detailed data. The algorithm is periodically reviewed to assess the burden of data submission for centers. If a recipient consents to participate in research, the algorithm determines the HCT follow-up data submission level: Post-TED forms or the CRFs. If an allogeneic recipient does not consent to participate in research, then the algorithm is not used, and HCT follow-up data must be submitted on the Post-TED form.

Last modified: Mar 06, 2024

Continuous Process Improvement Program (CPI)

Introduction

CIBMTR has established processes to assess and close any gaps that exist in data reported to the C.W. Bill Young Cell Transplantation Program (CWBYCTP). The assessment covers unrelated donor transplants facilitated by the CWBYCTP, both within the US and internationally, as well as US-related and unrelated donor transplants not facilitated by the CWBYCTP. CIBMTR works closely with NMDP, the current Single Point of Access Coordination Center (SPA-CC) contractor, to perform the gap assessment.

Purpose

CIBMTR established the CPI program to ensure timely and accurate submission of data. This data supports CIBMTR's goal of promoting collaborative research that increases access and improves outcomes of all cellular therapies. In addition, CPI supports the ability to perform benchmarking, and to provide accurate population level data. These data are also used to support quality assurance efforts for the programs providing the products, including Cord Blood Banks, Apheresis and Collection Centers.

Assessment Trimesters

For US Centers, assessment trimester are:

- Trimester 1: January 1 – April 30
- Trimester 2: May 1 – August 31
- Trimester 3: September 1 – December 31

For International Centers, assessment trimester are:

- Trimester 1: March 1 – June 30
- Trimester 2: July 1 – October 31
- Trimester 3: November 1 – February 28

Requirements

1. Maintain current regulatory documentation
    - US Centers: IRB
    - International Centers: DTA/MHA
2. Meet form completion standards
3. Complete the Consecutive Transplant Audit

Last modified: Mar 06, 2024

Center Compliance

Compliance Monitoring

Centers should monitor their compliance to the CPI requirements throughout the trimester.

The form completion categories are important to monitor as the total number of forms needed to meet the targets will fluctuate throughout the trimester. This fluctuation is a result of forms coming due after more data are provided. Examples include:

- Registering a new CRID will result in an Indication for CRID Assignment (2814) Form to come due. If an HCT is reported on the F2814, then a Pre-TED (2400) Form and Disease Classification (2402) Form will come due.
- When completing a CRF Post-Infusion Follow-Up (2100) Form, reporting a particular fungal or viral infection will result in the associated disease insert form to come due.

If the *due date* for any additional forms falls within the applicable trimester, the form will count toward the total forms expected for that trimester.

Monitoring Tools

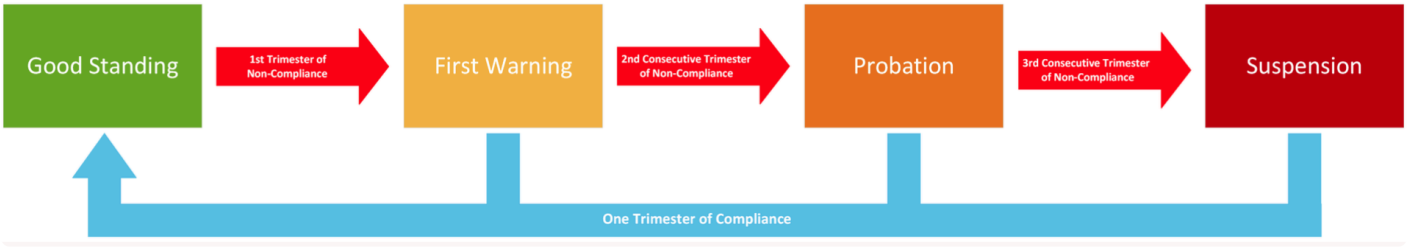
Centers can monitor their compliance to each CPI requirement by using the CPI Summary report. For specific forms due in the assessment trimester, centers can use the CPI Summary reports & utilize the Center Forms Due tool within FormsNet3.

CPI Compliance Stages

A center is in a *Good Standing* status if all CPI requirements are met by the end of the trimester.

If a center ends the trimester in a non-compliant status, one of the non-compliance statuses, as defined below, are assigned. The center's Primary Data Contact and Medical Director will receive a notification from the CIBMTR detailing the specific unmet CPI standards, the status assigned, and additional details as described below.

- **First Warning:** First trimester of non-compliance
- **Probation:** Second consecutive trimester of non-compliance
- **Suspension:** Third consecutive trimester of non-compliance



If the center does not return to a *Good Standing* status (must meet all target completion metrics) after the first trimester of non-compliance (*First Warning*), the center will move to the next stage of non-compliance (*Probation*). At this point, CIBMTR will contact the center to schedule a meeting to discuss the center's backlog. These meetings require attendance of the center's Medical Director and CIBMTR's Scientific Director. The goal of this meeting is to review the forms backlog and develop a comprehensive corrective action plan that addresses the outstanding forms and includes plans for ensuring the center stays in a *Good Standing* status once achieved again. This may result in the creation of a CPI Exemption plan, which will outline specific milestones the center must achieve in order to avoid *Suspension*. Additionally, CIBMTR study teams will be notified of the center's non-compliance and may take action to reduce or terminate a centers participation in ongoing or new studies.

If the center is non-compliant for a third consecutive trimester, the center will move to *Suspension* status. At this point, CIBMTR leadership will determine what additional consequences will be applied based on the forms backlog and quality concerns. These consequences may include:

- Exclusion from the annual Transplant Center Specific Survival Analysis (TCSA)
- Exclusion from Observational Research Studies
- Change to TED-only reporting (see Determining Reporting Levels)
- Deny center CIBMTR leadership roles or membership in CIBMTR administrative committees
- Restrict access to NMDP unrelated donors

NOTE: To achieve a *Good Standing* status after any level of non-compliance, the center must meet all required CPI standards for at least one trimester. However, if consequences have been applied after a *Suspension* status, the center must maintain a *Good Standing* status for three consecutive trimesters for the consequences to be removed.

Last modified: Mar 31, 2023

Regulatory Documentation Standards

Data Transmission and IRB Documentation

CIBMTR cannot reimburse for Comprehensive Report Forms (CRFs) until it has a current, signed Data Transmission Agreement (DTA) or Master Healthcare Data (MHA) and Sample Submission Agreement is on file. The DTA or MHA permits centers (both US and International) to transfer patient data to CIBMTR for use in its research. Data Transmission Agreements are submitted to the NMDP Contracts department designees, who are assigned to specific centers.

Additionally, all US centers must obtain IRB approval for both the “Protocol for a Research Database for Hematopoietic Stem Cell Transplantation, other Cellular Therapies, and Marrow Toxic Injuries” and “Protocol for a Research Sample Repository for Allogeneic Stem Cell Transplantation, Other Cellular Therapies, and Marrow Toxic Injuries”. Upon obtaining IRB approval, the center must send a copy of the IRB’s approval letter, approved protocols, and informed consent documents to CIBMTR.

Requirements:

1. NMDP (Contracts) must have an executed Data Transmission Agreement (DTA) or an updated Master Healthcare Data (MHA) and Sample Submission Agreement
2. CIBMTR must have current IRB documents (renewal letters and consents) including the following:
    - Current IRB documents
    - Approval letters
    - Approved consent forms
3. Renewal approval documentation submitted to CIBMTR must be received by the end of trimester
4. No patients consented during an approval lapse

NOTE: if the center utilizes the NMDP IRB, then the above documents do not need to be sent to CIBMTR.

Last modified: Mar 06, 2024

Form Completion Standards

CIBMTR has revised the CPI Form Completion Standards to better align the requirements with the data needs of the transplant community, as well as to simplify the metrics tracked to improve the quality and availability of research data. These updates will streamline the overall process, as well as increase the quality and quantity of data available for research.

Effective Date

US Centers: CIBMTR implemented the updated requirements for US centers beginning September 1, 2021.

International Centers: CIBMTR began to implement the updated requirements for International centers on July 1, 2022.

Form Completion Requirement Enhancements

Due Date in FormsNet

Form due dates, as specified in FormsNet3, will be the date that determines whether a form has been submitted on time to meet the CPI requirement (in the past it was the earliest complete date). The DUE DATE will encompass a grace period to ensure appropriate amount of time to complete the form.

Date Definitions

Event Date	Usually the infusion date. This date is used to inform the earliest complete dates and due date.
Earliest Complete Date	The first date CIBMTR would expect to receive data for that form.
Due Date	The date by which CIBMTR expects to receive the data whenever possible. For critical forms, the form must be completed by this date in order to meet the on-time critical forms requirement. All other forms (including critical forms with a due date in the previous trimester) must be completed by the CPI deadline.
CPI Deadline	The end of the trimester.

Target Completion Percentage by Form Category

CIBMTR has grouped forms into categories based on priority of submission and established target completion percentages based on those categories. For additional details on each category, see CPI Forms and Due Dates.

Requirement	Target Completion Percentage
Complete Critical Forms On Time (By Form Due Date) During Current Trimester	≥ 50% Completed by Due Date
Complete Critical Forms Due During the Previous Trimester	≥ 98% Complete by end of trimester
Complete Study Supplemental Forms Due During the Previous Trimester	100% Complete by end of trimester
Complete All Other Forms Due During the Previous Trimester	≥ 95% Complete by end of trimester
Resolve Queries Placed During the Previous Trimester	≥ 95% Complete by end of trimester

Last modified: Mar 06, 2024

CPI Forms and Due Dates

> **Adjusted Form Due Date**: The form due date will automatically recalculate if the new form added is more than four months past its original form due date. The adjusted due date will be the date the form was created minus four months. The FormsNet3 Forms Grid will indicate if a form has an adjusted due date with an asterisk (*) next to the adjusted due date. See example below.

Event	Earliest	Due	Complete
2021-06-24	2021-06-10	2021-09-30*	2022-01-31
2021-06-24	2021-06-10	2021-09-30*	2022-01-31
2021-06-24	2021-06-24	2021-09-30*	2022-01-31

Critical Forms

CIBMTR has identified the below forms as *Critical*. These forms capture critical data such as infusion, donor type and disease classification. If these forms are completed close to the actual infusion date, the subsequent forms triggered by critical forms will come due in a timelier manner. Forms completed in a timely manner will ensure specific study data, severe adverse infusion events, and product complaints, as well as data for participating registries, cord blood banks, and apheresis/collection centers are more readily available for use.

Requirements

- **Critical Forms On Time**: Complete **≥ 50%** of forms with the due dates in the current trimester *by the due date* listed in FormsNet3
- **Critical Forms Due During the Previous Trimester**: Complete **≥98%** of forms with due dates in the previous trimester by the end of the current trimester

Forms	Form Due Date (April 2021 FN Release)
Indication for CRID Assignment Form (2814)	CRID Registration Date + 30 days
Pre-TED (2400)	Infusion Date + 30 days
Pre-Cellular Therapy Essential Data (4000)* **To be implemented on January 1, 2024 for US Centers and March 1, 2024 for*	Infusion Date + 30 days

International Centers	
Disease Classification (2402)	Infusion Date + 30 days
HCT Infusion Form (2006)	Infusion Date + 45 days

Study Supplemental Forms

Participation in prospective studies is voluntary and requires a commitment from the transplant center Medical Director. If a center elects to participate in a study that requires additional (supplemental) forms to collect specific study data, CPI requirements will apply to these supplemental forms. In general, study supplemental forms should be submitted by the due date in FormsNet3 whenever possible.

Requirements

- Centers will be required to complete **100%** of these forms *by the end of the trimester following the due date* to meet CPI standards.

Forms	Visit	Form Due Date (July 2021 FN Release)
Tepadina® Supplemental Data Collection Form (2540)	100 day	Infusion Date + 130 days
	6 month	Infusion Date + 225 days
	1 year, 2 year	Anniversary Date + 45 days
	3, 4, 5 year	Anniversary Date + 60 days
Inotuzumab Ozogamicin (Besponsa™) Supplemental Data Collection Form (2541)	n/a	Infusion Date + 30 days
Mogamulizumab (Poteligeo) Supplemental Data Collection Form (2542)	100 day	Infusion Date + 130 days
	6 month	Infusion Date + 225 days
	1 year, 2 year	Anniversary Date + 45 days
Gemtuzumab Ozogamicin (Mylotarg ™) Supplemental (2543)	n/a	Administration Date
Veno-occlusive Disease (VOD) /	100 day	Infusion Date + 130

Sinusoidal Obstruction Syndrome (SOS) Supplemental Data Collection Form (2553)		days
	6 month	Infusion Date + 225 days
CMS Registration Form (2554)	n/a	Infusion Date + 30 days
CMS – MF Myelofibrosis Eligibility Form (2555)	n/a	Infusion Date + 30 days
Myelofibrosis Pre-HCT Supplemental Data (2556)	n/a	Infusion Date + 30 days
CMS-SCD Sickle Cell Disease Eligibility Form (2558)	n/a	Infusion Date + 30 days

The following forms are currently excluded from CPI: Forms 2008, 2800, 2801, and 5000-5002.

Other Forms

For all other forms not classified as *critical* or *study supplemental* forms, CIBMTR monitors completion rates for two trimesters after the form's due date.

Requirements

- Centers will be required to complete **95%** of these forms *by the end of the trimester following the due date* to meet CPI standards.

Forms	Form Due Date (April 2021 FN Release)
Eligibility (2500) Patient Contact (2820)	Infusion Date + 30 days
Pre-CT Baseline Form (4001)	Infusion Date + 30 days
CT Product Form (4003) CT Infusion Form (4006)	Infusion Date + 45 days
Gene Therapy Product (2003)	Infusion Date + 45 days
Baseline (2000) Infectious Disease Markers (2004) HLA Typing (2005) Pre-Infusion Disease / Infection (2010-2058)	Infusion Date + 60 days
100 Day Follow-up (2450, 2100, 4100, 4101) 100 Day Post-Infusion Disease / Infection Forms (2110-2158) 100 Day Chimerism Form (2451)	Infusion Date + 130 Days
6 Month Follow-up (2450, 2100, 4100, 4101) 6 Month Post-Infusion Disease / Infection Forms (2110-2158)	Infusion Date + 225 days

6 Month Chimerism Form (2451)	
1 Year Follow up, 2 Year Follow-up (2450, 2100, 4100, 4101) 1 Year Post-Infusion, 2 Year Post-Infusion Disease / Infection Forms (2110-2158) 1 Year, 2 Year Chimerism Form (2451)	Anniversary Date + 45 days
3+ Year Follow-up (2450, 2100, 4100, 4101) 3+ Year Post-Infusion Disease, Infection Forms (2110-2158)	Anniversary Date + 60 days
Secondary Neoplasm Form (3500) Pregnancy Form (3501)	Event Date + 30 days
Death Form (2900)	Death Date + 30 days
Donor Lymphocyte Infusion Form (2199)	Date Reported + 30 days

Query Resolution

Queries may be placed on missing data or to verify inconsistent data, or when clarification and/or documentation is needed to confirm the reported data. Whenever possible, query resolution should occur within six weeks after placement of the query.

Requirements

- Resolve **≥95%** of queries placed in the previous trimester.

Query Resources

- Query Functionality Overview
- Query Resolution Instructions
- How to Run a CPI List for Queries
- Queries eLearning

Last modified: Jan 11, 2024

CPI Resources

CIBMTR has created the following CPI resources to further support centers with the CPI compliance program. These tools can be utilized for workflow management, analysis, metrics and more. Please let CIBMTR know if any additional resources would be beneficial. Use the links below to navigate to a specific resource page.

- CIBMTR CPI Summary Report
- CPI Center Forms Due Tool
- Accessing CPI Memos on the CIBMTR Portal
- CPI Exemption Request
- New Password for FormsNet3 and the CIBMTR Portal
- CPI Excel Tools

Last modified: Mar 06, 2024

CIBMTR CPI Summary Report

The Recipient CPI Summary Report is automatically sent to the current Primary Data Manager(s). Additional center managers can request to be added to the CIBMTR CPI Summary distribution list by contacting CIBMTR via a CIBMTR Center Support ticket.

- After navigating to CIBMTR Center Support, click *Need Help?*
- Complete necessary fields and answer the following:
  - *What is your question regarding?* CPI/CTA
  - *Relating to:* CPI Process Question

Reports will be sent at the following timepoints:

- **Weekly**: Tuesday
- **Daily**: Last two weeks of the trimester
- **Twice Daily**: Last four days of the trimester

Real-time reports can be generated in FormsNet3 at any time using the Center Forms Due tool.

If there are questions about forms in these reports or if your center is not receiving this report, contact CIBMTR Center Support.

> ! Please include CIBMTRReports@NMDP.ORG in your Safe Senders list to ensure these emails make it to your inbox.

Definitions

Form Status – forms must be complete and error free to meet form completion targets.

Forms considered “complete” for CPI	AUD – Audited form
	CMP – Completed form
	LCK – Locked form (no external edits allowed)
	PND – Center’s response to a query is pending review by CIBMTR
	QRY – Form has an outstanding query
Forms considered “exempt” from CPI	LTF – Form is exempt because patient is lost to follow-up
	NRQ – Form is made exempt by CIBMTR
	SUR – Center indicated no clinical data known, but survival status provided

Forms considered “incomplete” for CPI	ERR – Form has an outstanding validation error
	SVD/MOD – Form has been edited, but not submitted to CIBMTR
	DUE – Form has not been started

Run Date

Indicates the date and time (Central Time) the report was generated. There may be a delay between the report generation and when it is distributed to transplant centers. Use the Center Forms Due feature in FormsNet3 for a real-time listing of outstanding forms.

CPI Summary Report Overview

The table below summarizes each of the CPI/CTA metrics, the specific requirement that must be met for the current trimester, the center’s current completion rate and CPI standing.

Metrics	Requirement	Current Status	CPI Standing
Submit Critical Forms On-Time	≥ 25% Completed by Due Date	42.6%	Meets Target
Complete Critical Forms Due During the Previous Trimester	≥ 90% Complete	88.8%	Below Target
Complete Study Supplemental Forms Due During the Previous Trimester	100% Complete	100%	Meets Target
Complete All Other Forms Due During the Previous Trimester	≥ 75% Complete	89.6%	Meets Target
Resolve Queries Placed During the Previous Trimester	≥ 90% Resolved	100%	Meets Target
Submit CTA List	Submit List	Complete	Requirement Met
Resolve CTA Discrepancies	Resolve All Discrepancies	Complete	Requirement Met
Resolve CTA Queries	Resolve All Queries	Complete	Requirement Met
Provide Current IRB Approval of CIBMTR / NMDP Research Database Consent form.	IRB Approval Expires: Not Applicable	Not Applicable	Not Applicable

- **Metrics** – Details on each of the metrics can be found on the Form Completion Standards page.
- **Requirements** – Indicates the target completion rate/passing criteria for each metric. *Note that if the center has been granted an exemption, these reports will NOT reflect any reduced or custom form completion targets.
- **Current Status** – Indicates the Status/Completion Rate for each metric as of the run date listed at the top of the report. The number of forms required to meet the CPI requirement is subject to change until the close of the trimester. When forms are completed, these may trigger other forms to come due,

such as the Pre-TED Forms (2400/2402). The forms that come due will count for CPI if the due date falls into the applicable time periods.

- **CPI Standing** – Indicates if the current status meets the passing requirements.
  - *Meets Target* – The center is currently meeting or exceeding the target completion percentage for this metric. Reporting new events or completing forms may cause new forms to come due in FormsNet3. This may cause this metric to change from “Meets Target” to “Below Target”, depending on the due dates of the new forms.
  - *Below Target* – The center is not meeting the target completion rate for this metric.
  - *Requirement Met* – The center has addressed all tasks for this requirement.
  - *Requirement Not Met* – The center has not yet addressed all tasks for this requirement. See CTA Standards for detailed expectations.
  - *Not Applicable* – The center is exempt from this metric.

Critical Forms to Be Completed Immediately

The CRIDs listed under this category have been created in FormsNet3, but do not have a completed Indication for CRID Assignment (2814) Form. This form must be completed within 30 days of creating the CRID in FormsNet3 or it will be counted as late when calculating the CPI metric. Delayed reporting of the 2814 may also result in delayed reporting of additional critical forms (e.g., 2400, 2402).

Instructions for completing the Indication for CRID Assignment (2814) Form:

- Complete the indication form to report a planned infusion/event date
  - If the infusion is cancelled, use the Cancellation Form (2008) in FormsNet3
  - If the infusion date is rescheduled, update the date by editing the form used to report the event (2814 or the follow-up form used to report the subsequent transplant)
- If the infusion is cancelled before the completion of the Indication for CRID Assignment (2814) Form, submit a CIBMTR Center Support to request the form be removed

Critical Forms To Be Completed Soon

These forms capture critical data such as donor type, disease classification, and product analysis counts. Forms completed in a timely manner will reduce additional requests from CIBMTR and ensure that follow-up forms are available to be completed on time as well. The forms listed under this category are considered critical and are due within the following two weeks.

> ! When completed, Forms 2400/2402 will always add more forms (unless the patient received an autologous transplant and declined research consent).

Outstanding Forms from Previous Trimester

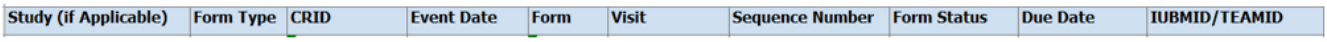
Forms under this category include study supplemental forms, critical forms (previous trimester) and all other forms. These forms have due dates in the previous trimester and are currently considered incomplete. This

may be because the form has not yet been started, has not been successfully submitted, or has unresolved validation errors. Ensure any remaining action is completed so the form is in complete (CMP) status by the end of the current trimester.

For additional information about each record, generate a list using FormsNet.

Filtering Forms from Previous Trimester:

- Click on Forms Due from Previous Trimester row (see below)



Study (if Applicable)	Form Type	CRID	Event Date	Form	Visit	Sequence Number	Form Status	Due Date	IUBMID/TEAMID

- Click “Sort and Filter”, then select “Filter”
- Click the filter on “Form Type”
  - TED/CRF/CT = other forms
  - Critical = critical forms (from previous trimester)
  - Study = study supplemental forms

Last modified: May 04, 2023

CPI Center Forms Due Tool

A real-time report can be run to generate a list of CPI forms due any time using the Center Forms Due tool. Under Recipient tab, select Center Forms Due from the Menu bar. For generalized instructions on creating a Forms Due list, please visit Recipient Center Forms Due.

CPI Center Forms Due Resources

- Generating a CPI Center Forms Due List
- Determining CPI Metrics from Center Forms Due Tool
- Determining Total Number of CPI Forms Due in a Trimester
- Determining Total Number of CPI Forms Completed in a Week

Last modified: Mar 31, 2023

Generating a CPI Center Forms Due Report

Step 1:

Status codes – Click on the 

Step 2:

Forms – Click on the 

Step 3:

Click on US CPI or Non-US CPI (should auto-populate)

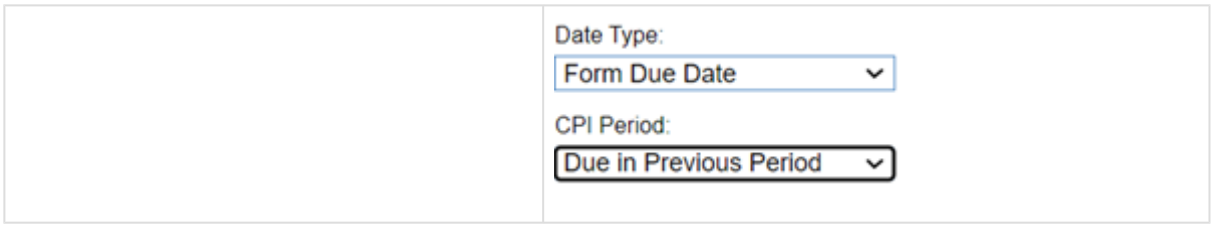
U.S. CPI:
January 1 - April 30
May 1 - August 31
September 1 - December 31

Non-U.S. CPI:
March 1-June 30
July 1-October 31
November 1-February 28/29

Step 4:

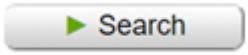
The Date Type will auto-populate to Form Due Date.

Critical Forms Due On Time	Forms Due during Previous Trimester
Click on CPI Period to equal Due Now (the start and end date will auto-populate) Date Type: Form Due Date CPI Period: Due Now	Click on CPI Period to equal Due in Previous Period (the start and end date will auto-populate)



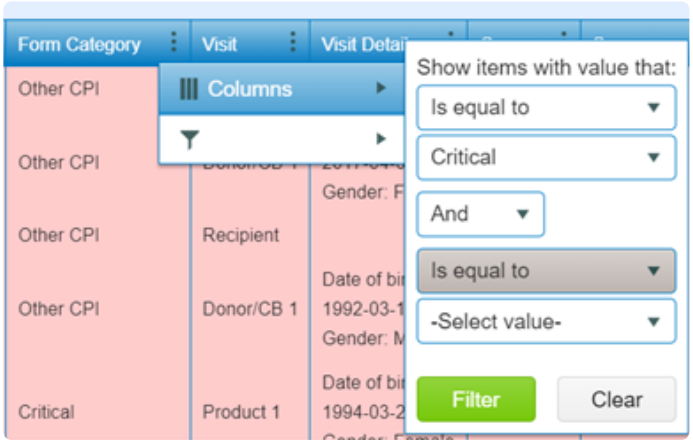
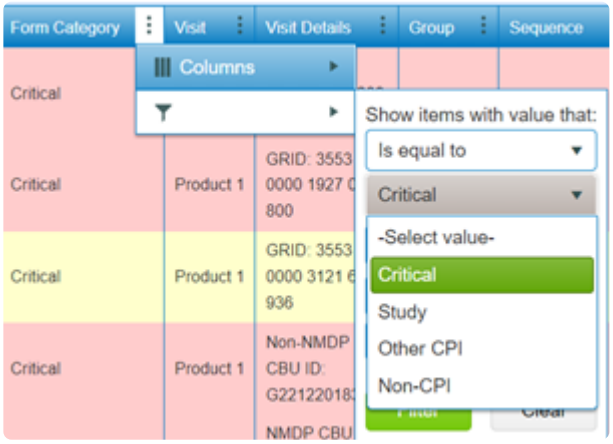
Step 5:

Click on Search to generate list



Step 6:

On the Forms Grid, filter Forms Category. Select Filter

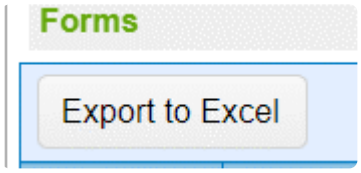
Critical Forms Due On Time	Forms Due during Previous Trimester
Forms Category to equal Critical 	Forms Category to equal Critical, Study, or Other CPI (depending on category want to view) 

Step 7:

On the bottom of the Forms Grid, the number of forms due for the designated category will appear.

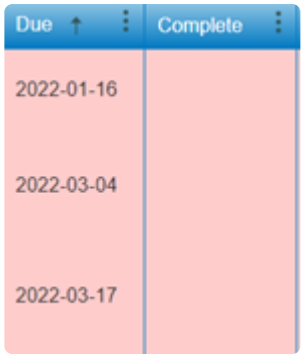
Step 8:

On the top left of the Forms Grid, an Export to Excel option is available.



Step 9: Critical Forms On Time only.

It is important to note the form due date on the Forms Grid. These forms need to be completed before the form due date to be counted for this category.



Last modified: May 19, 2022

Determining CPI Metrics from Center Forms Due Tool

Equation: (*total forms*) x (*% form requirement*) = (*forms to complete to meet requirement*) – (*forms completed*) = (*additional forms to complete to meet requirement*)

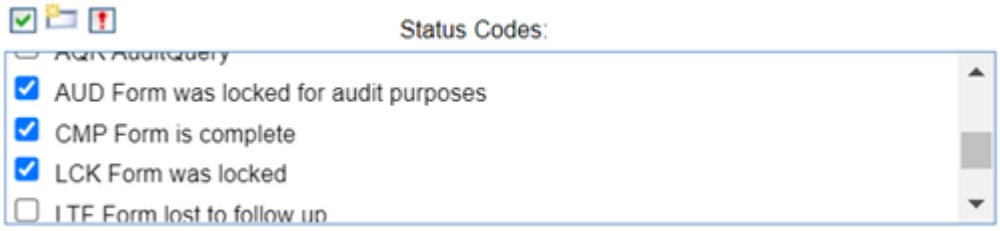
Step 1:

Once the number of center forms due (in the desired category) has been determined using the instructions above, center will determine the total number of forms (denominator) for the desired CPI form category.

Step 2:

Determining the denominator.

- Part 1: Determine the total number of completed forms.
  - Click Status Codes “AUD, CMP, LCK, QRY, & PND” (These are the form statuses that are considered “complete for CPI”)



  - Follow steps above (just change from generating forms DUE list to forms COMPLETE list)
  - Add the number of forms due + forms complete to determine denominator
    Example: 150 forms on form due list + 50 forms on forms complete list = 200 total forms (denominator)

Step 3:

Once the denominator has been determined, the forms complete will be considered the numerator (50 forms completed / 200 forms total)

Step 4:

Take the forms completed (numerator) divide by total forms (forms due + forms complete = denominator). This will provide the % of forms completed.
Example: 50 forms complete / 200 total forms = 0.25 = 25% forms completed (should correlate with metrics on CPI summary report)

Step 5:

Determining how many forms need to be completed to meet form requirement

- Part 1: Take the form completion requirement times the denominator. Then, subtract the forms already completed form the denominator to determine how many forms are still needed to complete to meet form requirement.
- Example:
  - If the form requirement was 50% form completion, take 0.50 × 200 (total forms) = 100 forms.
  - Subtract the number of forms that have been completed from the total number of forms that need to be complete to meet form completion requirement. 100 – 50 = 50 more forms to complete to meet 50% form requirement.

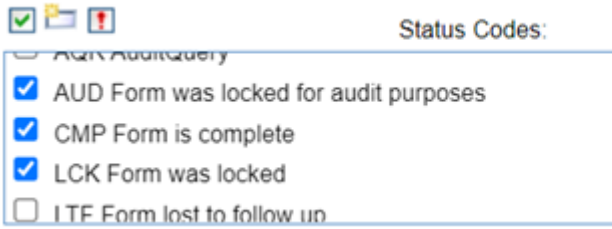
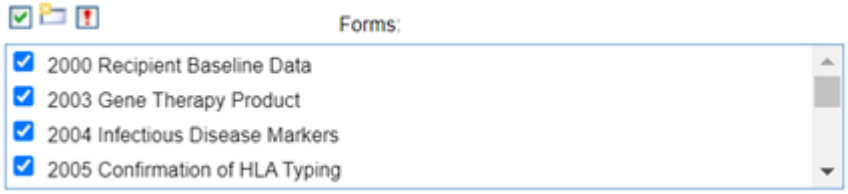
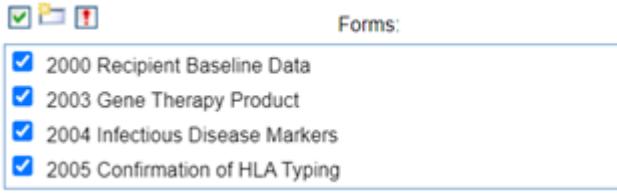
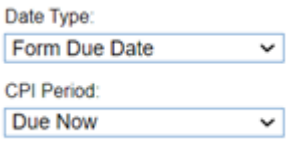
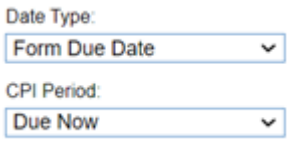
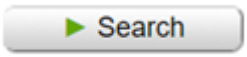
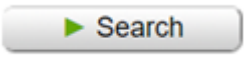
For Critical Forms On-Time category, forms in complete status may count against centers if completed after the form due date. (Generate a list of completed critical forms on time. Review the complete date and due date. If the complete date is after the due date, these forms will be considered “late” and count against CPI for this category.)

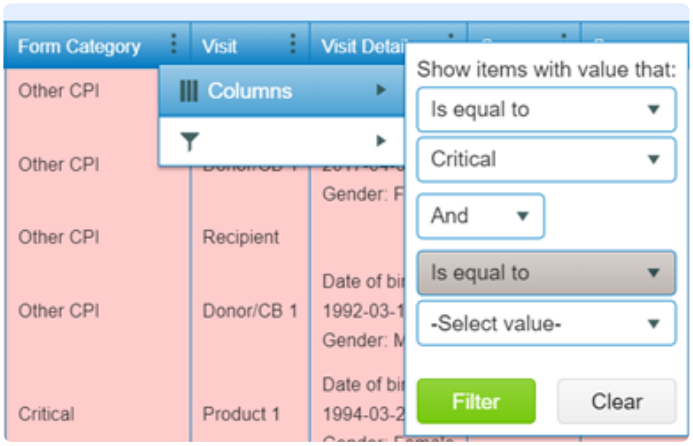
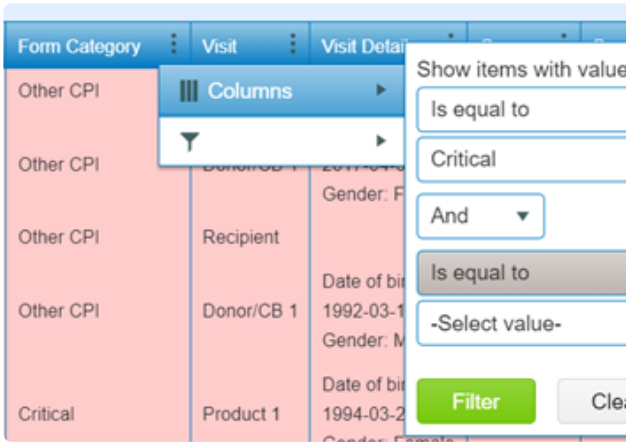
Equation Example: 200 (*total forms*) x 0.5 (*50% form requirement*) = 100 (*forms to complete to meet requirement*) – 50 (*forms completed*) = 50 (*additional forms to complete to meet requirement*)

Last modified: Mar 06, 2024

Determining Total # of CPI Forms Due in a Trimester

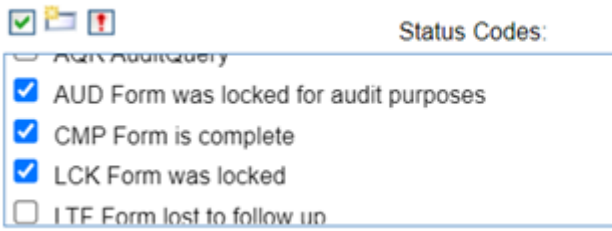
Determine the number of "Critical Forms On-time" that are DUE and COMPLETED

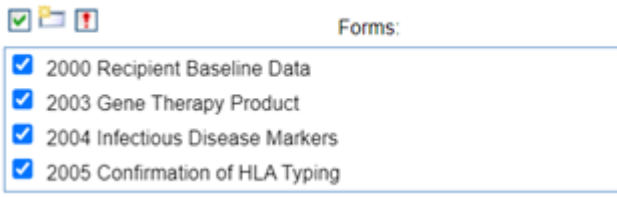
Critical Forms On-Time (Due)	Critical Forms On-Time (Completed)
Step 1: Status Codes – Click on the  	**Step 1**: Status codes – Click on "AUD, CMP, LCK, QRY & (These are the form statuses that are considered " 
Step 2: Forms – Click on the  	**Step 2**: Forms – Click on the  
Step 3: The Date Type will auto-populate to Form Due Date. Click on CPI Period to equal Due Now (the start and end date will auto-populate) 	**Step 3**: The Date Type will auto-populate to Form Due Dat Click on CPI Period to equal Due Now (the start and end date will auto-populate) 
Step 4: Click on Search to generate list. 	**Step 4**: Click on Search to generate list. 
Step 5: On the Forms Grid, filter Form Category to equal Critical.	**Step 5**: On the Forms Grid, filter Form Category to equal C

Select Filter 	Select Filter 
Step 6: On the bottom of the Forms Grid, the number of forms due for the designated category will appear. 1 - 5 of 5 items	**Step 6**: On the bottom of the Forms GRID, the number of f forms on time category will appear. 1 - 9 of 9 items
This is the total number of forms DUE for the "Critical Forms On-Time" category.	**This is the total number of forms COMPLETED Time" category.**

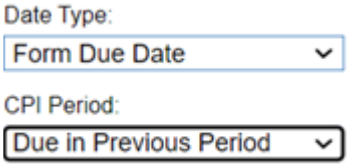
The total number of forms (Denominator) for the "Critical Forms On-Time" = 5 + 9 = 14 forms.

Determine the number of "Critical, Study, Other CPI Forms Previous Trimester" that are DUE and COMPLETED

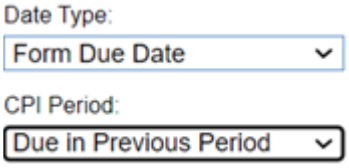
Critical, Study, Other CPI Forms Previous Trimester (Due)	Critical, Study, Other CPI Forms Previous Trim
Step 1: Status codes – Click on the 	**Step 1**: Status codes – Click on 'AUD', 'CMP', 'LCK', 'QRY (These are the form statuses that are considered " 
Step 2: Forms – Click on the	**Step 2**: Forms – Click on the



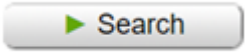
Step 3:
The Date Type will auto-populate to equal Form Due Date.
Click on CPI Period to equal Due in Previous Period
(the start and end date will auto-populate)



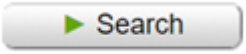
Step 3:
The Date Type will auto-populate to equal Form Du
Click on CPI Period to equal Due in Previous Perio
(the start and end date will auto-populate).



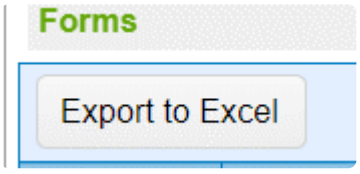
Step 4:
Click on Search to generate list.



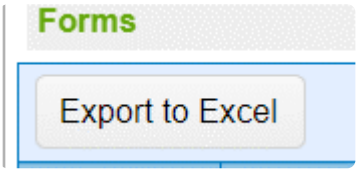
Step 4:
Click on Search to generate list



Step 5:
Click on Export to Excel



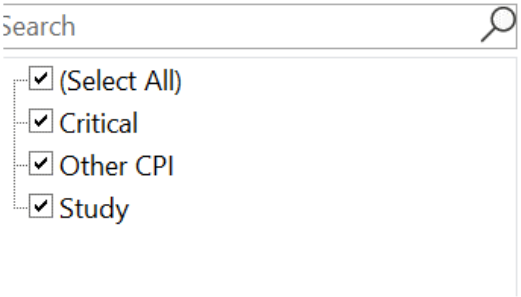
Step 5:
Click on Export to Excel



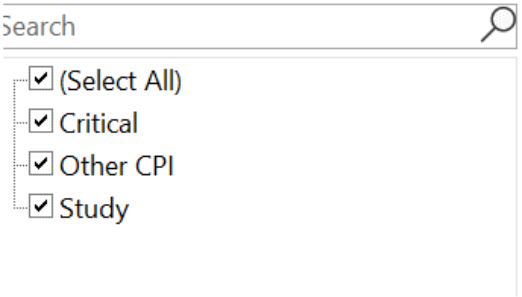
Step 6:
Open Excel spreadsheet and turn on the filter

Step 6:
Open Excel spreadsheet and turn on the filter

Step 7:
Filter by form category by selecting ‘Critical’, ‘Study’, and ‘Other CPI’.
Make sure ‘Non-CPI’ is not selected.

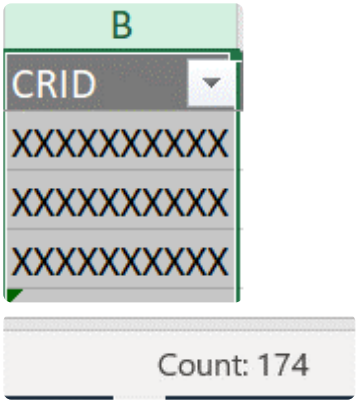
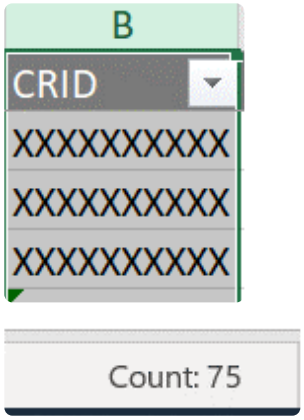


Step 7:
Filter by form category by selecting ‘Critical’, ‘Study
Make sure ‘Non-CPI’ is not selected.



Step 8:
Highlight Column B: CRID to determine how many forms are considered due.
The count will be posted at the bottom of the Excel spreadsheet.

Step 8:
Highlight Column B: CRID to determine how many
The count will be posted at the bottom of the Excel
(Make sure to subtract one to account for the CRID

(Make sure to subtract one to account for the CRID heading row) 	
This is the total number of forms DUE for the "Critical, Study and Other CPI" category.	**This is the total number of forms COMPLETED Other CPI" category.**

The total number of forms (Denominator) for the "Critical, Study, and Other CPI forms due in previous period" = 174 + 75 = 249 forms

The TOTAL number of CPI forms for a trimester for all categories = 14 + 249 = 263 forms

Last modified: Mar 06, 2024

Determining Total # of CPI Forms Completed in a Week

Step 1:

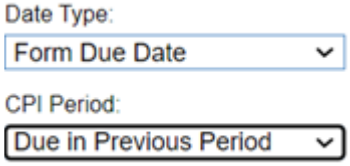
Status codes – Click on “AUD, CMP, LCK, QRY, and PND” (These are the form statuses that are considered “complete for CPI”)

Step 2:

Forms – Click on the

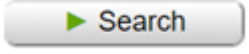
Step 3:

The Date Type will auto-populate to equal Form Due Date. Click on CPI Period to equal Due in Previous Period (the start and end date will auto-populate)



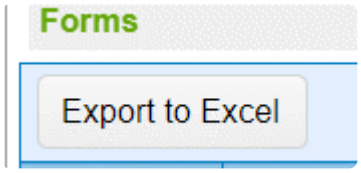
Step 4:

Click on Search to generate list



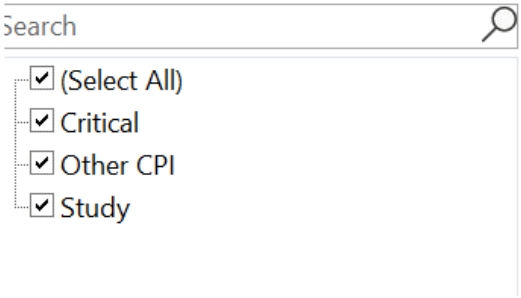
Step 5:

Click on Export to Excel



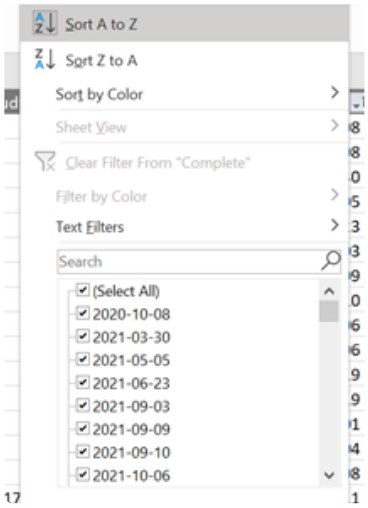
Step 6:

Open Excel spreadsheet and turn on the filter. Filter by either ‘Critical’, ‘Study’, or ‘Other CPI’



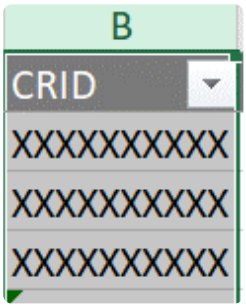
Step 7:

Filter by “Complete” and Sort A to Z to order the dates to either ascending or descending. Unselect all dates and only select a week to determine how many forms are completed for a category in 1 week. (Centers can do this step for a couple of weeks and take the average.)



Step 8:

Highlight Column B: CRID to determine how many forms are considered due. The count will be posted at the bottom of the Excel spreadsheet. (Make sure to subtract 1 to account for the “CRID” heading row)



Step 9:

Add the numbers from all categories (Critical forms on time, Critical forms previous trimester, Study forms previous trimester, and Other CPI Forms previous trimester) to determine the total number of forms completed in a week.

Last modified: Mar 06, 2024

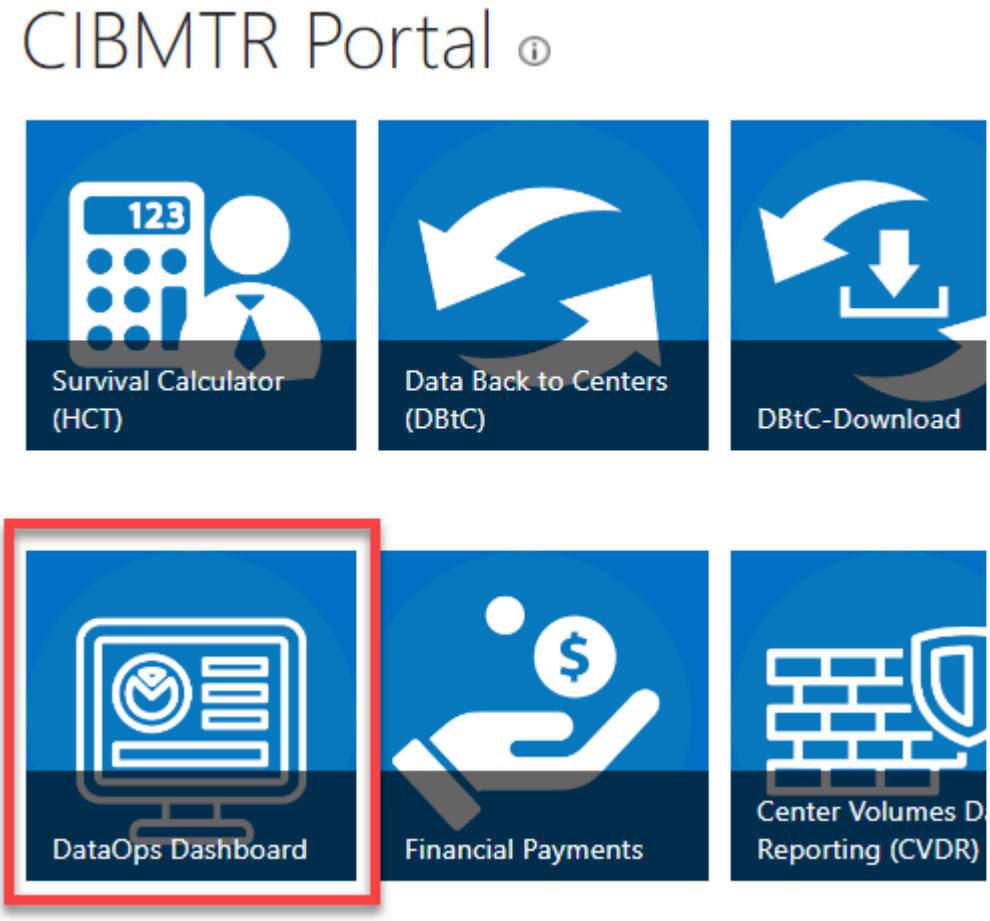
Accessing CPI Memos on the CIBMTR Portal

Since January 2021, memos detailing a center's final CPI standing for each trimester are located on the CIBMTR Portal. If documentation of a CPI standing prior to 2020 is needed, submit a CIBMTR Center Support ticket.

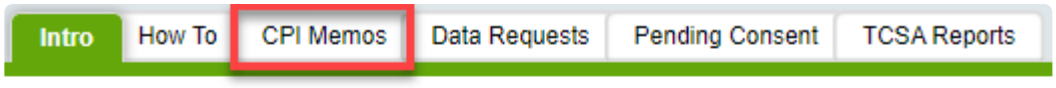
Access Instructions

Step 1: Log into CIBMTR Portal

Step 2: Select the Data Ops Dashboard tile on the CIBMTR Portal landing page



Step 3: Select the CPI Memos tab



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Sharing hope.

Step 4: Select the blue download link to download the desired file

- Submit a request to CIBMTR Center Support for help accessing the CIBMTR Portal, or if you have a user account and need additional access. Choose category “Access”, then choose “CIBMTR Portal”. If you do not have access to ServiceNow, please email cibmtr-centermaintenance@nmdp.org instead.

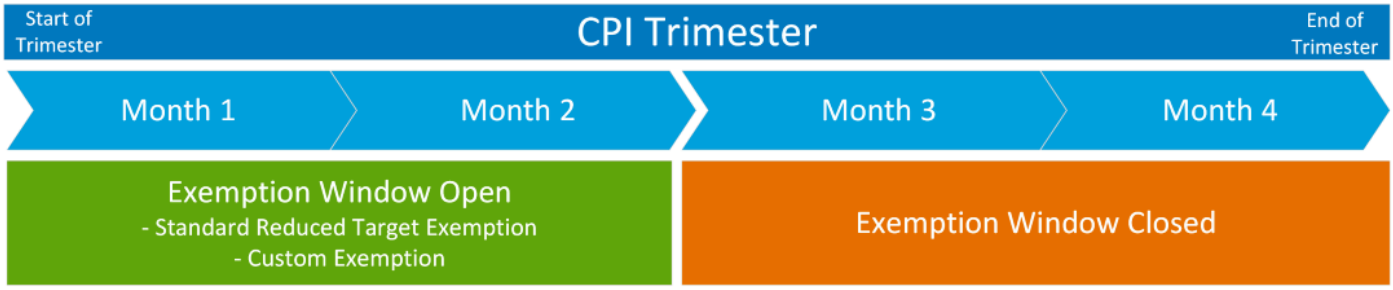
Last modified: Jan 09, 2024

CPI Exemption Request

CIBMTR acknowledges a site may have difficulty achieving CPI requirements in a given trimester due to extenuating circumstances, such as staff shortages/turnover, or other unforeseen challenges. To assist sites in meeting CPI requirements in these difficult situations, CIBMTR has established the CPI Exemption Request process.

If a site initiates this process and the request is approved by CIBMTR, the center's status will be noted as *Good Standing – Exemption* indicating the center did not meet the required CPI requirements in the current trimester but was allowed to "pass" the trimester with an exemption to specific CPI criteria.

> **IMPORTANT NOTE: An exemption request MUST be received prior to the end of the 8th week (2nd month) of the current CPI trimester. If a request is submitted after this date, it will NOT be considered.**



Click here for CPI Exemption Request Form

Exemption Categories

Custom Form Exemption

- Must meet all CTA requirements
- Must meet all IRB requirements
- Center's exemption request must be approved by CIBMTR following a meeting between CIBMTR, Center Medical Director, and Center Data Management. The meeting will establish:
  - Custom form completion targets
  - Specific form completion milestones

Reduced Target Exemption

- Meet all reduced form completion targets (see Reduced Target Metrics table below)
- Must meet all CTA requirements
- Must meet all IRB requirements

- If center was granted an exemption (any exemption) in the previous trimester, the center's request must be approved by CIBMTR following a meeting between CIBMTR, Center Medical Director, and Center Data Management.

Reduced Target Metrics

Requirements	Standard Targets	Reduced Target Exemption
Complete Critical Forms On Time	≥ 50% Completed by Due Date	≥ 35% Completed by Due Date
Complete Critical Forms Due During the Previous Trimester	≥ 98% Complete by end of trimester	≥ 80% Complete by end of trimester
Complete Study Supplemental Forms Due During the Previous Trimester	100% Complete by end of trimester	≥ 90% Complete by end of trimester
Complete All Other Forms Due During the Previous Trimester	≥ 95% Complete by end of trimester	≥ 80% Complete by end of trimester
Resolve Queries Placed During the Previous Trimester	≥ 95% Complete by end of trimester	≥ 80% Complete by end of trimester

Near-Miss Exemption

Automatic exemption is granted if a CPI form completion target is missed by a single form or less than a 0.5% difference in one metric and all other criteria are met. Centers do not need to submit an exemption request for this exemption type. This exemption is granted after final review of trimester standings by CIBMTR leadership. This automatic exemption may not be granted if any exemption(s) were granted during the previous trimester.

Process for Requesting CPI Exemption

Step 1. If center determines they will need to request an exemption for the current trimester, the center should access the CIBMTR CPI Exemption Request Form

Step 2. Center should complete the form detailing:

- Exemption requested (Reduced Target or Custom)
- CPI requirements that cannot be met
- Description of the issue preventing the center from meeting all CPI requirements
- Plan to resolve the issues
- Provide proposed milestones, if applicable

Step 3. CIBMTR Data Operations Leadership team will review the request and respond within three weeks.

Centers who meet all requirements of the exemption will receive a final status of *Good Standing – Exemption*. If a center requests an exemption, but is able to meet the standard targets, the final status will be Good Standing.

Milestone Requirements

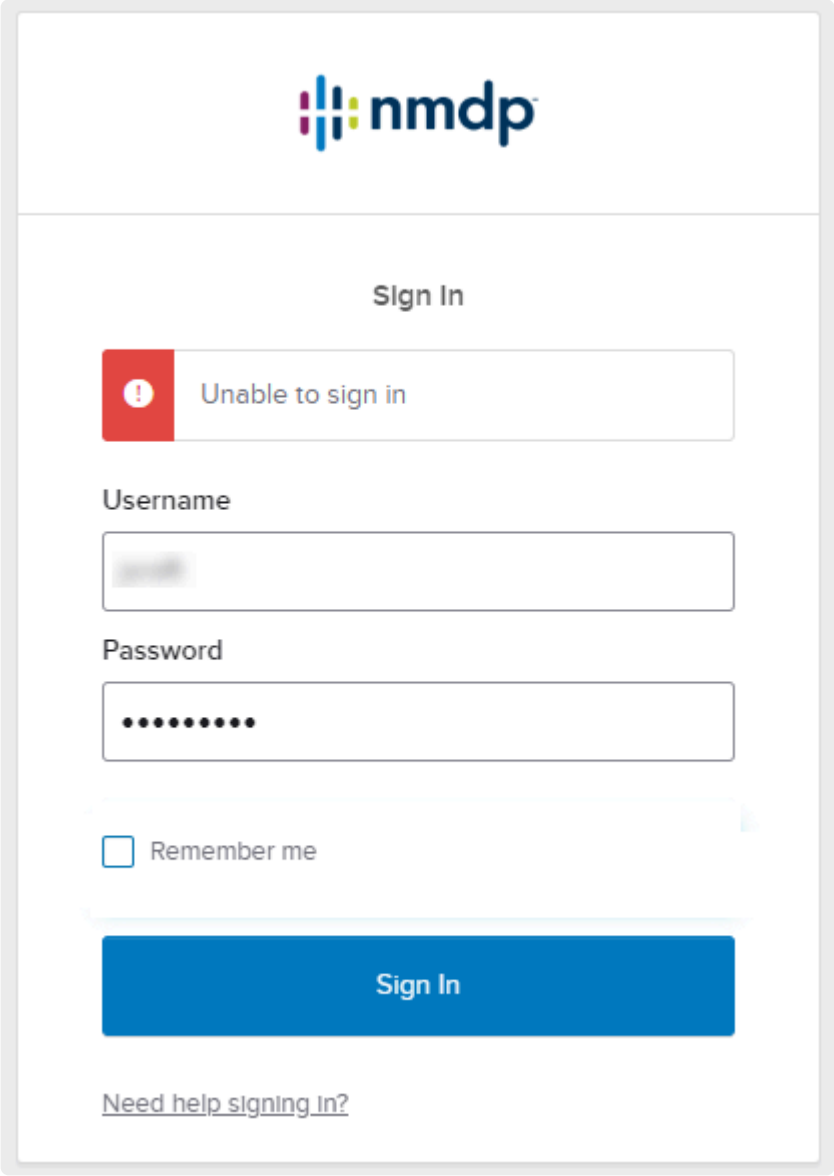
If a center is requesting reduced targets for a subsequent trimester, or if the center is requesting lower targets than noted above, additional milestones will be required to obtain the status of *Good Standing – Exemption*. These targets will generally be specific forms to complete within the existing categories (i.e., complete all forms for patients enrolled on a particular study) but could also include training objectives or quality reviews. There is no near-miss criteria for milestone requirements.

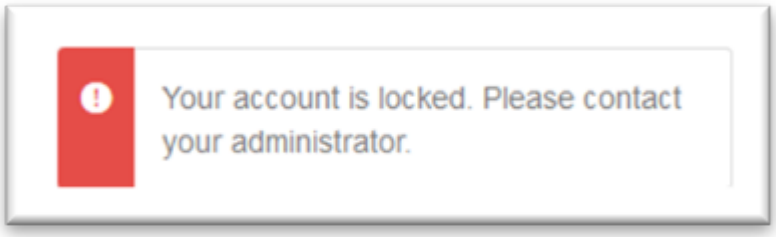
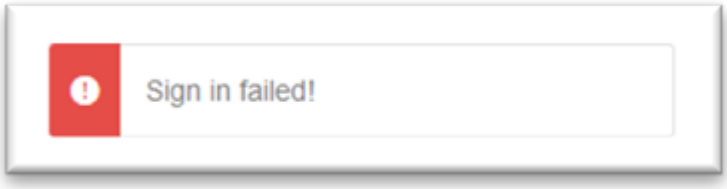
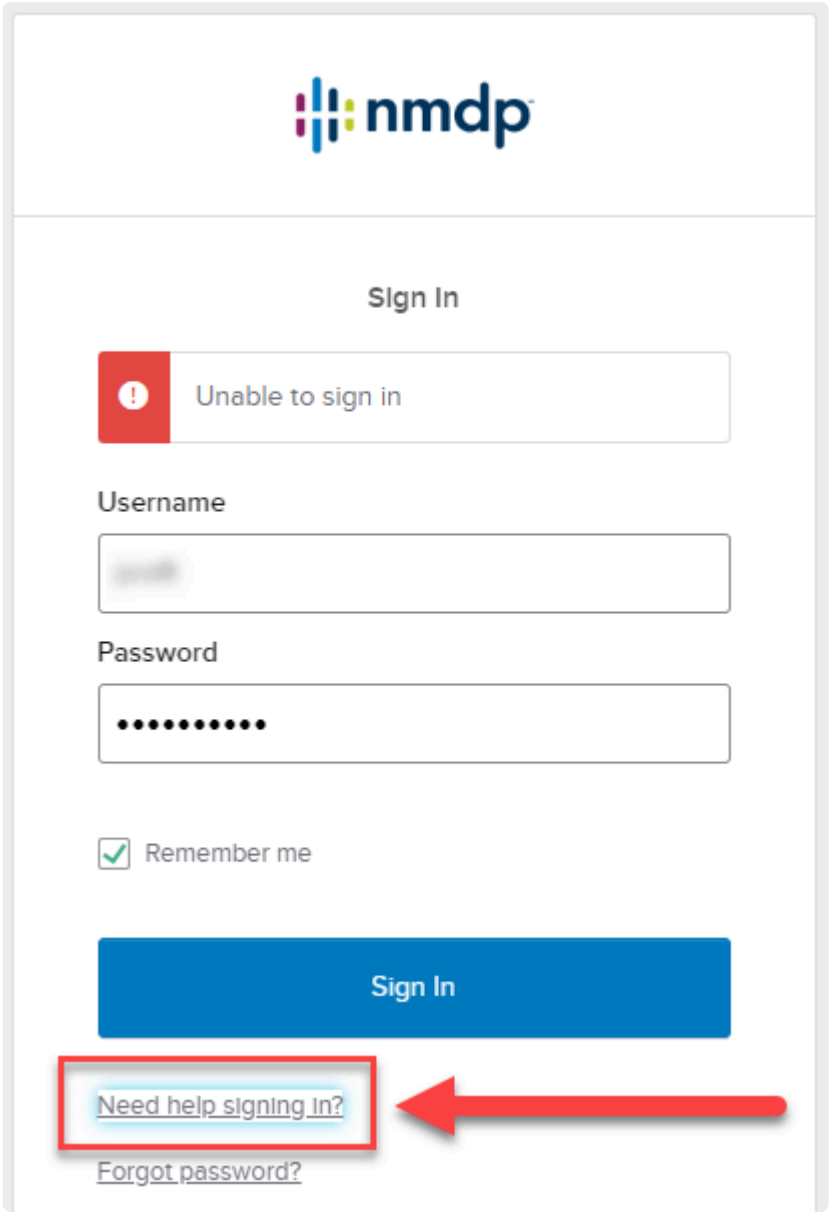
Last modified: Mar 06, 2024

New Password for FormsNet3 and the CIBMTR Portal

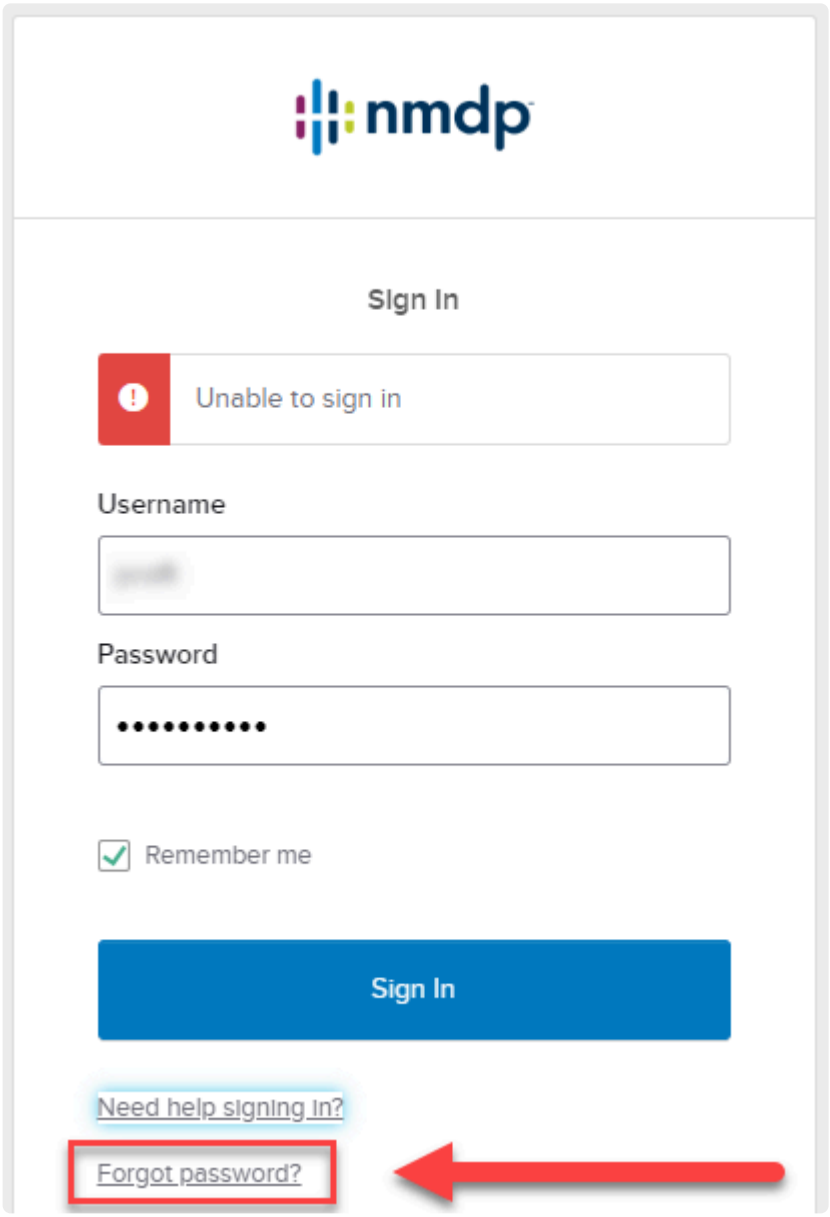
After the Primary Data Manager at your center creates an account for you in the Network Partner Portal, a notification will be sent to out with your username.

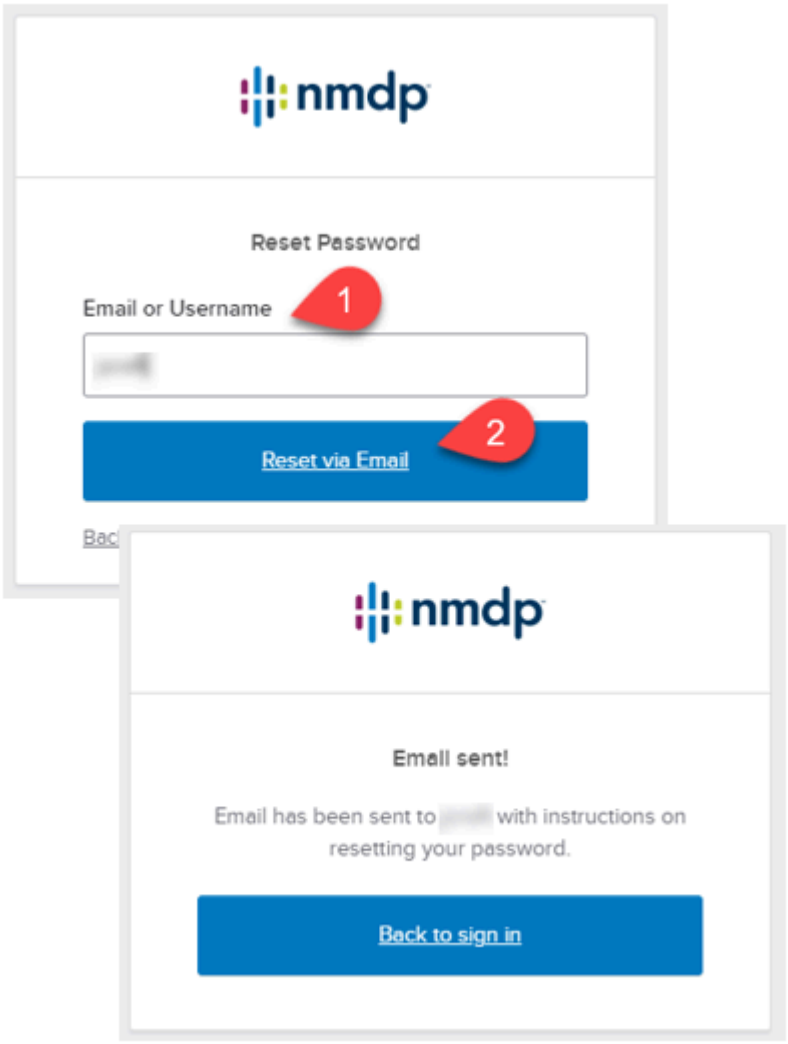
To set an initial password, begin at Step 2a (see below). A new password can be set from the login screen on FormsNet3 or CIBMTR Portal.

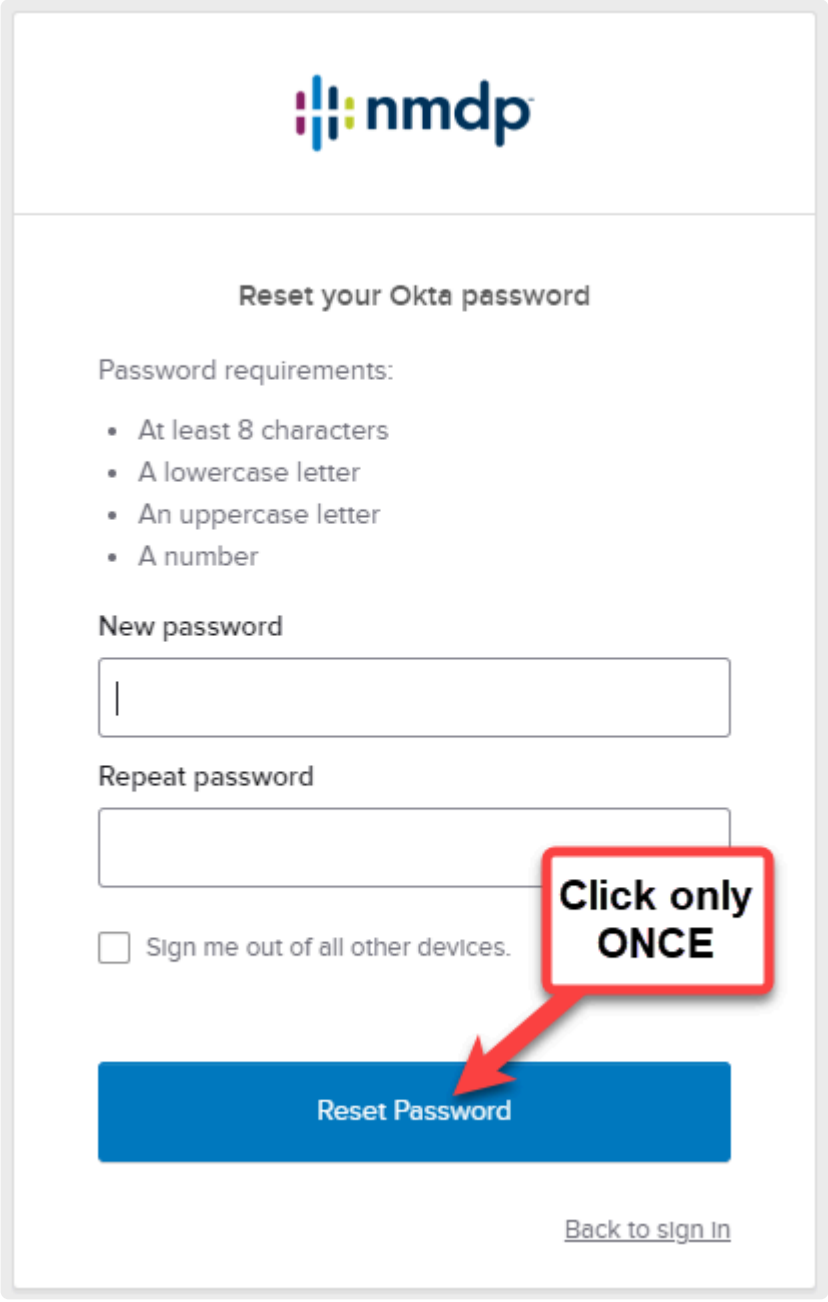
1. If login fails or your account is locked	

1a. If the error says the account is locked, **wait** **15 minutes** for the account to unlock. You may also call the Service Desk at 800-526-7809 ×3411 or (763) 406-3411 to unlock the account right away.	
2. If the error states “Sign in failed!”,	
2a. Click on “Need help signing in?”	

2b. Click on “Forgot password?”



2c. Enter **username** (suggested) and click “Reset via Email”	
3. An email will be sent to the address associated with your account in the Network Partner Portal and contain a link to reset your password. If it does not appear to be working, be certain the username is spelled correctly and reattempt.	
3a. If you do not receive an email after having checked your **username**, call the Service Desk (See Step 1a) or have a colleague submit a ticket via CIBMTR Center Support under Access	
3b. If the email associated with your account is incorrect or unknown, your Primary Data Manager can log into the Network Partner Portal to check or change the	

email address that is associated with your account.	
4. After the password reset email is received from noreply@okta.com, click the “Reset Password” link and ensure the new password meets requirements. Click only ONE TIME on the “Reset Password” button.	
4a. Return to the login screen for the application and try logging in again.	
4b. If you have trouble repeatedly, call the Service Desk or have a colleague submit a ticket via CIBMTR Center Support under Access.	

Last modified: Mar 05, 2024

Consecutive Transplant Audit (CTA)

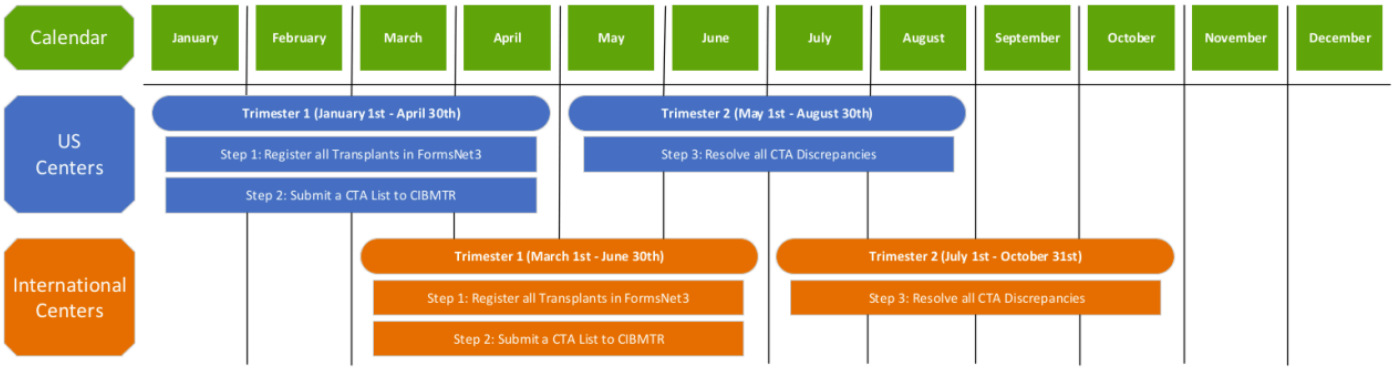
Each year CIBMTR performs a consecutive transplant audit (CTA) for all active centers to ensure the epidemiological integrity of the CIBMTR outcomes registry and to provide the US government with an accurate assessment of transplant activity. The audit ensures all hematopoietic cell transplantation (HCT) infusions performed in the prior calendar year (January – December), at each active center, have been reported to CIBMTR.

- For example, to be compliant with the CTA process in 2023, centers must include all HCT infusions performed from calendar year January 1, 2022 – December 31, 2022.

The CTA process requires centers report infusions in FormsNet3, then submit a CTA List to CIBMTR, and lastly, resolve any discrepancies to comply with the audit. Each of these steps aligns with the Continuous Process Improvement (CPI) trimesters. See the CTA timeline diagram below for details.

Centers must meet the CTA requirements to remain in "Good Standing" for CPI. *These requirements are not subject to any exemption.*

CTA Timeline



CTA Steps

- Step 1: Report Infusions in FormsNet3
- Step 2: Submit CTA List to CIBMTR
  - US Centers
  - International Centers
- Step 3: CTA Discrepancy Process

Last modified: Mar 06, 2024

Step 1: Report Infusions in FormsNet3

Centers must register new patients in FormsNet3 within 30 days of their first infusion.

Reporting Requirements

US Centers

The US Government requires all US Centers to report allogeneic related and unrelated donor HCTs performed at their center, regardless of patient consent. Additionally, if a center chooses to report autologous HCTs to the CIBMTR, then all autologous HCTs must be reported.

International Centers

International centers must comply with their governing body's requirements for data sharing to CIBMTR. Only centers with appropriate data sharing and research consent should report to CIBMTR.

Additional Reporting Resources

- Determining Reporting Levels: US Centers
- Determining Reporting Levels: International Centers
- For center reporting preferences or updating preferences, submit a CIBMTR Center Support ticket. Select "*What is your question regarding?*" = CIBMTR Center Maintenance, and "*Relating to*:" = Change Reporting Track"

Process for Reporting Infusions in FormsNet3

For a patient's first infusion, complete the following:

1. Register the patient in FormsNet3 by completing a CRID Assignment Tool (2804) form
    - How to create a CRID
    - How to complete the CRID Assignment Tool
2. Submit an Indication for CRID Assignment (2814) form
    - How to complete the Indication for CRID Assignment
3. Provide the patient's consent for research in the Consent Tool
    - How to complete the Consent Tool
4. Submit the Pre-TED (2400) form
    - How to complete a Pre-TED (2400) form

For subsequent infusions (for the same patient), complete the following:

1. Complete the follow-up (2450, 2100, or 4100) form for the prior infusion; report the date of the subsequent infusion.
    - **NOTE:** *If no follow-up forms exist for the prior infusion, an Indication for CRID Assignment (2814) form can be made due by selecting "Create Indication Form" after pulling up the CRID on the Recipient Forms page in FormsNet3.*

2. Submit the Pre-TED (2400) form
    - How to complete a Pre-TED (2400) form

> **NOTE:** All reportable events must have a Form 2400 completed in FormsNet3 before *Step 2: Submit a CTA List* can be processed.

Last modified: Mar 08, 2024

Step 2: US Centers – Submit CTA List to CIBMTR

In order to remain in Good Standing for CPI, centers must submit a list of all reportable infusions performed at their center in the previous calendar year by the end of Trimester 1 (April 30th). **This requirement is not eligible for exemption.**

Process for Submitting CTA List

1. Ensure Step 1: Report Infusions in FormsNet3 is complete before submitting a CTA List
2. Complete the CTA List using the CTA Template (link below)
    - The CTA list should be generated from a center's internal records
    - The list should include ALL infusions performed (not just the first allogeneic transplant)
    - The list should NOT include CAR-T, DLI/DCI, or other non-transplant therapy
    - The list should only include infusion types your center performs (example: If your center does not report autologous infusions to CIBMTR, do not include these infusions on the CTA List)
    - *Deviating from the format specified will delay the processing of center's list*
3. Submit the completed CTA list to the CIBMTR via a CIBMTR Center Support ticket
    - After navigating to the CIBMTR Center Support, click *Need Help?*
    - Complete necessary fields and answer the following
        - *What is your question regarding?* CPI/CTA
        - *Relating to:* CTA HCT List Submission/Resubmission
    - Attach the CTA list with the *Add Attachments* feature
    - Click submit
4. Once processed, the CPI team will respond to the ticket to inform centers if the list has been successfully processed and the ticket will be closed
    - If a ticket was not successfully processed, the CPI team will inform the center they need to resolve the issue and resubmit the CTA list until it is successfully processed
5. The weekly CPI Summary Report will note "Submit CTA List: Complete/Requirement Met"

Click here for US CTA Template

Required Data	Required Format
CIBMTR-assigned Research ID (CRID)	Number
Patient Date of Birth	Date, (YYYY-MM-DD)
Patient Sex	"M" or "F" (M = Male, F = Female)
Date of HCT	Date (YYYY-MM-DD)

Infusion	
Donor Type used for HCT	Must ONLY be reported as ALLO_U, ALLO_R, or AUTO • ALLO_U = Unrelated Donor • ALLO_R = Related Donor, including syngeneic • AUTO = Autologous (no donor) **Note:** If more than one donor product was infused in the same infusion, report the product of the least related (ALLO_U > ALLO_R > AUTO). For example, if patient received an unrelated and related product, then select only ALLO_U. Do not use terms such as “boost”, “haplo”, “MUD”, etc. – must specify ‘ALLO_R, ‘ALLO_U’, or ‘AUTO’ for each infusion.

Last modified: Apr 18, 2024

Step 2: International Centers – Submit CTA List to CIBMTR

In order to remain in Good Standing for CPI, centers must submit a list of all reportable infusions performed at their center in the previous calendar year by the end of Trimester 1 (June 30th). **This requirement is not eligible for exemption.**

Process for Submitting CTA List

1. Ensure Step 1: Report Infusions in FormsNet3 is complete before submitting a CTA List
2. Complete the CTA List using the CTA Template (link below)
    - The CTA list should be generated from a center's internal records
    - The list should include ALL infusions performed (not just the first allogeneic transplant)
    - The list should NOT include CAR-T, DLI/DCI, or other non-transplant therapy
    - The list should only include infusion types your center performs (example: If your center does not report autologous infusions to CIBMTR, do not include these infusions on your CTA list)
    - *Deviating from the format specified will delay the processing of center's list*
3. Submit the completed CTA list to the CIBMTR via a CIBMTR Center Support ticket
    - After navigating to the CIBMTR Center Support, click *Need Help?*
    - Complete necessary fields and answer the following
        - *What is your question regarding?* CPI/CTA
        - *Relating to:* CTA HCT List Submission/Resubmission
    - Attach the CTA list with the *Add Attachments* feature
    - Click submit
4. Once processed, the CPI team will respond to the ticket to inform centers if the list has been successfully processed and the ticket will be closed
    - If a ticket was not successfully processed, the CPI team will inform the center they need to resolve the issue and resubmit the CTA list until it is successfully processed
5. The weekly CPI Summary Report will note "Submit CTA List: Complete/Requirement Met"

Click here for International CTA Template

Required Data	FormNet3 Reportable Infusions	Non-Reportable Infusions
Is the infusion reportable to CIBMTR?*	Yes	No
Primary Disease	Leave Blank	Provide the patient's primary disease (maximum 100 characters allowed)
CIBMTR-Assigned Research ID (CRID)	Number	Leave Blank

Patient Date of Birth	Date (YYYY-MM-DD)	Provide YEAR of birth only. Use the alias month and day of January 1st (YYYY-01-01)
Patient Sex	“M” or “F” (M = Male, F = Female	Leave Blank
Date of HCT Infusion	Date (YYYY-MM-DD)	Provide the MONTH and YEAR of the infusion, using the alias of the 1st for the day [e.g., 2018-05-01] (YYYY-MM-01)
Donor Type Used for HCT	Must ONLY be reported as ALLO_U, ALLO_R, or AUTO • ALLO_U = Unrelated Donor • ALLO_R = Related Donor, including syngeneic • AUTO = Autologous (no donor) **Note:** If more than one donor product was infused in the same infusion, report the product of the least related (ALLO_U > ALLO_R > AUTO). For example, if patient received an unrelated and related product, then select only ALLO_U. Do not use terms such as “boost”, “haplo”, “MUD”, etc. – must specify ‘ALLO_R, ‘ALLO_U’, or ‘AUTO’ for each infusion.	Must ONLY be reported as ALLO_U, ALLO_R, or AUTO • ALLO_U = Unrelated Donor • ALLO_R = Related Donor, including syngeneic • AUTO = Autologous (no donor) **Note:** If more than one donor product was infused in the same infusion, report the product of the least related (ALLO_U > ALLO_R > AUTO). For example, if patient received an unrelated and related product, then select only ALLO_U. Do not use terms such as “boost”, “haplo”, “MUD”, etc. – must specify ‘ALLO_R, ‘ALLO_U’, or ‘AUTO’ for each infusion.

Definition of Reportable Infusions: Transplant center has agreed to report these types of infusions, the patient has signed a research consent, and the governing body does not have any restrictions that prevent the patient’s data from being reported in FormsNet3.

Last modified: Apr 18, 2024

Step 3: CTA Discrepancy Process

In order to remain in Good Standing for CPI, centers must address all discrepancies between the provided CTA list and the data reported to FormNet3 by the end of Trimester 2 (August 31st for US centers, October 31st for International centers). **This requirement is not eligible for exemption.**

Discrepancy Process Overview

1. First, CIBMTR will compare the center's submitted CTA list against FormNet3/ NMDP Operations data for discrepancies
2. Next, centers will resolve all discrepancies between CTA list and FormsNet3/NMDP Operations data
3. Lastly, centers will resolve all queries placed on FormsNet3 forms containing discrepancies

Discrepancy Resolution Timeline

Since discrepancy resolution and query resolution both occur within the same trimester and need to be completed sequentially, please refer to the timeline below.

- Part 1: Resolve any discrepancies between the CTA list and FormsNet3/NMDP Operations data
  - US Centers: ***July 31***
  - International Centers: ***September 30***
- Part 2: Resolve discrepancies within the FormNet3 Forms [queries will be placed on forms]
  - US Centers: ***August 31***
  - International Centers: ***October 31***

Last modified: Mar 06, 2024

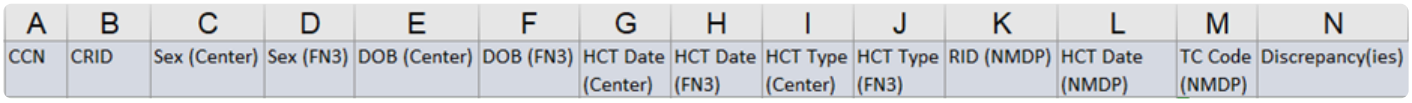
Part 1: Resolve Discrepancies Between CTA List and FormsNet3/NMDP Operations Data

Discrepancy Process

1. During trimester 2, CIBMTR will generate and post a refreshed CTA discrepancy file (see preview below) on the CIBMTR Portal for centers to download every Friday
    - How to download CTA files
2. Centers need to review and resolve the discrepancies listed in the file
    - Use the instructions below to determine how to resolve the discrepancy based on the category
    - If no file exists, discrepancies were not identified and center will be in “Good Standing” for *Resolve CTA Discrepancies* and *Resolve CTA Queries* categories
3. Once all discrepancies have been resolved, center will be in “Good Standing” for *Resolve CTA Discrepancies* category

CTA Discrepancy File Preview and Sources

The CTA discrepancy file (pictured below) displays the data reported from each source (CTA list vs FormsNet3/NMDP). This table allows centers to view the discrepancies across the different variables. Additionally, the last variable notifies centers of the discrepancy category.



A	B	C	D	E	F	G	H	I	J	K	L	M	N
CCN	CRID	Sex (Center)	Sex (FN3)	DOB (Center)	DOB (FN3)	HCT Date (Center)	HCT Date (FN3)	HCT Type (Center)	HCT Type (FN3)	RID (NMDP)	HCT Date (NMDP)	TC Code (NMDP)	Discrepancy(ies)

Variable	Source	Description
CCN	N/A	CIBMTR Center Number
CRID	N/A	Patient’s CRID
Sex (Center)	CTA List	Patient’s sex reported on CTA List
Sex (FN3)	FormsNet3	Patient’s sex reported in FormsNet3
DOB (Center)	CTA List	Patient’s date of birth reported on CTA List
DOB (FN3)	FormsNet3	Patient’s date of birth reported in FormsNet3
HCT Date (Center)	CTA List	HCT infusion date reported on CTA List
HCT Date (FN3)	FormsNet3	HCT infusion date reported in FormsNet3
HCT Type (Center)	CTA List	Donor type reported on the CTA List
HCT Type (FN3)	FormsNet3	Donor type reported in FormsNet3
RID (NMDP)	NMDP Operations	NMDP recipient ID from NMDP Operations records

HCT Date (NMDP)	NMDP Operations	HCT infusion date reported in NMDP Operations records
TC Code (NMDP)	NMDP Operations	Transplant Center Code in NMDP Operations records
Discrepancies	N/A	List of discrepancies affecting each record

Discrepancy Categories and Resolution Steps

There are eight different discrepancy categories. If a record has more than one discrepancy category assigned, the order in which the discrepancies are resolved is important. Resolving in the order displayed will prevent additional discrepancies from occurring.

The table below provides the discrepancy category, suggested order to resolve the discrepancy, description and action steps.
Click the "Discrepancy Name" for instructions on how to solve discrepancy.

Discrepancy Name	Order to Resolve	Description
Missing CRID	1	FormsNet3 does not have a record of the CRID on CTA List.
RID Not Reported in FormsNet3	2	The patient's NMDP RID is not reported in FormsNet3.
HCT Not Reported in FormsNet3	3	NMDP has a record of a product that was provided to a center The infusion may exist in FormsNet3, but the infusion dates between FormsNet3 and NMDP are more than 10 days apart.
HCT Date Missing	4	FormsNet3 does not have a record of the HCT reported on the CTA List. For these cases, a CRID exists, and the infusion will need to be reported in FormsNet3.
DOB [Date of Birth] Mismatch	5	The patient's date of birth is discrepant between FormsNet3 and the CTA list.
Sex Mismatch	5	The patient's sex is discrepant between FormsNet3 and the CTA list.
HCT Date Mismatch	5	The HCT infusion dates is discrepant between FormsNet3 and the CTA list.
HCT Type Mismatch	5	The HCT type is discrepant between FormsNet3 and the CTA list.

Last modified: Mar 06, 2024

Discrepancy: Missing CRID

FormsNet3 does not have a record of the CRID on the CTA list.

Steps to Follow to Correct Discrepancy

- **Confirm correct CRID is reported on the CTA list. If the CTA list has an error, make corrections to the CTA list and resubmit via a CIBMTR Center Support ticket.**
  - After navigating to the CIBMTR Center Support, click *Need Help?*
  - Complete necessary fields and answer the following
    - *What is your question regarding?* CPI/CTA
    - *Relating to:* CTA HCT List Submission/Resubmission
  - Attach the CTA list with the *Add Attachments* feature
  - Click submit

- **If patient has not been registered in FormsNet3, add the CRID and infusion in FormsNet3.**
  - Complete a CRID Assignment tool (2804) form
    - **NOTE:** If this not the patient's first HCT and/or cellular therapy, a different CRID in FormsNet3 may already exist. Search using the Search/Edit CRID tool to determine if a CRID already exists for the patient.
      - How to Create a CRID
      - How to complete the CRID Assignment Tool form
  - To register an HCT infusion, follow the steps for Discrepancy: HCT Date Missing

Last modified: Mar 06, 2024

Discrepancy: RID Not Reported in FormNet3

The patient's NMDP RID is not reported in FormsNet3.

- This could be due to
  - NMDP RID blank in the CRID Assignment tool
  - NMDP RID in the CRID Assignment tool is incorrect
  - CRID has not yet been assigned in FormsNet3

Steps to Follow to Correct Discrepancy

- Add the NDMP RID in FormsNet3
  - Navigate to the CRID Assignment tool for the CRID in question by following the Search for a CRID guide
  - Edit the CRID Assignment form by following the Editing a CRID Assignment guide
    - Add the patient's NDMP RID

Last modified: Mar 10, 2023

Discrepancy: HCT Not Reported (Between NMDP and FormsNet3)

NMDP has a record of a product that was provided to a center. The infusion may exist in FormsNet3, but the infusion dates between FormsNet3 and NMDP are more than 10 days apart.

Steps to Follow to Correct Discrepancy

- **If the infusion did NOT occur, submit a CIMBTR Center Support ticket to inform CIBMTR.**
  - CIBMTR will work with NMDP to remove the infusion

- **If the infusion did occur, but the date is incorrect in either NMDP's system and/or FormNet3.**
  - If NMDP is incorrect, submit a CIBMTR Center Support ticket to inform CIBMTR
    - CIBMTR will work with NDMP to resolve the date discrepancy
  - If FormsNet3 is incorrect, update the event date in FormsNet3

- **If the infusion occurred and NMDP is correct/updated, but the event is missing in FormsNet3.**
  - Register the patient or search for the CRID in FormsNet3.
    - To register the patient in FormsNet3, complete the CRID Assignment tool form (2804)
      - **NOTE:** If this is not the patient's first HCT and/or cellular therapy, there may be a different CRID within FormsNet3. Search in the Search/Edit CRID tool to determine if a CRID already exists for the patient.
        - How to create a CRID
        - How to complete the CRID Assignment Tool form
  - To register an HCT infusion, follow the steps for Discrepancy: HCT Date Missing

Last modified: Mar 06, 2024

Discrepancy: HCT Date Missing

FormsNet3 does not have a record of the HCT reported on the CTA list. For these cases, a CRID exists, and the infusion will need to be reported in FormsNet3.

Steps to Follow to Correct Discrepancy

- **For a patient's first infusion, complete the following**
  - Submit an Indication for CRID Assignment (2814) form
    - How to complete the Indication for CRID Assignment form
  - Submit the Pre-TED (2400) form
    - How to complete the Pre-TED 2400 form
      - **NOTE:** Center will need to provide the patient's consent for research before the Pre-TED (2400) can be completed
      - How to complete the Consent Tool

- **For subsequent infusions (for the same patient), complete the following**
  - Report the subsequent infusion on the prior infusion's follow-up form (2450, 2100, or 4100)
    - **NOTE:** If no follow-up forms exist for the prior infusion, an Indication for CRID Assignment (2814) form can be made due by selecting "Create Indication Form" after pulling up the CRID on the Recipient Forms page in FormsNet3
  - Submit the Pre-TED (2400) form
    - How to complete the Pre-TED 2400 form

> ! **NOTE:** Subsequent transplants should ONLY be reported in a Form 2814 if no follow-up forms exist for the prior event.

Last modified: Nov 22, 2023

Discrepancy: DOB (Date of Birth) Mismatch

The patient's date of birth is discrepant between FormsNet3 and the CTA list.

Steps to Follow to Correct Discrepancy

- **If the CTA list is incorrect, centers should correct the CTA list and resubmit via a CIBMTR Center Support ticket.**
  - After navigating to the CIBMTR Center Support, click *Need Help?*
  - Complete necessary fields and answer the following
    - *What is your question regarding?* CPI/CTA
    - *Relating to:* CTA HCT List Submission/Resubmission
  - Attach the CTA list with the *Add Attachments* feature
  - Click submit

- **If the date in FormsNet3 is incorrect, centers must correct FormsNet3 by updating the CRID Assignment (2804) form and then reprocess all forms that contain the patient's date of birth.**
  - Navigate to the CRID Assignment form for the CRID in question by following the Search for a CRID guide
  - Edit the CRID Assignment form by following the Editing a CRID Assignment guide
    - Correct the patient's date of birth
  - Reprocess all other forms that contain the patient's date of birth
    - Open each form via the Edit icon > allow auto-population to update the patient's date of birth > submit form to complete
    - Open form with Edit icon > manually correct patient's date of birth > submit form to complete

! NOTE: Recipient forms with the patient's date of birth include 2400, 2000 (r3), and 2450 (except r4). Error corrections may also be required for non-FormsNet3 editable forms.

Last modified: Mar 06, 2024

Discrepancy: Sex Mismatch

The patient's sex is discrepant between FormNet3 and the CRA list.

Steps to Follow to Correct Discrepancy

- **If the CTA list is incorrect, centers should correct the CTA list and resubmit via a CIBMTR Center Support ticket.**
  - After navigating to the CIBMTR Center Support, click *Need Help?*
  - Complete necessary fields and answer the following
    - *What is your question regarding?* CPI/CTA
    - *Relating to:* CTA HCT List Submission/Resubmission
  - Attach the CTA list with the *Add Attachments* feature
  - Click submit

- **If the sex in FormsNet3 is incorrect, centers must correct FormsNet3 by updating the CRID Assignment (2804) form and then reprocess all forms that contain the patient's sex.**
  - Navigate to the CRID Assignment form for the CRID in question by following the Search for a CRID guide
  - Edit the CRID Assignment form by following the Editing a CRID Assignment guide
    - Correct the patient's sex
  - Reprocess all other forms that contain the patient's sex
    - Open each form via the Edit icon > allow auto-population to update the patient's sex > submit form to complete
    - Open form with Edit icon > manually correct patient's sex > submit form to complete

> ! NOTE: Recipient forms with the patient's sex include 2400, 2000 (r3), and 2450 (except r4). Error corrections may also be required for non-FormsNet3 editable forms.

Last modified: Mar 08, 2024

Discrepancy: HCT Date Mismatch

The HCT event date is discrepant between FormsNet3 and the CTA list.

Steps to Follow to Correct Discrepancy

- **If the CTA list is incorrect, centers should correct the CTA list and resubmit via a CIBMTR Center Support ticket.**
  - After navigating to the CIBMTR Center Support, click *Need Help?*
  - Complete necessary fields and answer the following
    - *What is your question regarding?* CPI/CTA
    - *Relating to:* CTA HCT List Submission/Resubmission
  - Attach the CTA list with the *Add Attachments* feature
  - Click submit

- **If the infusion date in FormsNet3 is incorrect, centers must correct the infusion dates on the Indication for CRID Assignment (2814) form/follow-up form used to report the infusion. Centers will then need to reprocess all forms for that infusion which are in status other than DUE.**
  - Navigate to the Recipient Tab in FormsNet3 > Recipient Forms subtab
  - Enter the CRID in the “Search For” box and click “Search”
  - Correct the Indication for CRID Assignment (2814) form OR the follow-up form used to report the HCT infusion
  - Submit the form to complete
  - Reprocess additional forms for the event that are in a status other than DUE
    - Open each form via the Edit icon > allow auto-population to update HCT event date > submit form to complete

> ! **NOTE:** Error corrections may also be required for non-FormsNet3 editable forms

Last modified: Mar 10, 2023

Discrepancy: HCT Type Mismatch

The HCT type is discrepant between FormsNet3 and the CTA list.

Steps to Follow to Correct Discrepancy

- **If the CTA list is incorrect, centers should correct the CTA list and resubmit via a CIBMTR Center Support ticket.**
  - After navigating to the CIBMTR Center Support, click *Need Help?*
  - Complete necessary fields and answer the following
    - *What is your question regarding?* CPI/CTA
    - *Relating to:* CTA HCT List Submission/Resubmission
  - Attach the CTA list with the *Add Attachments* feature
  - Click submit

- **If FormsNet3 is incorrect, then the Pre-TED form (2400) in FormsNet3 donor/HCT type needs to be corrected.**
  - Navigate to the Recipient Tab in FormsNet3 > Recipient Forms subtab
  - Enter the CRID in the “Search For” box and click “Search”
  - Find the form 2400 for the event in question and click the Edit icon
  - Scroll to the Donor Information section and correct the donor/HCT type
    - NOTE: There may be more than one donor and donor instance in this section. Ensure all donor types are reported correctly
  - Submit the form to complete
  - Reprocess additional recipient forms for the donor(s) that were corrected (forms 2004, 2005, and/or 2006). The visit details on the FormsNet3 forms grid will often display the donor used
    - Open each form via the Edit icon > allow auto-population to update donor/HCT type > complete any questions that may have come due > submit form to complete
    - Open form with Edit icon > manually correct donor/HCT type > complete any questions that may have come due > submit form to complete

> ! **NOTE:** Error corrections may also be required for non-FormsNet3 editable forms

Last modified: Mar 06, 2024

Part 2: Resolve Discrepancies within FormsNet3 Forms (Query Resolution)

Discrepancy Process (Queries)

1. Once the CTA discrepancies have been resolved, CIBMTR will place queries on FormsNet3 forms containing discrepancies. A list of these queries will be uploaded to the CIBMTR Portal.
    - How to download CTA files
2. Centers will need to locate CTA queries in FormsNet3
    - These queries can be found in the FormsNet3 homepage "*Recipient Query Tasks*" table
    - Use the "Query Placed" date and/or sequence number on the uploaded query list to filter for the CTA queries in the "*Recipient Query Tasks*" table
    - CTA queries will also have the prefix: "CTA YYYY" in the query comments
3. Centers will need to resolve CTA queries
    - See query resolution instructions below
4. Once all queries have been resolved, center will be in "Good Standing" for *Resolve CTA Queries* category

CTA Query Resolution Instructions

1. Update the discrepant question's answer
    - **Auto-populated update:** When entering the form using the Edit form icon, the question's answer may be updated by auto-population. Centers will see a pop-up with the question, the question's new answer, and the question's previous answer. Select "OK" to close out of the pop-up and continue to step 2.
    - **Manual update:** If no auto-population runs to resolve the discrepant question's answer, the answer will need to be manually updated.
2. Interact with the query icon located next to the discrepant field
    - For detailed instructions, please visit the How to Resolve a Query page
3. Answer other questions that may be been enabled
    - When an answer is changed within the form, this may cause more questions to be enabled and must be answered. Complete these questions before continuing to step 4.
4. Submit the form to pending (PND) status
    - Once the form is in PND status, the CIBMTR will review the query and updates. Updates will either be approved or rejected.
        - If approved, the form should go to complete status (CMP).
        - If rejected, please review the most current CIBMTR query comment for further instructions.

Last modified: Mar 14, 2023

Downloading CTA Files

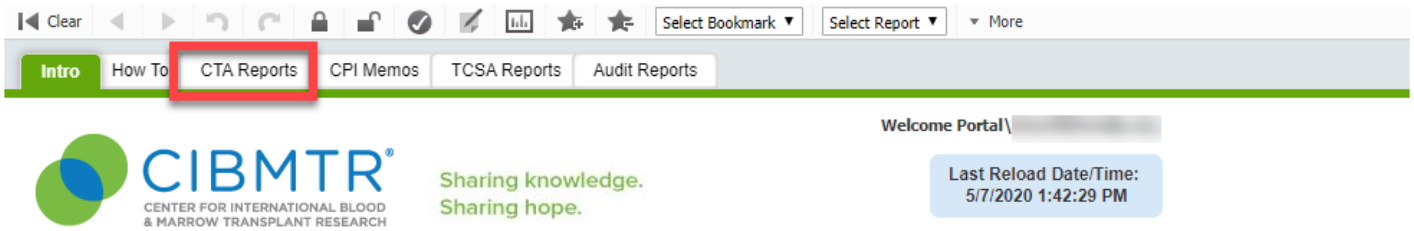
Steps to Access and Download the CTA File

1. Log into CIBMTR Portal (https://portal.cibmtr.org)

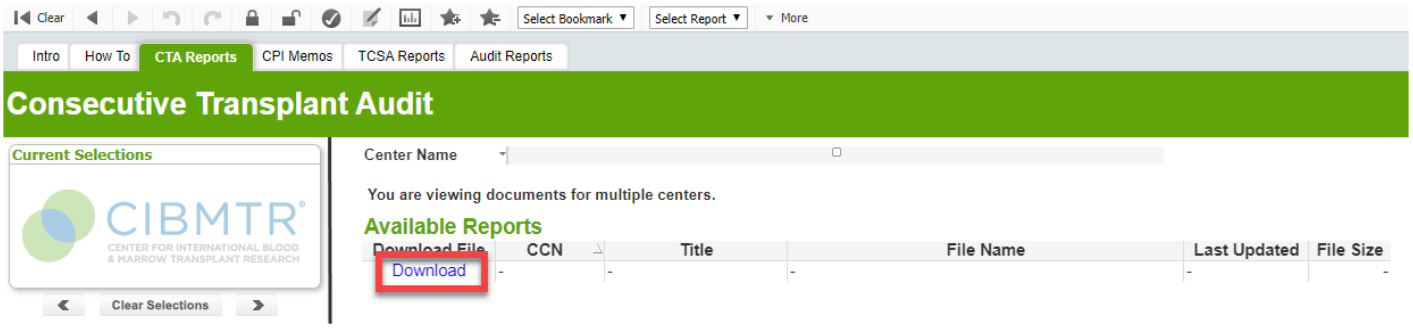
- Submit a request to CIBMTR Center Support if you have any trouble accessing the CIBMTR Portal or if you have a user account and need additional access.
- Choose category Access > CIBMTR Portal
- If you do not have access to CIBMTR Center Support, email cibmtr-centermaintenance@nmdp.org instead.

2. Select the Data Operations tile on the CIBMTR Portal landing page.

3. Select the CTA Reports tab



4. Select the blue Download button to download the desired file



If additional assistance is needed, contact CIBMTR Center Support

Last modified: Nov 03, 2023

Center Volume Data Reports (CVDR)

CIBMTR has created the following resources to further support centers with Center Volume Data Reports (CVDR). These tools can be utilized for workflow management, analysis, metrics and more. Please let CIBMTR know if any additional resources would be beneficial. Use the links below to navigate to a specific resource page.

- Overview & Timeline
- Dataset
- Status Submission
- Resources
    - Frequently Asked Questions
    - New User in FN3

Last modified: Aug 31, 2023

Overview & Timeline

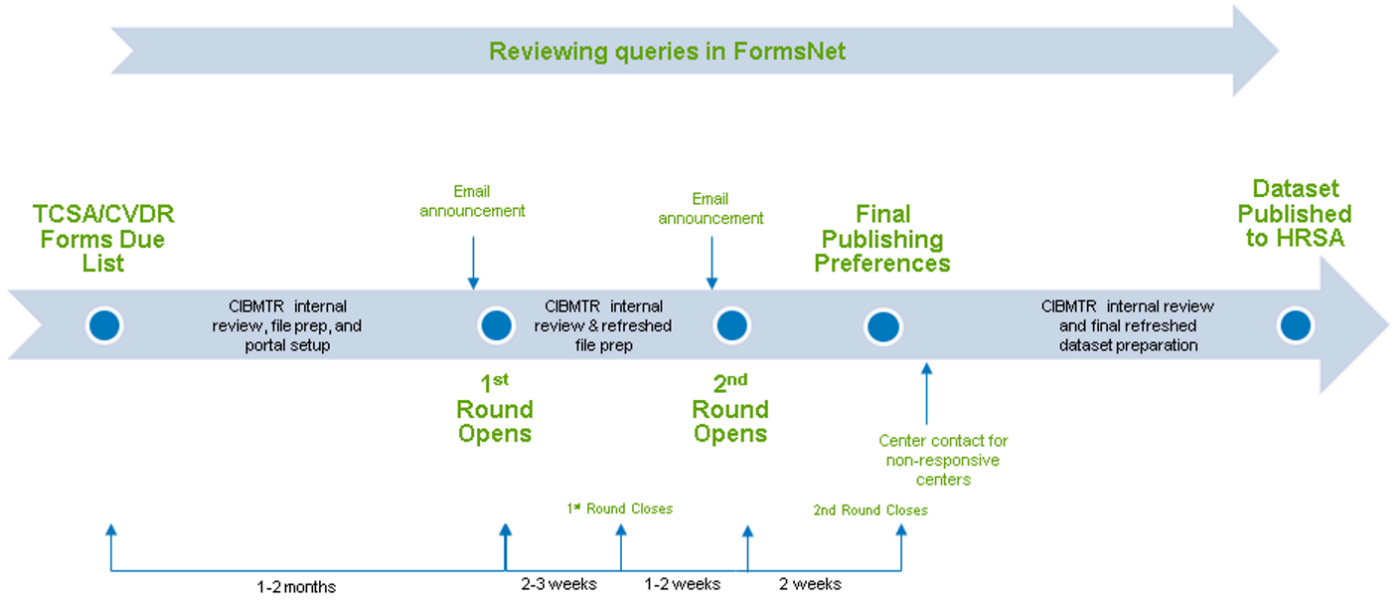
Overview

Annually, as part of our contract with the U.S. Health Resources and Services Administration (HRSA), CIBMTR publishes transplant center volumes data on the C.W. Bill Young Cell Transplantation Program government website. The hematopoietic cell transplantation (HCT) volumes and demographic data, by transplant center, will be made accessible to the public and transplant community.

The Center Volume Data Reports (CVDR) provided in the CIBMTR Portal represents the total number of transplants reported in the last 5 years using FormsNet3^{SM}. The data reflected in the charts, found within the CIBMTR Portal application, are the latest refreshed dataset from FormsNet3.

Timeline

- **Ongoing:** CIBMTR places queries, centers resolve queries and complete forms
- **June – August:** Centers ensure all CVDR data is accurate and complete (resolve remaining queries and complete forms)
- **September:** CVDR Portal Opens – Round 1 (3 weeks)
- **October:** CVDR Portal Closes (3 weeks)
- **November:** CVDR Portal Opens – Round 2 (2 weeks)
- **December:** CIBMTR Final Review (validation assessment, leadership review, HRSA posting)



Last modified: Aug 31, 2023

Dataset

The CVDR report includes transplants from the past five years performed by domestic transplant centers. The variables in these reports include identifiers (CCN, center name, center city, center state, CRID, event date, and event year), recipient demographics (ethnicity, gender, race, date of birth, age), disease information (broad disease, specific disease, disease status), and donor information (donor, product, cell type). Please refer to the CVDR Data Dictionary located in the CIBMTR CVDR Portal for additional details.

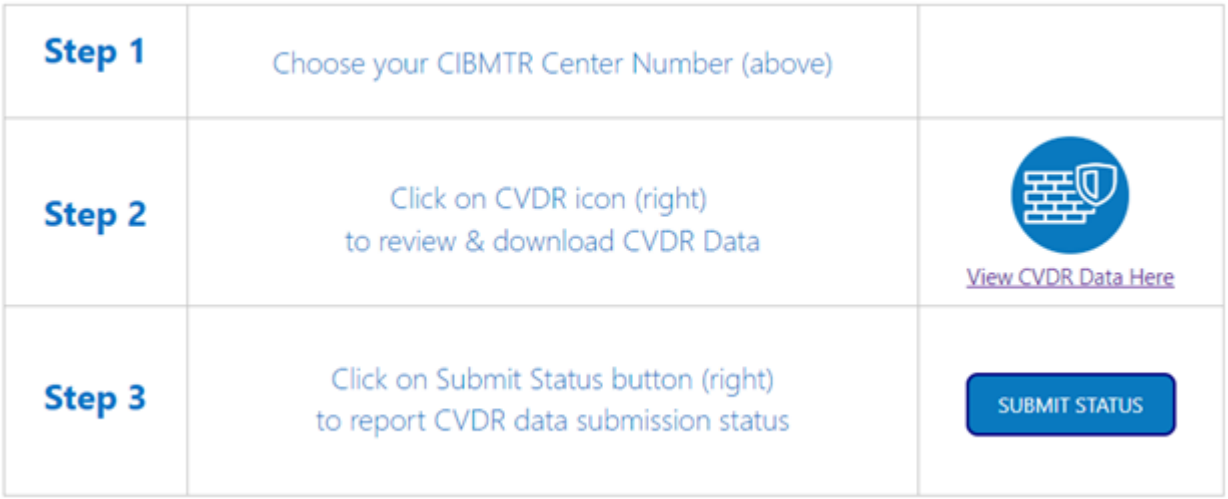
CVDR Dataset Preparation

CIBMTR will review the CVDR data and place queries on any missing/discrepant data, and will reach out to centers with incomplete forms. Prior to the CVDR dataset pull (which occurs late summer), centers should resolve queries and complete forms to ensure all record(s) are included in the dataset. Once the dataset is generated and loaded to the CIBMTR Portal, CIBMTR will distribute an eBlast informing centers of the CVDR timeline.

CVDR Portal Login & Dataset Access

1. Login to the CIBMTR CVDR Portal
2. Select the **Center Volumes Data Reporting (CVDR)** tile on the CIBMTR Portal landing page

3. Centers will land on **CVDR Home Page** where they will follow the steps listed.



CVDR Dataset Review

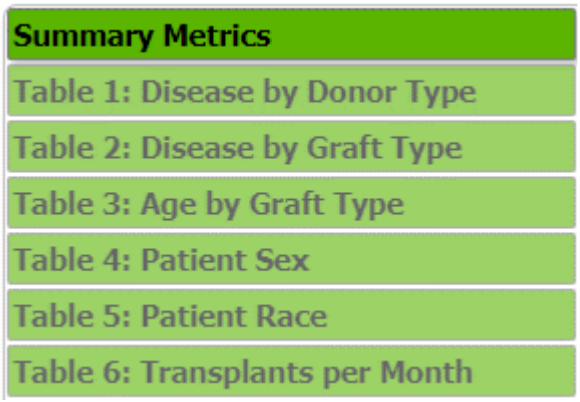
Once CIBMTR has notified centers the CVDR portal is open and dataset is ready for review, centers will login to the CIBMTR CVDR Portal and review the dataset with their medical director.

Once in the CVDR Portal, centers can review their data multiple ways:

Table View

1. Select the infusion year(s) tab to review:

2. The data will be displayed in the following tables:

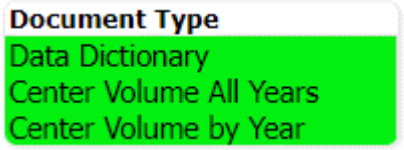


- **Summary Metrics**
  - Summary metrics for the report year (infusion year) selected, count of patients, and count of infusions
- **Table 1: Disease by Donor Type**
  - List of diseases (broad & specific diseases) by donor type
- **Table 2: Disease by Graft Type**
  - List of diseases (broad & specific diseases) by graft type
- **Table 3: Age by Graft Type**
  - List of patient age (categorized in ranges) by graft type
- **Table 4: Patient Sex**
  - Count of infusions by gender
- **Table 5: Patient Race**
  - Count of infusions by race
- **Table 6: Transplants per Month**
  - Count of infusions per month

Download Dataset

1. Select “Download Extract” tab across the top or “Document type” found on the left side of the screen

OR



2. Click **Download** under the available reports

Download File
Download
Download
Download
Download
Download

3. Files will be available for the following reports:
    a. Report for each infusion year (5 reports total; distinct for each infusion year)
    b. Report for all infusion years (comprehensive report with 5 years data included)
    c. Data Dictionary

Centers need to ensure the records match between the tables and extracts. Once confirmed, centers will review the data to verify the counts and records are accurate for each field.

Once the data has been reviewed and approved, centers will submit their CVDR data status.

Troubleshooting

If the records do not match, missing records, discrepant records, or inaccurate records, please do the following:

1. Review the CVDR Data Dictionary to determine the data source.
2. Review FormsNet to ensure forms are complete and data has been entered correctly. CIBMTR will exclude records if forms and data are not completed.
3. If further assistance is requested, please submit a ticket to CIBMTR Center Support > CVDR.

Last modified: Aug 31, 2023

Status Submission

CIBMTR allows centers to review data, suggest changes, and submit publishing preference. CIBMTR will then close the Portal (to refresh the dataset) and allow the centers one last opportunity to view the refreshed data. Any corrections to data submitted through FormsNet3 can be made directly in the application. CIBMTR encourages centers to review the data with the medical director before submitting publishing preference.

There are four submission options available:

Data Complete/Correct – Publish ALL Data

Selecting this option indicates that center volume data from FormsNet3 are complete and accurate as displayed in the tables and data. Center agrees to have all data published on the HRSA website.

Data Complete/Correct – Publish ALLO Data and NOT AUTO Data

Choosing this option indicates that center volume data from FormsNet3 are complete and accurate as displayed in the tables. Center agrees to have "Allogeneic Transplant Volume Data and NOT Autologous Transplant Volume Data" published on the HRSA website. The disclaimer below will be used for the center on the HRSA website: *"Autologous data are reported voluntarily and are not available for this center."*

Data Pending for Correction – Updates in Progress*

During the first round, this option may be chosen to indicate that the data are still being reviewed by the center, the center may need to make changes in FormsNet3, or the center has questions for CIBMTR regarding their dataset. Once updates are made in FormsNet3, the data will be refreshed for review during the second round. The center will need to submit center status again for the second round if this option is selected during the first round.
**This option is not available for Round 2*

DO NOT PUBLISH Data for the Center

Selecting this options means the center does not agree to publish Transplant Center Volume Data. However, CIBMTR will review all center statuses and reserves the right to publish a center's data even if this publishing preference is submitted.

- **If the final decision is made to publish a centers data**, it will be made available to the public and transplant community and the following statement will appear on the government website: *"Although data were provided for transplants performed, the completeness of the reporting was not confirmed by the below centers before being included in this report. Allogeneic transplant data for these centers are made available for informational purposes for the SCTOD, as required by U.S. law."*
- **If the final decision is made to not publish a centers data**, it will not be made available to the public and transplant community and the following statement will appear on the government website: *"Although these centers performed transplants, their data could not be included in the U.S. Transplant Data by Center Report. Most of these centers did not provide data within the timeframe needed for*

this report. A few centers did provide data, but their data could not be validated in time for this report."

- **If centers do not submit a final data status** ("Data Pending" is not considered a final status), the default setting is to publish all the center's information. Centers that report allogeneic HCT will have this data published at a minimum.

> ! Please submit a ticket to CIBMTR Center Support with data issues before submitting "Data Incomplete/Incorrect," as most of the time, this status needs to be redacted after the data is corrected.

> ! Please submit a CIBMTR Center Support ticket if center submitted "Data Pending" and CIBMTR needs to investigate record(s).

Last modified: Aug 31, 2023

Resources

CIBMTR has created multiple CVDR resources for Transplant Centers to utilize. Please review the following for FAQ page, data dictionary, and more for additional CVDR details and instructions.

Questions

- **If center has a question regarding dataset, submission, or general questions relating to CVDR, please submit a ticket to the CIBMTR Center Support.**
  - After navigating to the CIBMTR Center Support, click *Need Help?*
  - Complete necessary fields and answer the following
    - *What is your question regarding?* CVDR
    - *Relating to:* Select either “CVDR Question” or “CVDR Submission”

- **If center has a question regarding Portal Account Credentials, please submit a ticket to CIBMTR Center Support.**
  - After navigating to the CIBMTR Center Support, click *Need Help?*
  - Complete necessary fields and answer the following
    - *What is your question regarding?* Access
    - *Relating to:* CIBMTR Portal

- **If center needs to change primary contact, please do so through the Network Partner Portal.**

Last modified: Mar 06, 2024

Frequently Asked Questions (FAQ)

How will CIBMTR inform my center the CVDR Portal is open and dataset ready for review?

An eBlast announcement will be distributed to centers informing them of the dates the CIBMTR CVDR dataset/portal will be open and available for review.

When should I review my dataset?

Please review your dataset as soon as the announcement is distributed since the portal is only open for a short period. Additionally, please submit a ticket to CIBMTR Center Support as soon as possible to allow time for investigation, updates, and corrections.

Why is a record missing on my dataset?

A record may be excluded from your dataset due to data discrepancies, missing data, and/or a form not in complete status.

Why does disease reported in FormsNet not match with the CVDR diseases?

CIBMTR has recategorized some of the broad and specific diseases to match with disease reporting on the C.W. Bill Young Transplantation Program. Please see the CVDR Data Dictionary on the CIBMTR Portal for additional information.

How are cancelled or postponed HCTs reported?

Any cancelled HCTs that were reported, have been removed from the HCT count. If you still have any cancelled transplants in FormsNet, please complete the Form 2008.

Does my center need to submit a data status for the second round if a status was submitted for the first round?

If a center selects “Data Complete/Correct” or “Data Incomplete/Incorrect” for the first round, centers do not need to submit a center status for the second round. However, if “Data Pending for Correction” is selected, centers will need to submit a center status for the second and final round.

Who is authorized from my center to submit data status?

Only the medical director/primary data contact or designated member from your center can submit/update the data status. If you are not one of the aforementioned people, you will see the following message displayed:

"*You are not authorized to submit/change FN data status for your center. Only the medical director or primary data contact of your center has this privilege. To find out your center's status, please contact your center's medical director/primary data contact. However, you can view the reports pertaining to your center.*"

If your center needs to update a contact, please update through the Network Partner Portal.

What happens once I submit the data status?

Once you submit the data status, an email will be sent to your center's medical director and the submitter. A copy of the submit status will also be sent to the CVDR team. Your submission details will be stored in the application and made available for further communication with you.

Can I update my center's status once I submit a data status?

Please carefully review your data with your medical director before you submit your center status. If you have submitted an incorrect status due to error, please submit a ticket to CIBMTR Center Support. CIBMTR will remove the incorrect submit status and your center will be allowed to re-submit the correct status.

What if I do not submit my status within the timeframe provided?

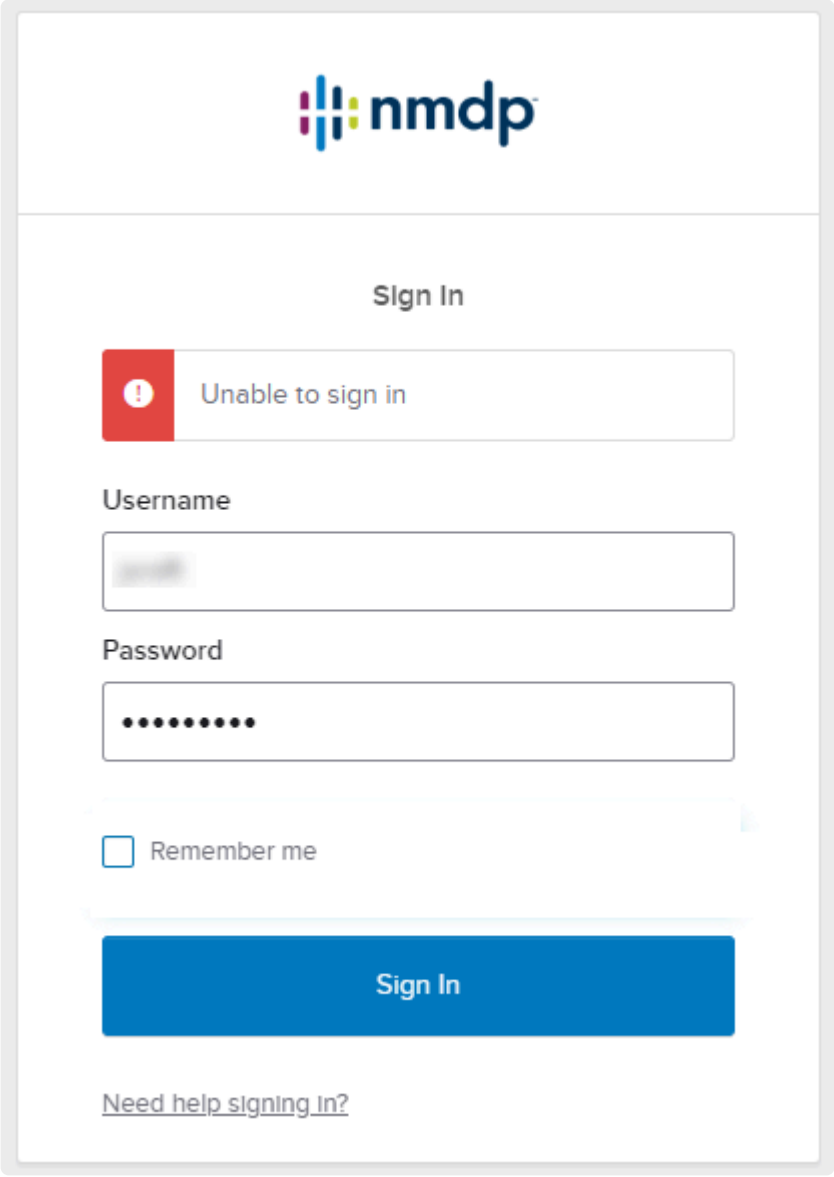
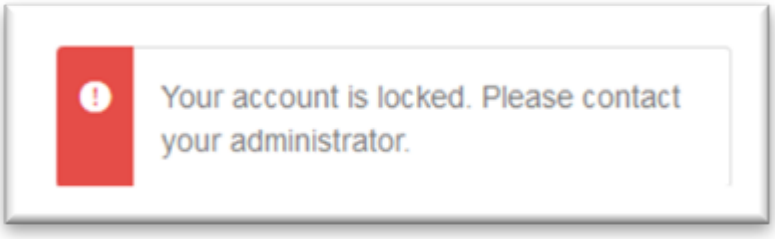
CIBMTR will reach out to centers who did not submit a final data status. In circumstances where transplant centers do not have CIBMTR Portal activity, or who do not submit any center data status by the end of the process, centers final status will be determined by CIBMTR leadership team.

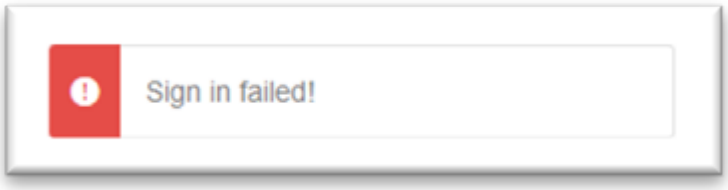
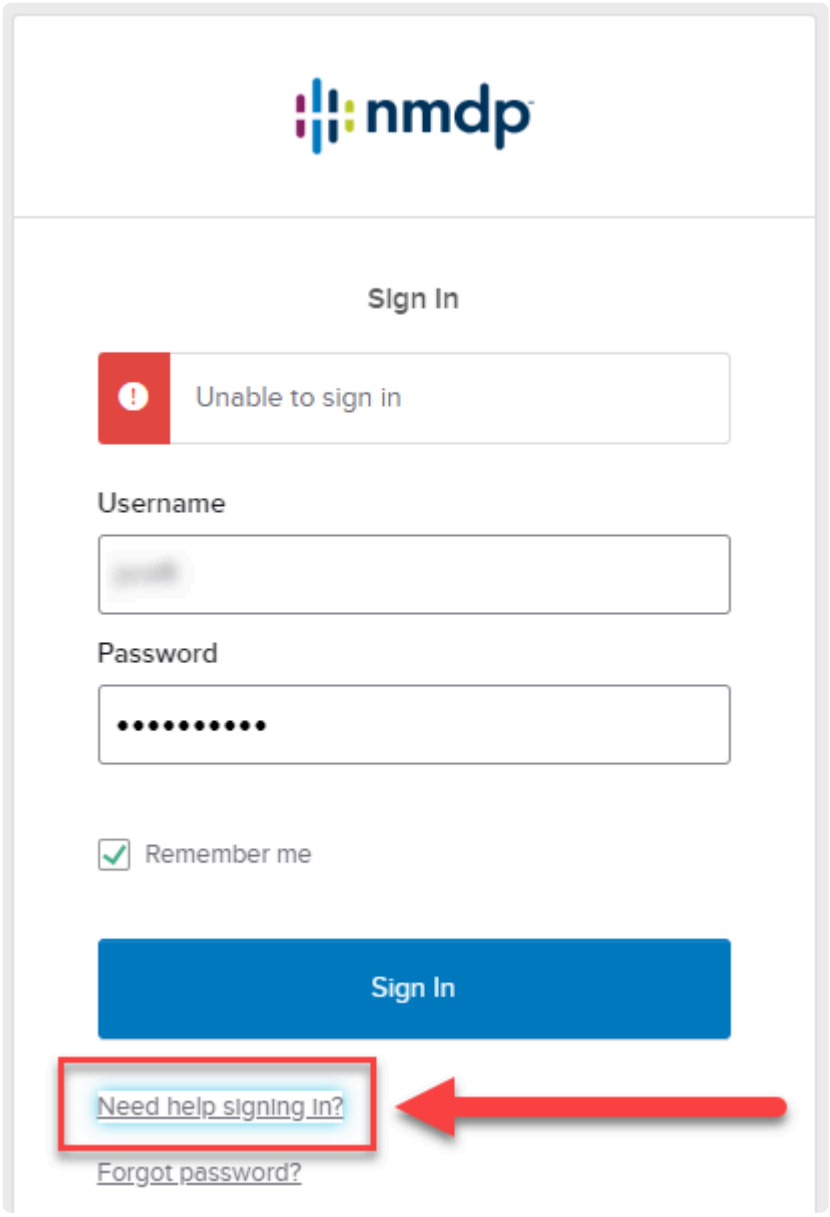
Last modified: Aug 31, 2023

New User in FN3

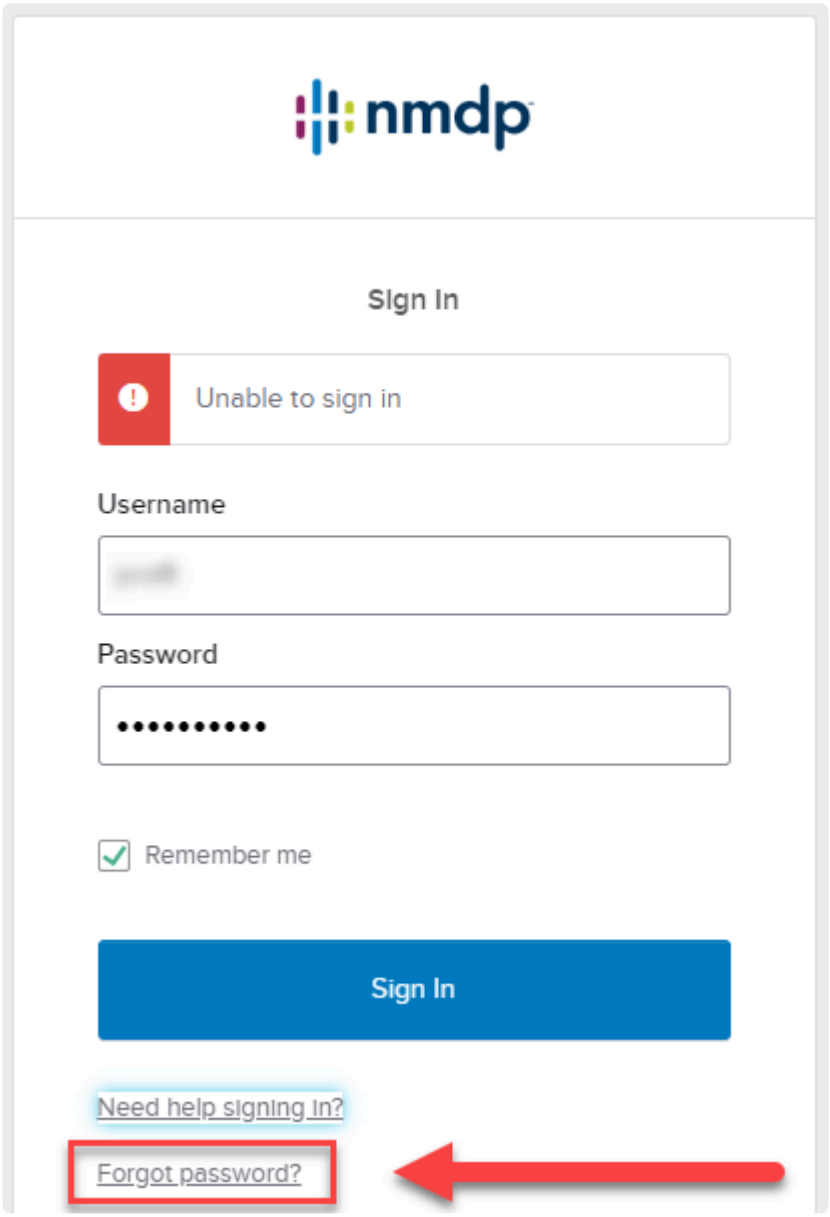
After the Primary Data Manager at your center creates an account for you in the Network Partner Portal, you will receive a notification with your username.

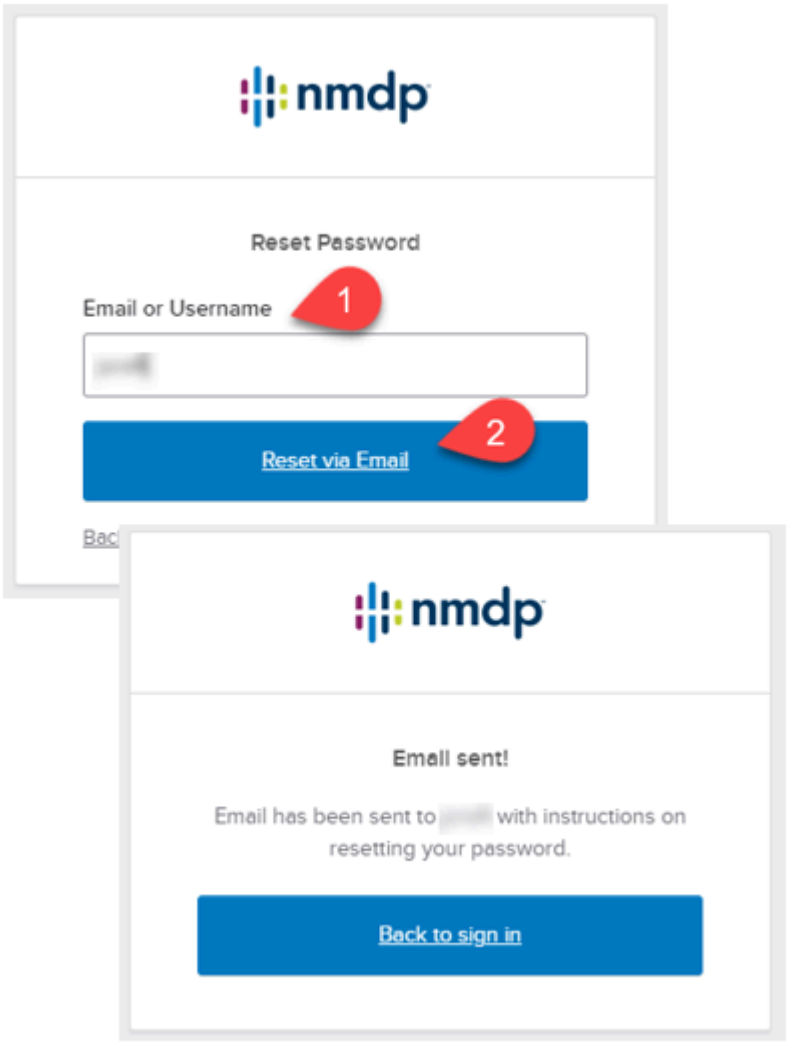
To set an initial password begin at step 2a (see below). You can set a new password from the login screen of FormNet3 or CIBMTR Portal.

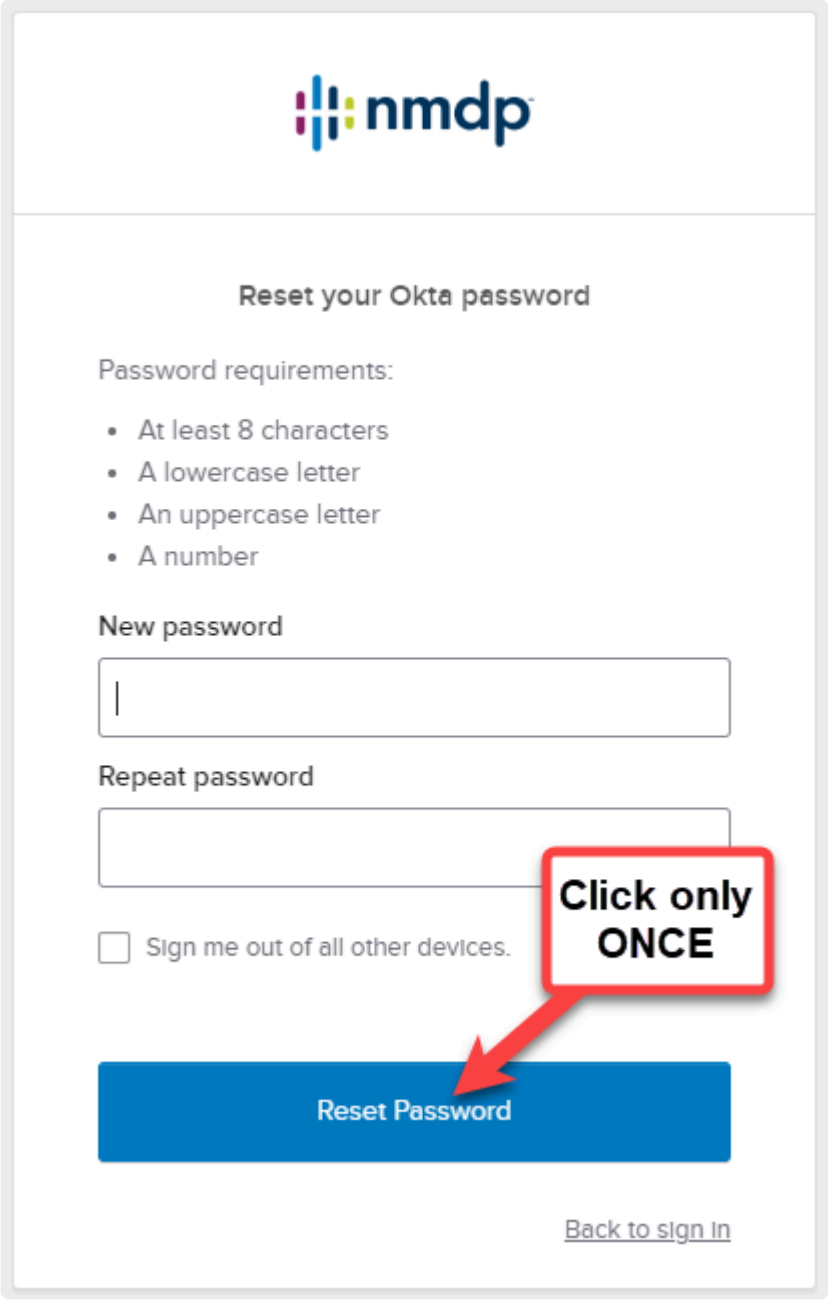
1. If login fails or your account is locked	
1a. If the error says that your account is locked, you will need to **wait 15 minutes** for the account to unlock. You may also call the Service Desk at 800-526-7809 ×3411 or (763) 406-3411 to unlock the account right away.	

2. If the error says “Sign in failed!”	
2a. Click on “Need help signing in?”	

2b. Click on “Forgot password?”



2c. Enter your **username** (suggested) and click “Reset via Email”	
3. An email will go to the email associated with your account in the Network Partner Portal and contain a link to reset your password. If it doesn’t seem to be working, double check your username to be sure it is spelled correctly and reattempt.	
3a. If you do not receive an email after having checked your **username**, call the Service Desk (*See Step 1a*) or have a colleague submit a ticket via CIBMTR Center Support under Access	
3b. If the email associated with your account is incorrect or unknown, your Primary Data Manager can log into the Network Partner Portal to check or change the	

email address that we have associated with your account.	
4. After you receive the password reset email from **noreply@okta.com**, click on the “Reset Password” link and make sure your new password meets requirements. Click only **ONE TIME** on the “Reset Password” button.	
4a. Return to the login screen for the application and try to log in again.	
4b. If you have trouble repeatedly call the Service Desk or have a colleague submit a ticket via CIBMTR Center Support under Access.	

Last modified: Mar 05, 2024

Transplant Center Specific Analysis (TCSA)

To learn more about Transplant Center Specific Analysis (TCSA), see the topics listed below:

- Overview & Timeline
- Inclusion Criteria
- Posting
- International Information
- Questions & Resources

Last modified: Nov 28, 2023

Overview & Timeline

What is TCSA?

Transplant Center Specific Analysis (TCSA), also referred to as Center Specific Analysis (CSA) or Center Outcomes Analysis, is used to predict one-year survival of first allogeneic transplants, based on data reported to CIBMTR. This program is mandatory for US centers performing allogeneic transplants. Reporting center-specific survival rates is a requirement of the TRANSPLANT Act of 2021, previously the Stem Cell Therapeutic and Research Act of 2005 (reauthorized in 2010 and 2015), and prior to that, the 1990 Transplant Amendments Act.

The analysis is dependent upon the accuracy and completeness of reporting from centers. Since centers vary considerably in the risk level of cases treated, a statistical model was developed to adjust for several risk factors known or suspected to influence transplant outcomes.

This model is used to predict an “expected” 1-year (365+ days) survival post-first allogeneic transplant for a center, given the types of patients and diseases treated. The actual survival observed at a center is then compared against the “expected” survival. The center will receive one of the following scores: Below expected, Meets expected, or Exceeds expected survival.

Purpose of TCSA

This robust analysis provides an equitable, balanced, and scientific performance measurement tool that can be used by the transplant community to define and improve quality.

The results of this analysis are considered in FACT Accreditation and insurance companies may determine coverage based upon a center’s score.

TCSA Timeline

The analysis begins in December with CIBMTR gathering an initial dataset. The dataset includes first related or unrelated donor transplants performed in a three-year time interval.

CIBMTR reviews the initial dataset for incorrect or missing information and places queries in FormsNet3. Raw datasets are then provided for centers to be reviewed in CIBMTR Portal (Portal > DataOps Dashboard> TCSA). The datasets include all allogeneic HCTs performed within the three-year interval, allowing centers to identify patterns and outliers, and to validate HCT history.

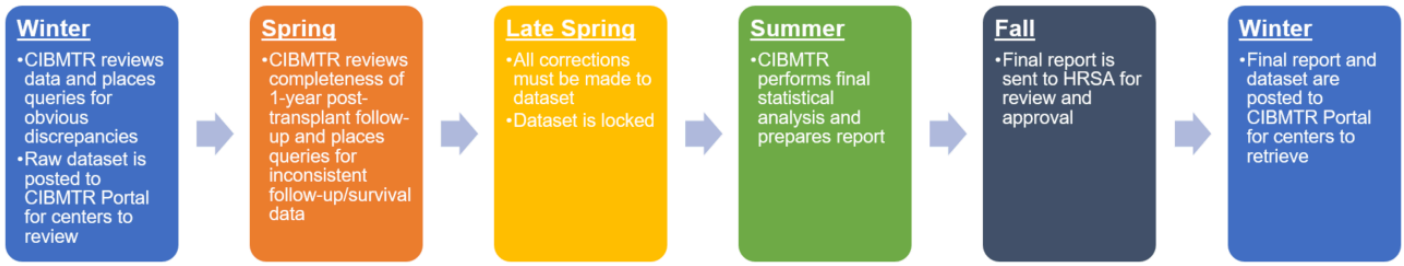
These datasets are split into multiple files to make the disease data easier to review. These files include several more variables than the Center Volumes Data Report (CVDR). Centers should make any necessary corrections in FormsNet3 by as soon as practical. Monitor communications for specific deadlines. *See Center-Specific Survival Analysis for more information on methodology and FAQs.*

In March, CIBMTR begins reviewing completeness of the 1-year follow-up. Queries will be placed for

inconsistent follow-up/survival data. Cases must have follow-up reported through one-year post-transplant or report of patient death.

Once the dataset is locked, CIBMTR performs a statistical analysis to prepare the final report sent to Health Resources and Service Administration (HRSA) at the end of summer. After HRSA has granted their approval, the final report is posted to the HRSA public website and CIBMTR Portal. The report is usually available to centers in December. When it is posted on the CIBMTR Portal, the schedule for the following year is also posted.

The timeline below displays a further breakdown of these timeframes.



Last modified: Jan 18, 2024

Inclusion Criteria

TCSA Inclusion Criteria

Inclusion criteria for this dataset are based on center activity and patient characteristics. For a transplant to be included, it must be a patient's first allogeneic transplant, it must have been given at a U.S. or select international center, and it must have at least one year of follow-up data submitted (or death reported). This means that 100% of allogeneic transplants must have completed forms 2814, 2400, and 2402 at minimum, and 90% of recipients must have 1-year survival data (or death reported).

It is important to recognize that one-year survival does not mean that the one-year form has been completed. This means there is a contact date that has been reported and it is at least 365 days after the transplant of interest. Patients reported on later than 335 days, but less than 365 days, will count towards the completeness of follow-up, but will not be factored into the survival statistics. Forms for subsequent transplants and/or cellular therapy may need to be completed to have sufficient follow-up for the first transplant.

If contact date is the only information the center has, it is permissible to report the most recent contact date using the Survival Tool (SUR). One-year survival is the only endpoint for this analysis. No attempts are made to incorporate other outcomes, such as relapse or disease-free survival.

If no follow-up data is submitted, the patient is included in total volume of HCTs, but not counted as surviving for one year. Patients who are "lost to follow-up (LTF)" earlier than one year will count against completeness.

> ! Data without consent is never used for research purposes but would be used to analyze survival for a center as well as transplant volume metrics.

TCSA Data and Variables

TCSA includes all Center Volume Data Report (CVDR) variables including:

- Transplant type
- Donor type
- Product
- Patient age
- Patient sex
- Patient race/ethnicity
- Disease subtype
- Disease status

Several other TCSA-specific variables are reported including:

- Transplant history
- Donor demographics
- Comorbid conditions (HCT-CI)
- CMV status
- Specific disease characteristics

Centers are provided with a data dictionary which includes all pre-HCT variables used in the analysis.

At 1-year post follow-up the following are reported:

- Survival status
- Most recent date of contact

Last modified: Nov 28, 2023

Posting

Public Posting: HRSA Transplant Outcomes

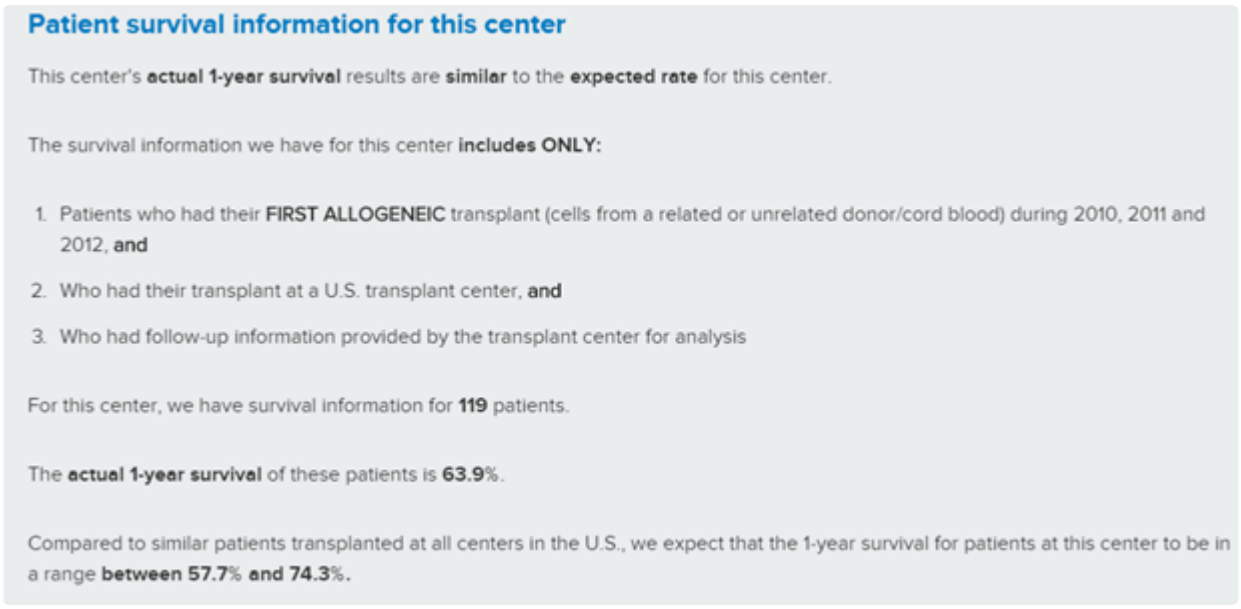
The data posted by Health Resources and Service Administration (HRSA), known as Transplant Outcomes, includes reports of patient outcomes and other information about transplants. Transplants in these reports were performed at transplant centers in the United States. Available reports include:

- US Patient Survival
- US Transplant Data by Center
- Us Transplant Data by Disease

Public reports are text-based single-center descriptions of outcome vs. “expected” outcome. Reports are posted online in January and accessible through HRSA and NMDP.

CIBMTR Portal Posting

Individual centers can see their report on the CIBMTR Portal (Portal > DataOps Dashboard> TCSA). Reports are available from 2016 to the present. An example of a report can be found below:



Patient survival information for this center

This center's **actual 1-year survival** results are **similar** to the **expected rate** for this center.

The survival information we have for this center **includes ONLY:**

1. Patients who had their **FIRST ALLOGENEIC** transplant (cells from a related or unrelated donor/cord blood) during 2010, 2011 and 2012, **and**
2. Who had their transplant at a U.S. transplant center, **and**
3. Who had follow-up information provided by the transplant center for analysis

For this center, we have survival information for **119** patients.

The **actual 1-year survival** of these patients is **63.9%**.

Compared to similar patients transplanted at all centers in the U.S., we expect that the 1-year survival for patients at this center to be in a range **between 57.7% and 74.3%.**

Last modified: Mar 08, 2024

International Information

Beginning in 2025, the program will open to international centers. Participation in this project is **voluntary** for international centers. Complete information for variables used in the multivariate analysis is essential to produce a valid report. If a center has limitations related to national regulations preventing reporting of essential data elements, the center will not be eligible for participation.

For centers to participate, they must meet the same data quality and completeness standards expected of US centers included in the analysis. More specifically, centers must meet the following eligibility requirements:

Eligibility Requirements

1. Maintain a fully executed Data Transmission Agreement (DTA) with CIBMTR acknowledging compliance with human subjects' protection and privacy regulations. Centers will also be requested to complete a short addendum to the DTA, acknowledging the submission of data from patients who may not have signed informed consent for quality improvement purposes of the international center specific analysis.
2. Provide a consecutive transplant (CTA) list to the CIBMTR and resolve any discrepancies in the reported data. Details and instructions are located in the CTA section of the Data Management Guide.
    a. CTA must be completed for **all** years included in the analysis. If centers have not submitted CTA lists for prior years, the lists must be completed as well.
3. Achieve a CPI status of "Good Standing" for 3 consecutive trimesters.
4. Provide complete and accurate data (TED or CRF) on all first allogeneic HCT during the period of inclusion for the annual report. Follow-up data for the allogeneic recipients must be at least 90% complete through one year after transplantation, or the center will be omitted from the analysis. This is to ensure data reported by the center is not unintentionally biased.
    a. If an institution's policies permit, data for unconsented patients may still be provided to ensure appropriate analyses; these patients' data will not be used for any purpose except the center specific analysis.
5. **If there have been allogeneic transplants where forms 2814, 2400, and 2402 have not been completed, it is not possible for the center to participate in the program.**
6. Respond to data queries from the CIBMTR as part of the CIBMTR's routine processes to ensure complete, high-quality data.
7. Provide HLA typing information for allogeneic recipients to facilitate proper assignment of HLA match grade by submitting any requested Form 2005.
8. Use FormsNet to submit both data and data corrections.
9. Agree to participate in the CIBMTR auditing program to ensure completeness and accuracy of the data.

Application Process

Centers who wish to participate in this program should apply for inclusion. The comparison/benchmark group is generated from analysis of data from US centers.

Centers requesting to participate should complete the application linked below.

TCSA Application Link

Following application, CIBMTR will review CPI compliance history and communicate the initial inclusion decision and next steps. Participating centers will receive extra communication from CIBMTR, including data queries and guidance on prioritization. Eligibility will be assessed at the close of each CPI trimester, and centers not able to meet CPI requirements will be removed from the cohort.

Expected outcomes for the international centers may not be well-represented by this comparison group, which may have unintended consequences depending upon the utilization of the report. This could include effects related to the COVID pandemic for recipients of allogeneic HCT. International centers may vary substantially from US centers as CIBMTR does not plan to adjust for pandemic-related effects based on analyses conducted in 2021 and 2022. International centers requesting to participate must acknowledge these limitations as a condition of participation.

Last modified: Jan 18, 2024

Questions & Resources

For any TCSA related questions or concerns submit a CIBMTR Center Support ticket > TCSA.

For more information visit:
Center Specific Survival Analysis Methodology
Center Specific Survival Analysis FAQ

Last modified: Nov 28, 2023

FormsNet3 Process and Tool Instructions

The FormsNet3 Process and Tool Instructions section contains information on the successful completion of the various FormsNet3 tools.

Contents of this section:

2804: CIBMTR Research ID Assignment
FormsNet3 Consent Tool
2814: Indication for CRID Assignment
Recipient Transfer Tool
2008: Infusion Canceled or Delayed
2820: Recipient Contact Information

Section Updates:

Date	Topic	Add/ Remove/ Modify	Description
7/ 26/ 21	2820: Recipient Contact Information	Add	Transferred F2820 Manual from the Forms Instruction Manual to the Data Management Guide
7/ 26/ 21	2814: Indication for CRID Assignment	Add	Transferred F2814 Manual from the Forms Instruction Manual to the Data Management Guide
7/ 26/ 21	2804: CIBMTR Research ID Assignment Form	Add	Transferred 2804 Manual from the Forms Instruction Manual to the Data Management Guide
7/ 23/ 21	Recipient Transfer Tool	Add	Added instructions for using the NEW Recipient Transfer Tool
7/ 16/ 21	2008: Infusion Canceled or Delayed	Modify	General updates (format, links)

Last modified: Mar 08, 2024

2804: CIBMTR Research ID Assignment

The CIBMTR Research ID (CRID) is a unique identifier assigned when an individual is registered with CIBMTR as receiving a cellular therapy, including hematopoietic stem cell transplant (HCT), cellular therapy (CT), treatment for marrow toxic injuries, or certain non-cellular therapies. The CRID Assignment Form 2804 collects the information required to create a lifelong identification number specific to an individual, and certain data fields are used to ensure that the same individual does not inadvertently receive multiple CRID assignments.

> Reporting of all HCTs is important to ensure the continued epidemiological integrity of the CIBMTR outcomes registry. The exception to this is if your center performs but does not report autologous HCTs.

By creating a unique identifier and ensuring participants receive only a single CRID, CIBMTR is better able to carry out its charge as a co-contractor of the C.W. Bill Young Transplantation Program with the responsibility for maintaining the Stem Cell Therapeutic Outcomes Database (SCTOD). The CRID is used to ensure the accuracy of center-specific outcomes by adjusting survival expectation for patients receiving multiple HCTs and allowing for verification of survival status within the National Death Index. Additionally, the CRID can be used to help re-establish contact with individuals who are lost to follow-up and to ensure that all allogeneic HCT recipients in the United States, or who receive a product from the United States, are reported to CIBMTR.

Completeness of the Form 2804 is important for ensuring that individuals are not assigned multiple CRIDs over their lifetime. The system is able to assign an identification number when some identifying fields are missing, but this increases the risk of duplicate reporting. Therefore, the following guidelines have been established:

- **For all individuals**, complete the form as thoroughly as possible.
- In the event of a state law or IRB policy that supersedes federal statute, centers may opt out of providing some of these data.

CIBMTR carefully ensures that identifying information is collected and stored in a secure manner. The electronic systems that generate CRIDs have undergone rigorous certification and authorization from HRSA’s Office of Information Technology and they comply with all United States regulations relevant to security of data in federal databases.

Once the identifying data are entered into FormsNet3 and a CRID is assigned, the identifying data are held within the CIBMTR Research ID Assignment (2804) Form and are not visible in any other locations in FormsNet3. For that reason, it is important that the information is accurate when submitted. The identifying information used to create the CRID will not appear on any subsequent forms or correspondence.

Transplant centers need to take appropriate measures at their site to secure the identifying information used to generate the CRID.

This form only needs to be completed for patients who have not previously been assigned a CIBMTR Research ID (CRID). If a duplicate CRID is inadvertently created or identified, please contact the CIBMTR Center Support to resolve.

Q1-13: Demographics
Q14-18: Recipient Identifiers
Q19-22: Outcomes Registry Reporting

Manual Updates:
The most recent updates to the manual can be found below. Please note, the below updates were to the Forms Instruction Manual. All updates to the 2804 will now be documented in FormsNet3 Instructions.

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

Date	Manual Section	Add/ Remove/ Modify	Description
3/9/ 2021	2804: CIBMTR Research ID Assignment Form	Add	Added the following instructions to question 10: *Indicate the detailed race of the recipient. If this recipient has reported that they are more than one detailed race, check each detailed race indicated in the list below that applies. If the race detail is not documented or is not known, select "unknown."*
3/9/ 2021	2804: CIBMTR Research ID Assignment Form	Remove	Removed the following instructions from question 9: *Indicate the recipient's race. If this recipient has reported that they are more than one race, check each race indicated in the list below that applies. The race groups provided are specific to the United States. ~~If the recipient is White, Southeast Asian, or Pacific Islander, but a more specific Race Detail is not available, report the patient is "Other [White, Southeast Asian, or Pacific Islander respectively].~~*
2/10/ 2020	2804: CIBMTR Research ID Assignment Form	Remove	Removed the warning boxes above questions 8, 9, and 10 indicating that the fields were disabled. These fields were enabled at the time of the Winter 2020 release.
10/ 25/ 19	2804: CIBMTR Research ID Assignment	Modify	Version 5 of the 2804: CIBMTR Research ID Assignment section of the Forms Instructions Manual released. Version 5 corresponds to revision 6 of the Form 2804.

	Form		

Last modified: Mar 08, 2024

Q1-13: Demographics

This form must be completed for all individuals on whom data is submitted to CIBMTR. CIBMTR is a Public Health Authority (PHA) under the Health Insurance Portability and Accountability Act (HIPAA). In this capacity, CIBMTR is authorized to collect individually identifiable health information without consent or authorization of the individual. The PHA designation also allows transplant centers, which fit the definition of covered entities, to disclose these data to CIBMTR under 45 CFR 164.512 (Privacy Rule) without direct consent or authorization of the recipient.

Complete all data fields as thoroughly as possible.

Questions 1-2: First Name, Last Name

Report the individual's complete legal first name in question 1 and complete legal last name in question 2. If you are unable to report the full legal name, reporting initials or partial name can reduce duplicate CRIDs.

Question 3: Date of birth

Reporting the individual's date of birth is **required for all Form 2804** submissions. Report the individual's date of birth and continue with question 4.

Questions 4-6: Location of birth

Report the individual's country of birth in question 4. If applicable, specify city and state of birth in questions 5-6, respectively.

Question 7: Sex

Reporting the individual's sex is **required for all Form 2804** submissions. Report the individual's biological sex and continue with question 8.

Question 8: Ethnicity

Indicate the recipient's ethnicity. The United States Office of Management and Budget (OMB) has defined ethnicity as culturally or geographically determined. The distinction between Hispanic and non-Hispanic is for the purpose of the United States census and reporting of SCTOD data. According to OMB, "Hispanic" is an ethnic designation based upon where someone (his or her ancestors) was raised (e.g., "Latin America"). Hispanic people may be of any race. CIBMTR recognizes regional differences with regard to the interpretation of ethnicity throughout the world.

If the recipient is not a resident of the USA, select "not applicable."

If the recipient declines to provide this information or the recipient's ethnicity is not documented, select "unknown."

For more information regarding ethnicity, see Appendix I .

Question 9: Race (check all that apply)

Indicate the recipient's race. If this recipient has reported that they are more than one race, check each race indicated in the list below that applies. The race groups provided are specific to the United States.

For non-U.S. centers, select "not reported" if the rules / regulations of your country prohibit the collection or reporting of race data (or due to lack of documentation). If race is reported, it may be necessary to consult with the recipient to select the race group(s) with which they most closely identify.

If the recipient declines to provide this information, select "not reported."

If the recipient's race is not documented, select "unknown."

For more information regarding race, see Appendix I .

Question 10: Race detail (check all that apply)

Indicate the detailed race of the recipient. If this recipient has reported that they are more than one detailed race, check each detailed race indicated in the list below that applies.

If the race detail is not documented or is not known, select "unknown."

For more information regarding race, see Appendix I .

Question 11: Social security number

Report the individual's social security number. If the individual's social security number is unknown or the individual is not a United States citizen, leave this data field blank.

Question 12: Cadastro de Pessoas Físicas (CPF) (Brazilian citizens only)

If the individual is a citizen of Brazil, report their 11-digit Cadastro de Pessoas Físicas (CPF). If the individual's CPF is unknown or the individual is not a Brazilian citizen, leave this data field blank.

Question 13: Patient's mother's maiden name (optional for non-U.S. centers)

Report the individual's mother's maiden name. This field may be left blank if the individual's mother's maiden name is unknown, the HCT recipient declined to release mother's maiden name, or your transplant center is located outside the United States.

Section Updates:

Question Number	Date of Change	Add/ Remove/	Description	Reasoning (If

		Modify		applicable)
Q9	3/9/ 2021	Remove	The following instructions were removed: _Indicate the recipient's race. If this recipient has reported that they are more than one race, check each race indicated in the list below that applies. The race groups provided are specific to the United States. ~~If the recipient is White, Southeast Asian, or Pacific Islander, but a more specific Race Detail is not available, report the patient is "Other [White, Southeast Asian, or Pacific Islander respectively].~~	Removed incorrect instructions
Q10	3/9/ 2021	Add	The following instructions were added: *Indicate the detailed race of the recipient. If this recipient has reported that they are more than one detailed race, check each detailed race indicated in the list below that applies. If the race detail is not documented or is not known, select "unknown."*	Added for clarification

Last modified: Mar 06, 2024

Q14-18: Recipient Identifiers

Complete all additional individual identifiers, as applicable.

Question 14: Recipient NMDP ID

Report the seven-digit recipient ID (RID) assigned by NMDP. If the individual has never been assigned an NMDP RID, leave this data field blank. **For RELATED donors, do not report the repository sample ID in this field. For UNRELATED donors, the RID is the sample ID.**

> ! If an NMDP RID is assigned after the initial submission of the CRID Assignment (2804) Form or it was missed at initial entry, please edit the CRID Assignment page to add this data.

Question 15: Recipient IUBMID

Report the six-digit IUBMID previously assigned to the individual. The IUBMID is the individual identifier previously assigned by the International Bone Marrow Transplant Registry (IBMTR), which was the precursor to the current CRID system. If an IUBMID was previously assigned, complete and continue with question 16; if no IUBMID was previously assigned, continue with question 17.

Question 16: Team ID

Report the four-digit team ID; this data field is required if question 15 is answered. The Team ID is a precursor to the current CIBMTR center number (CCN) system, used by the IBMTR. If the individual has a previously assigned IUBMID, there should be an associated Team ID.

Question 17: Institution-specific subject ID

Report the subject identifier used for any center-specific outcomes registration, transplant study protocol(s), or other unique subject identifier used for internal institutional tracking. Do not report the recipient medical record number (MRN). If the individual does not have an institution-specific subject ID, leave this data field blank.

Question 18: Transplant Registry Unified Management Program (TRUMP ID) (Japanese centers only)

If the individual is a citizen of Japan, report their 12-digit Transplant Registry Unified Management Program (TRUMP ID). If the individual's TRUMP ID is unknown or the individual is not a Japanese citizen, leave this data field blank.

Section Updates:

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

.	.	.	.	.

Last modified: Mar 05, 2024

Q19-22: Outcomes Registry Reporting

Indicate and provide identifiers for all other outcomes registries the individual's data are being reported to. If the individual's data are not being reported to any other outcomes registries, continue with the signature section of the form. If the individual's data are being reported to multiple additional outcomes registries, create a new instance for each additional outcomes registry.

Question 19: Specify outcomes registry

Indicate all outcomes registries the individual's data are being reported to; if the individual is participating in more than one registry, add a new instance for each. As a reference, the registry acronyms and instructions for proceeding with the remainder of the form are detailed below:

- EBMT: European Society for Blood and Marrow Transplantation, continue with question 20.
- USIDNET: United States Immunodeficiency Network, continue with question 22.
- APBMT: Asia-Pacific Blood and Marrow Transplantation Group, continue with question 22.
- CBMTG: Canadian Blood and Marrow Transplant Group, continue with the signature section of the form or create an additional instance of questions 19-22 to report additional outcomes registries.
- EMBMT: Eastern Mediterranean Blood and Marrow Transplantation Group, continue with question 22.
- The National MDS Study: The National MDS Study refers to an NHLBI-sponsored study looking at the natural history of MDS; this is not the same as 10-CMSMDS-1, the HCT for MDS Medicare Study. If the individual's data are being reported to the National MDS Study, continue with question 22.
- Other outcomes registry, continue with question 21

Question 20: EBMT CIC

For individual with data reported to EBMT, report the four- to five-digit Centre Identification Code (CIC) identifying the transplant center. Continue with question 22 and specify the EBMT subject identifier.

Question 21: Specify other outcomes registry

Report the other outcomes registry individual data are being reported to. Use the complete registry name, rather than acronyms or abbreviations. Continue with question 22.

Question 22: Outcomes registry subject ID

Report the registry subject ID for the applicable registry; if multiple instances of questions 19-22 are being reported, ensure the registry subject ID corresponds with the registry indicated in the same instance of question 19.

Section Updates:

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

Last modified: Feb 20, 2023

FormsNet3 Consent Tool

Recipient consent for the CIBMTR research database (ClinicalTrials.gov Identifier: NCT01166009) is collected in the Consent Tool within FormsNet3. The Consent Tool allows recipient consent status and contact information to be collected as soon as possible after the CRID is created. It also enables the CIBMTR Survey Research Group (SRG) to approach patients prior to their infusion to conduct patient-reported outcomes (PRO) surveys.

> **Consent Status and Baseline Forms**
> If a consent status has not yet been reported for a recipient, the edit form icon for the Pre-Transplant Essential Data (2400), Pre-Transplant Essential Data Disease Classification (2402) and Pre-Cellular Therapy Essential Data (4000) forms will appear **disabled** (see Figure 1 below). When the user hovers over the icon, it will display that consent has not yet been reported for that recipient (see Figure 2 below). The user should go to the Consent Tool (see Navigation to the Consent Tool) and document the recipient's consent status in order to enable the edit icon and allow for completion of the form.

Figure 1. Disabled Edit Form Icon

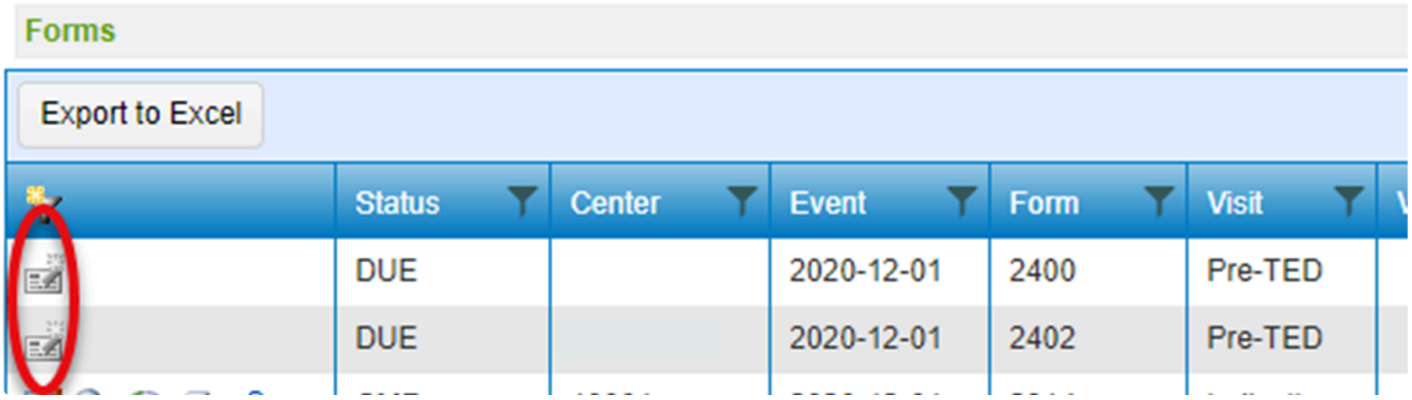
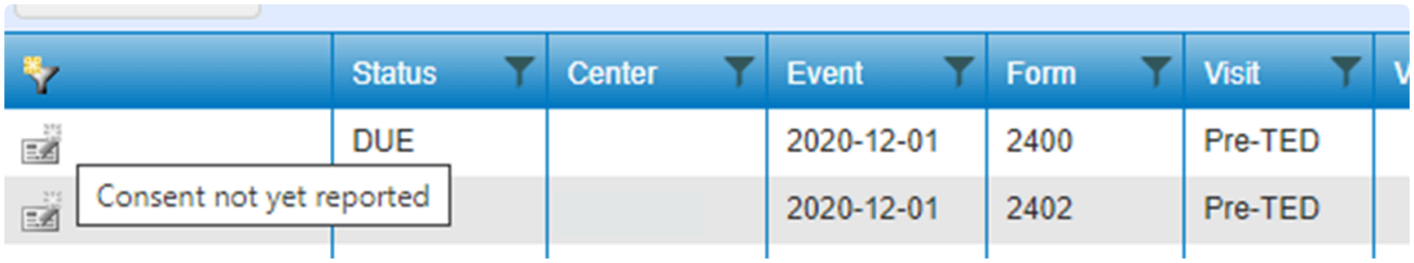


Figure 2. Hovered Text, Consent Not Yet Reported



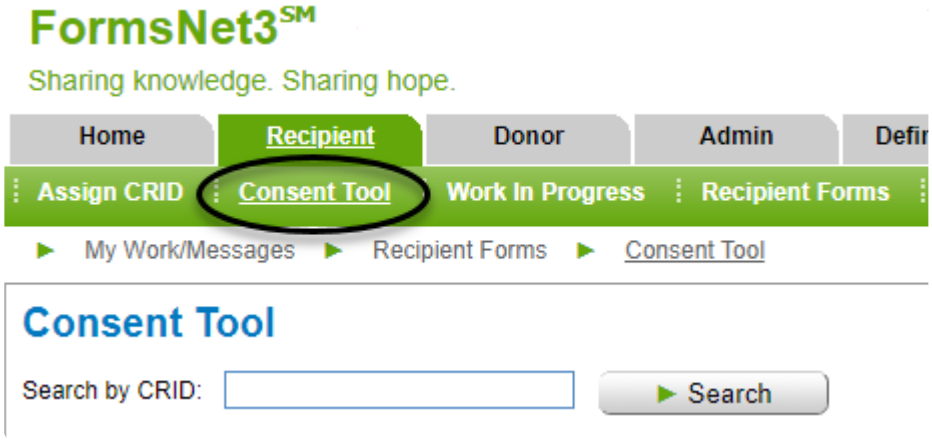
Links to Sections of the Consent Tool Instructions:

Navigation to the Consent Tool
Consent Tool Grids
Adding and Updating Consent
Q1-10: Consent Information

Last modified: Mar 08, 2024

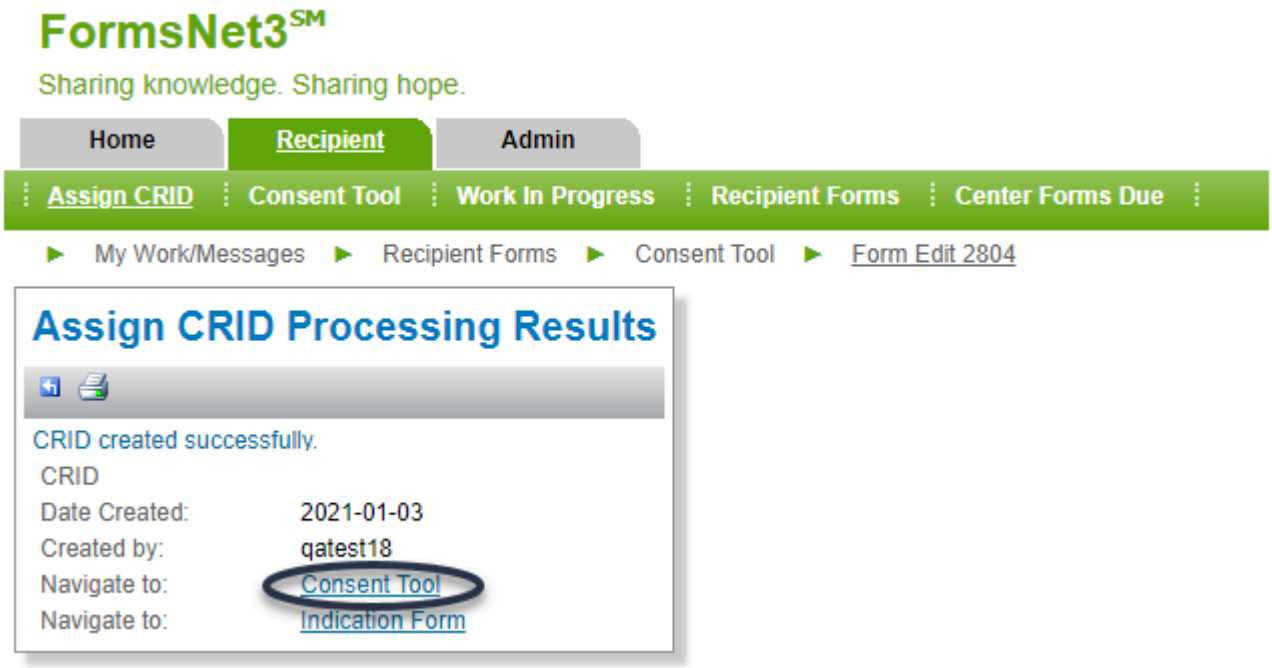
Navigation to the Consent Tool

The Consent Tool can be found by selecting the recipient tab and selecting consent tool. Then, search for the Consent Tool by entering the CRID in the search box.

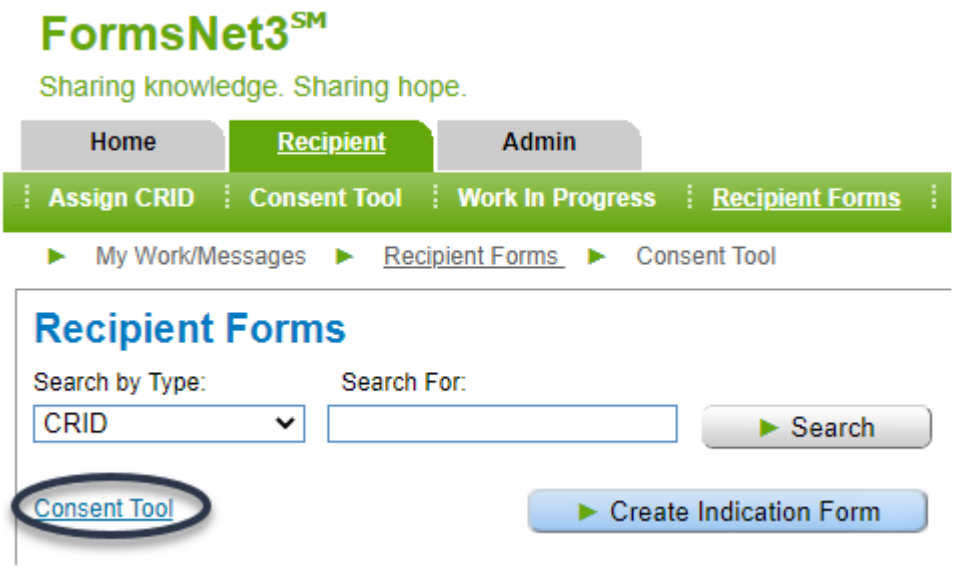


There are two additional ways to navigate to the Consent Tool (listed below):

1. The Consent Tool can be accessed by completing the CRID Assignment (2804)



2. Additionally, the Consent Tool can be accessed by using the Consent Tool hyperlink when a recipient is pulled up under the recipient forms page

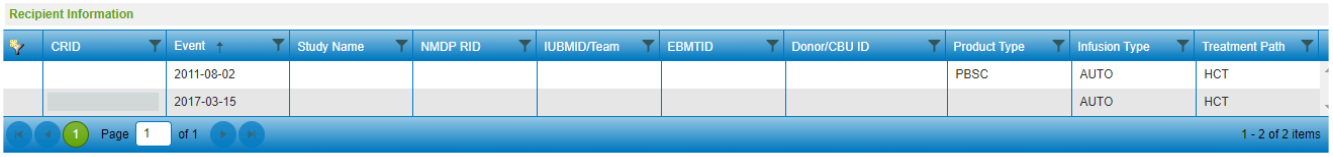


Last modified: Nov 20, 2023

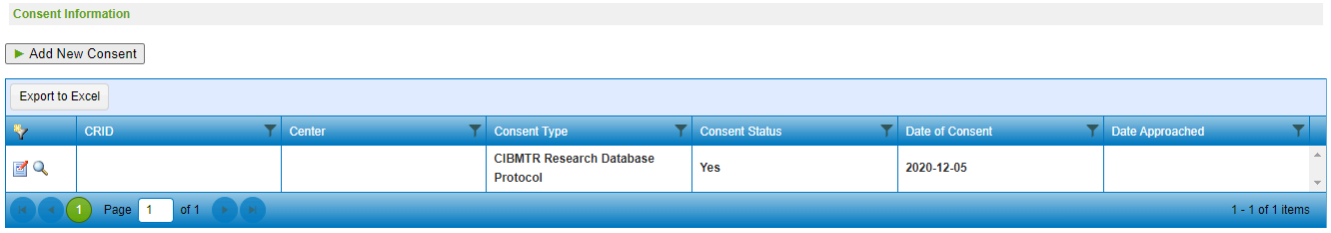
Consent Tool Grids

There are three grids within the Consent Tool:

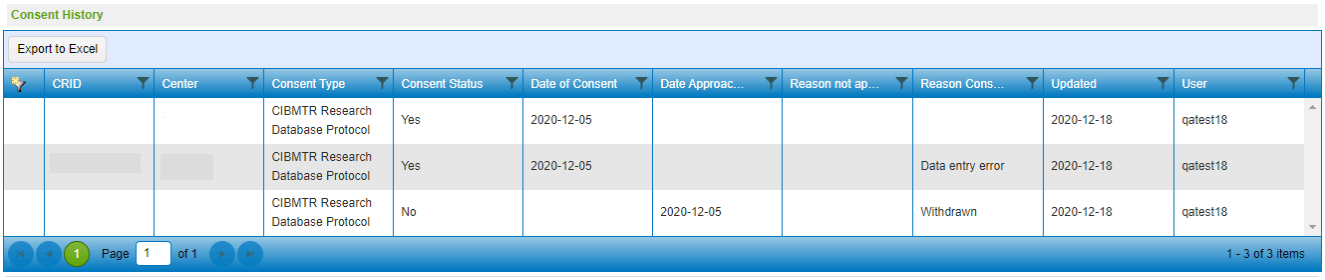
1. **The Recipient Information Grid**: This grid is identical to the 'Recipient Information' grid found under the recipient forms. The only difference is that unscheduled forms cannot be generated from the Consent Tool, they can only be created within the recipient forms.



2. **The Consent Information Grid**: This grid will display the consent information for the recipient. If a recipient has been approached for consent multiple times, there will be a row for each consent. The row with the recipient's current consent will appear in bold.



3. **The Consent History Grid**: This grid is an audit trail of any changes that have been made to the recipient's consent, including any changes made by CIBMTR staff, such as locking a consent record for audit. Each time a change to a consent record is made, a new row will appear in the consent history grid.

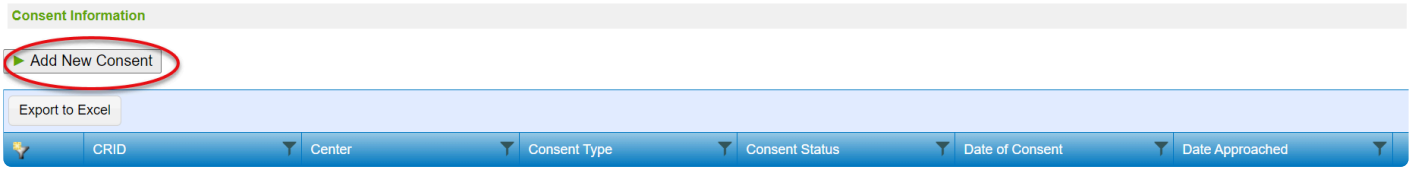


Last modified: Nov 20, 2023

Adding and Updating Consent

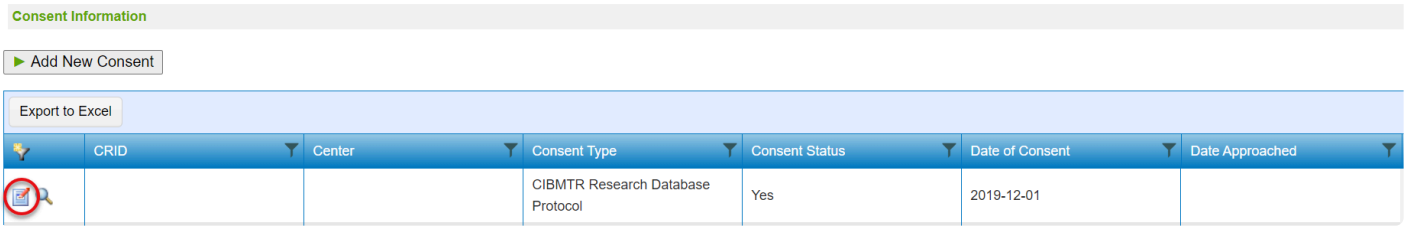
Adding Consent:

A new consent row should be added each time the recipient is approached for consent to the CIBMTR research database. To add a new consent, select the 'Add New Consent' button within the Consent Information grid. When this button is selected, a pop-up window will appear with the consent questions. Once all required questions are answered and submitted, a row will appear within the Consent Information grid.



Updating Consent:

If consent needs to be updated after it has been reported, the edit icon within the consent information grid should be selected.



When this icon is clicked, the consent questions pop-up window will appear with all previously entered data. The user will not be allowed to submit if no changes are made to the data. If a change is made, a change reason will be required before the data can be submitted. After the changes are submitted, the data will be updated and a row will be added to the Consent History grid.

Last modified: Nov 20, 2023

Q1-10: Consent Information

Consent Information

CIBMTR Center Number: **12001** CIBMTR Research ID:

Consent for Research Database for Hematopoietic Cell Transplantation and Cellular Therapies (NCT01166009)

1. Consent status for submitting research data to CIBMTR
   - ○ Yes *(provided permission and signed)*
   - ○ No *(declined, withdrew, or no response)*
   - ○ Not approached
   - ○ Reconsent Pending

2. Consented to be contacted for future research
   - ○ Yes *(provided permission and signed)*
   - ○ No *(declined, withdrew, or no response)*
   - ○ Not applicable *(institution not currently participating or local IRB does not allow collection of data)*

3. Date consent signed:

4. Date approached:

5. Reason not approached

6. Indicate language preference

7. Specify other language preference:

8. Specify other reason not approached:

9. Reason consent status changed
   - ○ CIBMTR initiated change
   - ○ Consent not appropriately obtained
   - ○ Data entry error
   - ○ Recipient transfer
   - ○ Site initiated reconsent *(e.g., age of majority, different infusion type, center required to re-consent)*
   - ○ Withdrawn *(recipient initiated change in response)*
   - ○ Other

10. Specify other:

▶ Submit ▶ Cancel

Question 1: Consent status for submitting research data to CIBMTR

> ! To be compliant with Federal Regulation for human research protection, centers must obtain IRB-approved informed consent from recipients and donors (if applicable, for the related donor sample repository) to allow data submitted to the CIBMTR to be used for observational research. Informed consent must also be obtained from the recipients and donors prior to submitting blood samples to the Research Sample Repository. The NMDP / CIBMTR has written protocol and informed consent documents for the Observational Database and Research Sample Repository. All centers must have local IRB approval for the Observational Database protocol. All centers that are NMDP member centers must also have local IRB approval for the Research Sample Repository protocol. With the exception of some selected sites (participating in the related sample repository), centers performing only related donor transplants and / or autologous transplants will not be submitting research samples and do not need to obtain local IRB approval for the repository protocol. The NMDP IRB has approved these protocol and consent forms, and the documents are provided to participating sites to include with their local IRB submissions.
> International Centers must obtain consent of each patient participating in the Observational Database in a manner consistent with the laws and regulations of that country.
> Under federal legislation, U.S. centers are required to submit outcomes data on all allogeneic transplants, related and unrelated. Data submitted without informed consent from the recipient should be reported on the TED Forms and will only be used for federally required research such as the center-specific outcomes analysis.

When a recipient consents to participate in the Observational Database, their data are contained in the CIBMTR's Observational Database and used for research. The database includes recipient baseline and outcome data for related and unrelated allogeneic transplants from any cell source, and for autologous transplants. Data are also collected on unrelated donors and their donation experiences.

The primary purpose of the Observational Database is to have a comprehensive source of data that can be used to study hematopoietic cellular transplantation. Studies using these data include:

- How well recipients recover from their transplants
- How recovery after transplantation can be improved
- The long-term outcomes after transplantation
- How access to transplantation for different groups of recipients can be improved
- How well donors recover from collection procedures
- The application and success of transplantation in the management of marrow toxic injuries

Indicate if the recipient has signed an IRB-approved consent form to participate in the Observational Database. If **Yes (provided permission and signed)**, continue with question 2. If **No (declined, withdrew, or no response)**, continue with question 4. If **Not approached**, continue with question 5. If **Reconsent Pending**, continue with question 3.

> ✻ **When to use the "Not approached" option for the Research Database Consent**
> CIBMTR expects all transplant centers to approach all patients for the Research Database

consent. The **Not approached** option should only be used in the rare event when the physician feels it would be in the best interest of the patient not to be consented.

Note that if a center is required to approach a recipient for consent after the initial consent, the **Not approached** option will be disabled. If it is necessary that a subsequent consent be reported as **Not approached** please submit a ticket to CIBMTR center support, and CIBMTR staff will review the specific details for the recipient and ensure that the correct consent status is added to FormsNet3^{SM} if necessary.

Question 2: Consented to be contacted for future research

Indicate **Yes (provided permission and signed)**, **No (declined, withdrew, or no response)**, or **Not approached (Institution not currently participating or local IRB does not allow collection of data)**, if the recipient has given permission to be directly contacted by the NMDP/CIBMTR for future research as documented on the research database consent form.

If **Yes (provided permission and signed)** is selected, the Recipient Contact Information (2820) form will also need to be completed.

Below is an example of this permission found in the NMDP/CIBMTR Research Database for Hematopoietic Cell Transplantation and Cellular Therapy Consent Form (Version 10.0).

VIII. PERMISSION TO CONTACT FOR FUTURE CIBMTR RESEARCH STUDIES
Do you agree to give CIBMTR permission to contact you in the future to tell you about research studies for which you are eligible? These studies are different from the studies that use your medical data. These studies would involve you directly, for example, asking you to complete a survey. You may decide if you want to participate in a specific study when you are contacted. By checking the “AGREE” box below, you are only agreeing that CIBMTR can contact you to tell you about the study.
Due to the need to follow up with you after your transplant, please tell your transplant center if your contact information changes. If the contact information on file is no longer valid, it might be necessary to use an internet-based search service to find you. By agreeing to be contacted for future studies, you authorize CIBMTR to use such a service to search public and non-public information only for the purpose of trying to locate you. ☐ I AGREE to allow CIBMTR to contact me about future studies. ☐ I DO NOT want CIBMTR to contact me about future studies.

Question 3: Date consent signed

Report the date the CIBMTR research database consent form was signed by the recipient. Do not report the date that the witness or health care professional signed the consent form.

Question 4: Date approached

If **No (declined, withdrew, or no response)**, was reported in question 1, report the date the recipient was originally approached with the CIBMTR research database consent form.

Question 5: Reason not approached

If **Not approached**, was reported in question 1, report the reason and/or details as to why the recipient could not be approached with the CIBMTR research database consent form. Choose from the options in the drop-down box:

- **Consent form pending IRB approval / renewal**: At the time of consent for the Research Database, a valid consent form is not available at the center.
- **Consent form unavailable in patient's language**: At the time of consent for the Research Database, a consent form / short form is not available in the recipient's language and an interpreter was not available.
- **Patient died before consent obtained**: The recipient passed away prior to consenting to the Research Database.
- **Patient incarcerated**: At the time of consent for the Research Database, the recipient is incarcerated.
- **Patient too ill**: At the time of consent for the Research Database, the recipient is too ill to consent.
- **Other reason**: Select this option if the recipient is not approached for the Research Database for any other reason not listed above.

> ! It has been determined that a recipient lacking mental capacity to consent to the Research Database is not considered a valid option. Adult recipients with diminished capacity should have an assigned representative who works with the recipient on the consent process. CIBMTR will query the **Other reason** option if the reason is reported as 'lacking mental capacity' in the the specify other reason data field.

Question 6-7: Indicate language preference

If **consent form unavailable in patient's language** was reported in question 5, select the recipient's language preference from the drop-down menu. If the language is not present in the list, select 'other' and then specify other language preference in question 7.

Question 8: Specify other reason not approached

If **Not approached** was reported in question 1 and **other reason** was reported in question 5, report the other reason not approached.

Question 9-10: Reason consent status changed

If a change is made to the consent status in an existing consent row or an additional consent row is added, report the reason that the consent status changed in question 9. If the reason for changing consent is not listed, select **Other**, and specify the reason in question 10.

Question 9 will always be required when editing a consent row or adding subsequent consent after the initial consent.

Last modified: Mar 06, 2024

2814: Indication for CRID Assignment

The Indication for CRID Assignment (Form 2814) collects information to initiate CIBMTR reporting on 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). Subsequent interventions of the same indication – hematopoietic cellular transplant, non-transplant cellular therapy, marrow toxic injury, and non-cellular therapy – do not require an additional Form 2814; however, a subsequent, new indication may require completion of another Form 2814. Examples of an indication change that would require completion of another Form 2814 include:

- Transplant recipient becomes a marrow toxic injury RITN patient
- Cellular therapy recipient becomes a marrow toxic injury RITN patient
- Marrow toxic injury RITN patient receives cellular therapy or transplant
- Non-cellular therapy patient with any indication change

! Effective August 2021: Centers should now create an on demand indication form (2814) 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.

Q1: Indication
Q2-5: Hematopoietic Cellular Transplant
Q6: Cellular Therapy
Q7: Marrow Toxic Injury
Q8-10: Non-Cellular Therapy

Manual Updates:
The most recent updates to the manual can be found below. Please note, the below updates were to the Forms Instruction Manual. All updates to the 2804 will now be documented in FormsNet3 Instructions.

Date	Manual Section	Add/ Remove/ Modify	Description
11/1/ 2021	2814: Indication for CRID Assignment	Update	Updated instructions to coincide with the Fall 2021 Release
8/3/ 2020	2814: Indication for CRID	Add	Provided instructions on generating an on demand F2814 Centers should now create an on demand indication form (2814) to report a subsequent infusion when there are NO follow up forms (F2100, F2450 or F4100) available to report

	Assignment		this information.
7/31/2020	2814: Indication for CRID Assignment	Add	Provided instructions in question 1 on which option to select if the infusion is gene therapy: If the infusion type is gene therapy, select “Hematopoietic cellular transplant.”
7/31/2020	2814: Indication for CRID Assignment	Add	Added the blue information box above question 1 notifying that if the infusion is gene therapy, the recipient will be placed on the HCT CRF track: Gene Therapy: If the infusion type is a gene therapy, the recipient will be placed on the HCT CRF track.
4/6/2020	2814: Indication for CRID Assignment	Add	Added sentence to question 5 providing guidance on when to select ‘no’.
1/29/2020	2814: Indication for CRID Assignment	Add	Added the following instruction for how to report the date of transplant for intrauterine transplants: **Intrauterine Transplants** For intrauterine transplants, report the date of birth as the date of transplant to avoid errors from occurring in FormsNet3^{SM}.
4/26/19	2814: Indication for CRID Assignment	Modify	Version 3 of the 2814: Indication for CRID Assignment section of the Forms Instructions Manual released. Version 3 corresponds to revision 3 of the Form 2814.

Last modified: Nov 01, 2021

Q1-2: Indication

Gene Therapy: If the infusion type is a gene therapy, the recipient will be placed on the HCT CRF track.

Question 1: What is the indication for CIBMTR Research ID (CRID) assignment?

Indicate whether the individual will be receiving hematopoietic cellular transplant (HCT), non-transplant cellular therapy, marrow toxic injury therapy, or non-cellular therapy.

Hematopoietic cellular transplant (HCT) is a transplant of bone marrow, peripheral blood stem cells, umbilical cord blood, or other cellular product containing CD34+ cells, also known as hematopoietic progenitor cells. If the infusion type is gene therapy, select “Hematopoietic cellular transplant.”

Non-transplant cellular therapies may be derived from a hematopoietic or non-hematopoietic tissue source and can be utilized for a broad range of indications, including autoimmune, cardiovascular, peripheral vascular, and neurologic diseases; these are often referred to as cellular therapies for regenerative medicine (CTRM).

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-transplant radiation therapy or for accidental, isolated exposures to radiation.

If you are 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 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.

If the reported indication is:

- Hematopoietic cellular transplant, complete questions 2-3.
- Non-transplant cellular therapy, complete question 2
- Marrow toxic injury, complete question 2
- Non-cellular therapy, complete questions 4-6

Question 2: Event Date (or planned event date)

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 FormsNet3, as this data field is used to populate the date of infusion on the patient’s other data collection forms. If the recipient has a previous transplant already reported to CIBMTR, review previous

transplant follow-up forms and ensure the subsequent transplant is correctly reported on the follow-up forms, which will prompt appropriate follow-up forms to come due; a new or additional Form 2814 is not required.

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

Last modified: Mar 08, 2024

Q3: Hematopoietic Cellular Transplant (HCT)

Questions 3: Is the product genetically modified? For multiple products, report "Yes" if ANY of the products are genetically modified.

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
- Transduction: A process by which foreign DNA is introduced into a cell by a virus or viral vector These techniques alter its gene expression through the insertion of different genes or editing of genes. If more than one product is being infused, indicate if any of the products are genetically modified.

Last modified: Nov 01, 2021

Q4-6: Non-Cellular Therapy

Question 4: Specify the disease / study for which non-cellular therapy was given

Indicate if the individual is participating in the BMT CTN 17-02 study or receiving non-cellular therapy as treatment for MDS, multiple myeloma, myelofibrosis, sickle cell disease, or another disease. If the research participant is enrolled in a study or receiving therapy for a disease that is not captured in any of the above categories, specify in question 5

Question 5: Specify other disease / study

If you have indicated in question 4 ‘other disease/study’ please enter the disease or study patient has or will be given therapy for.

Question 6: Enrollment date (date of consent)

Report the date of consent for enrollment on non-cellular therapy protocol. Continue with the signature section of the form.

Signature Lines:

The FormsNet3SM application will automatically populate the signature data fields, including name and email address of person completing the form and date upon submission of the form.

Last modified: Nov 01, 2021

2820: Recipient Contact Information

The Recipient Contact Information Form 2820 collects contact information on recipients who have agreed to be contacted directly by CIBMTR for the purpose of inviting them to participate in research activities. If the recipient is a minor, contact information for the parent or legal guardian will be collected. Contact information for an alternate contact is collected if participation in a specific study requires it.

The Form 2820 becomes due in one of two ways.

1. Consent Tool, “Did the recipient give permission to be directly contacted by CIBMTR for future research”, is answered “yes.”
2. The patient is enrolled in a clinical trial (e.g. BMT CTN or RCI BMT) that includes a patient reported outcome (PRO) component. When the patient is enrolled the enrollment form triggers Form 2820 to become due.

Only one Form 2820 will become due for any given patient.

The contact information provided in Form 2820 will allow CIBMTR to contact recipients for the purpose of inviting them to participate in patient reported outcomes (PRO) data collection for the CIBMTR Research Database or other BMT CTN or RCI BMT research studies. To maintain privacy and keep contact information protected, the data provided in Form 2820 is stored in a separate area of the CIBMTR database. Access to these data is highly restricted and governed by CIBMTR policy.

Links to Sections of the Form:
Q1-5: Indication
Q6-21: Recipient Contact Information
Q22-38: Parent / Legal Guardian Contact Information
Q39-58: Alternate Contact Information

Manual Updates
The most recent updates to the manual can be found below. Please note, the below updates were to the Forms Instruction Manual. All updates to the 2804 will now be documented in FormsNet3 Instructions.

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
1/21/ 2021	2820: Recipient Contact Information	Modify	Instruction text updated: *This question should be answered ‘yes’ if the recipient has given permission to be directly contacted by CIBMTR for research as indicated on the ~~Pre-TED F2400~~ consent tool. This will allow CIBMTR to contact the patient and invite them to participate in PRO data collection or other*

			research studies.
8/2/18	2820: Recipient Contact Information	Modify	Version 2 of the 2820: Recipient Contact Information section of the Forms Instructions Manual released. Version 2 corresponds to revision 2 of the Form 2820.

Last modified: Mar 06, 2024

Q1-5: Indication

Question 1: Did this Form 2820 become due because the recipient agreed to direct contact by CIBMTR for research studies as indicated on Form 2400?

This question should be answered 'yes' if the recipient has given permission to be directly contacted by CIBMTR for research as indicated on the consent tool. This will allow CIBMTR to contact the patient and invite them to participate in PRO data collection or other research studies.

Question 2: Did this Form 2820 become due because the recipient agreed to participation in a specific study (e.g. BMT CTN)?

This question indicates if contact information is being provided for a patient who is enrolled in a specific clinical trial instead of, or in addition to, contact for future research.

Question 3: Indicate for which of the following studies the contact form will be used (check all that apply)

Indicate the specific study or studies the recipient is enrolled in. Currently this includes BMT CTN 1702 (Donor Source/CTRL-ALT-D), 1703/1801 (aGVHD prophylaxis/Mi-Immune) and 1704 (CHARM) studies, all of which include Patient Reported Outcome data collection by CIBMTR. If the recipient is co-enrolled in multiple studies, then copy and paste questions 3 and 4 to indicate more than one study.

Question 4: Study enrollment date:

Enter the date the recipient enrolled in the study or studies listed in question 3. If the recipient is co-enrolled in multiple BMT CTN studies then copy and paste questions 3 and 4 to report each date of enrollment.

Question 5: Is the recipient an adult (18 years of age or older) or emancipated minor?

Select 'yes' to question 5 if:

1. The recipient is a legal adult.
2. The recipient is an emancipated minor.

If the recipient is not a legal adult or emancipated minor then the parent / legal guardian section of this form (Q22- Q38) will be enabled and must be completed.

Select 'no' to question 5 if the recipient is over the age of 18 but does not show adequate capacity to consent for themselves. The parent / legal guardian section of this form (Q22 – Q38) will be enabled to capture contact information for the surrogate providing consent for the recipient.

Section Updates:

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

		Modify		
Q1	1/21/ 2021	Modify	Instruction text updated: *This question should be answered 'yes' if the recipient has given permission to be directly contacted by CIBMTR for research as indicated on the ~~Pre-TED F2400~~ consent tool. This will allow CIBMTR to contact the patient and invite them to participate in PRO data collection or other research studies.*	Instruction updated to reflect the changes made to the consent questions on the Pre-TED 2400 with the Winter 2021 release

Last modified: Jul 28, 2021

Q6–21: Recipient Contact Information

Question 6 – 7: First Name, Last Name

Report the recipient's complete legal first name in question 1 and complete legal last name in question 2.

Question 8: Indicate language preference:

Select the recipient's primary language preference. If the recipient's language is not listed as an option, value select 'other' and proceed to question 9.

Question 9: Specify other language preference:

Indicate the recipient's language preference in the open text field provided.

Question 10: Does this contact have a U.S. mailing address?

Indicate if the recipient has a street address located in the U.S. (only inclusive of the 50 states and Washington D.C.). If the recipient resides in a U.S. territory including: Puerto Rico, Northern Mariana Island, United States Virgin Islands, American Samoa, or the United States minor outlying islands, then answer 'no' and complete the form using the international address question format in question 12.

Question 11: Street, City, State, Zip Code:

Indicate the recipient's current U.S. home address.

Question 12: Country, International address:

Indicate the recipient's current U.S. territory or international home address.

Question 13: Specify time zone (of mailing address)

Indicate the time zone of the recipient's mailing address based on Universal Coordinated Time (UTC). If the recipient has a U.S. mailing address within the Samoa or Chamorro time zone or has an international mailing address, then select 'other' and report time zone in question 14.

Question 14: Specify other time zone:

Only answer this question if the time zone for the recipient's mailing address was not listed above. Indicate time zone in the open text field.

Questions 15 – 18: Phone number(s) – Home / Work / Cell / Other:

For questions 15 – 18, provide phone numbers at which the recipient can be contacted for each type of phone number available. A phone number does not need to be provided for each phone number type however; at least one phone number is required.

Indicate area code when reporting U.S. phone numbers. Indicate country code for all international phone numbers.

Question 19: Specify other phone number type:

If the recipient's preferred phone number type is not a home / work / or cell phone number, indicate the other phone number type here. Examples may include: spouse / significant other's phone number, nursing home phone number, etc.

Questions 20 – 21: E-mail address(es) – primary / secondary

Indicate the recipient's primary and secondary e-mail address (if applicable). When using the open text field be sure to provide a complete e-mail address including: user e-mail prefix, "@" symbol, and e-mail domain (ex: JohnDoe@comcast.net, JaneDoe@gmail.com).

Section Updates:

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

Last modified: Jul 28, 2021

Q22–38: Parent / Legal Guardian Contact Information

Question 22 – 23: First Name, Last Name

Report the complete legal first name of the recipient's parent / legal guardian in question 22 and complete legal last name in question 23.

Question 24: Indicate language preference

Select the parent / legal guardian's primary language. If the parent / legal guardian's language is not listed as an option value select 'other' and proceed to question 25.

Question 25: Specify language preference

Indicate the parent / legal guardian's language preference in the open text field provided.

Question 26: Does the parent / legal guardian have the same contact information as the recipient? (completed above)

If the parent / legal guardian resides at the same street address as the recipient then select 'yes' to question 26.

Question 27: Does the contact have a U.S. mailing address?

Indicate if the parent / legal guardian has a street address located in the U.S. (only inclusive of the 50 states and Washington D.C.). If the parent / legal guardian resides in a U.S. territory including: Puerto Rico, Northern Mariana Island, United States Virgin Islands, American Samoa, or the United States minor outlying islands, then answer 'no' and complete the form using the international address question format in question 29.

Question 28: Street, City, State, Zip code

Indicate the parent / legal guardian's current U.S. home address.

Question 29: Country, International address

Indicate the parent / legal guardian's current international home address.

Question 30: Specify time zone (of mailing address)

Indicate the time zone of the parent / legal guardian's mailing address as based off of Universal Coordinated Time (UTC). If the parent / legal guardian has a U.S. mailing address within the Samoa or Chamorro time zone or has an international mailing address, then select 'other' and report time zone in question 31.

Question 31: Specify other time zone:

Only answer this question if the time zone for the parent / legal guardian's mailing address was not listed above. Indicate time zone in the open text field.

Question 32 – 35: Phone number(s) – Home / Work / Cell / Other:

For questions 32 – 35, provide phone numbers at which the parent / legal guardian can be contacted for each type of phone number available. A phone number does not need to be provided for each phone number type however; at least one phone number is required.

Indicate area code when reporting U.S. phone numbers. Indicate country code for all international phone numbers.

Question 36: Specify other phone number type:

If the parent / legal guardian's preferred phone number type is not a home / work / or cell phone number, indicate the other phone number type here.

Questions 37 – 38: E-mail address(es) – primary / secondary

Indicate the parent / legal guardian's primary and secondary e-mail address (if applicable When using the open text field be sure to provide a complete e-mail address including: user e-mail prefix, "@" symbol, and e-mail domain (ex: JohnDoe@comcast.net, JaneDoe@gmail.com)

Section Updates:

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

Last modified: Jul 28, 2021

Q39–58: Alternate Contact Information

This section will enable when a specific study requires an alternate contact, such as a caregiver, who is not the recipient's parent / guardian. This section is currently disabled as it is not required for the following studies: BMT CTN 1702, BMT CTN 1703, or BMT CTN 1704.

Question 39: Does the study require additional participant's contact details?

This question is currently disabled. This question will indicate if the study in which the recipient is enrolled requires contact information for additional individuals besides recipient and parent / guardian.

Question 40: Relationship to recipient

Indicate the alternate contact's relationship to the recipient. If the relationship is not listed as an option value, select 'other' and proceed to question 41.

Question 41: Specify other relationship:

Indicate the alternate contact's relationship to the recipient in the open text field provided.

Question 42 – 43: First Name, Last Name

Report the alternate contact's complete legal first name in question 42 and complete legal last name in question 43.

Question 44: Indicate language preference:

Select the alternate contact's primary language. If the alternate contact's language is not listed as an option value select 'other' and proceed to question 45.

Question 45: Specify other language preference:

Indicate the alternate contact's language preference in the open text field provided.

Question 46: Does the alternate contact have the same contact information as the recipient? (completed above)

If the alternate contact resides at the same street address as the recipient then select 'yes' to question 46.

Question 47: Does this contact have a U.S. mailing address?

Indicate if the alternate contact has a street address located in the U.S. (only inclusive of the 50 states and Washington D.C.). If the alternate contact resides in a U.S. territory including: Puerto Rico, Northern Mariana Island, United States Virgin Islands, American Samoa, or the United States minor outlying islands, then answer 'no' and complete the form using the international address question format in question 49.

Question 48: Street, City, State, Zip code

Indicate the alternate contact's current U.S. home address.

Question 49: Country, International address

Indicate the alternate contact's current international home address.

Question 50: Specify time zone (of mailing address)

Indicate the time zone of the alternate contact's mailing address as based off of Universal Coordinated Time (UTC). If the alternate contact has a U.S. mailing address within the Samoa or Chamorro time zone or has an international mailing address, then select 'other' and report time zone in question 51.

Question 51: Specify other time zone:

Only answer this question if the time zone for the alternate contact's mailing address was not listed above. Indicate time zone in the open text field.

Question 52 – 55: Phone number(s) – Home / Work / Cell / Other:

For questions 52 – 55, provide phone numbers at which the alternate contact can be contacted for each type of phone number available. A phone number does not need to be provided for each phone number type however; at least one phone number is required.

Indicate area code when reporting U.S. phone numbers. Indicate country code for all international phone numbers.

Question 56: Specify other phone number type:

If the alternate contact's preferred phone number type is not a home / work / or cell phone number, indicate the other phone number type here.

Questions 57 – 58: E-mail address(es) – primary / secondary

Indicate the alternate contact's primary and secondary e-mail address (if applicable). When using the open text field be sure to provide a complete e-mail address including: user e-mail prefix, "@" symbol, and e-mail domain (ex: JohnDoe@comcast.net, JaneDoe@gmail.com)

Section Updates:

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

Last modified: Jul 28, 2021

2008: Infusion Canceled or Delayed

The Canceled or Delayed (2008) form is expected whenever an infusion was canceled or delayed indefinitely. To submit this form, use the **Create Unscheduled Form** icon in the appropriate infusion row on the Recipient Information Grid. In order for the Infusion Canceled or Delayed (2008) form to be enabled as on-demand, the Indication for CRID Assignment (2814) form must be submitted.

✻ If the infusion has been delayed, but the rescheduled date is known, do not use the Infusion Canceled or Delayed (2008) form. In that case, please update the planned infusion date on the existing Indication for CRID Assignment (2814).

! FormsNet3 will not allow submission of the Infusion Canceled or Delayed (2008) form if the Indication for CRID Assignment (2814) form has not yet been submitted. If the infusion needs to be canceled prior to providing a planned infusion date, contact CIBMTR Center Support.

When the Canceled or Delayed (2008) form is completed, the infusion row, the Pre-TED (2400) and Disease Classification (2402) forms, along with any other forms completed in FormsNet3 will be removed for the canceled infusion.

Links to Form Sections

Q1 – 2: Reason(s) for the Infusion Cancellation or Delay

Last modified: Mar 06, 2024

Q1-2: Reason(s) for the Infusion Cancellation or Delay

Question 1. Specify the reason(s) for the infusion cancellation or delay (Check all that apply)

Specify the reason(s) why the infusion was cancelled or delayed. Select all that apply. If the reason why the infusion was canceled or delayed is not listed on the form, select **Other reason** and continue with question 2.

Example 1: A recipient had a transplant scheduled on 11/26/2019; however, when reviewing the CPI list, it was discovered the transplant was cancelled because the recipient had disease progression and was moved to hospice care. In this scenario, select the options **Disease relapse / progression** and **Patient sent to hospice or receiving palliative care only** as the reason why the infusion was canceled.

Example 2: The recipient died before transplant. The reason why the infusion was canceled should be reported as **Patient died**.

Specify other reason

Specify the Other reason why the infusion was canceled or delayed.

Example 3: The transplant for the recipient was canceled for insurance reasons and the recipient did not receive conditioning treatment. Report '*Transplant for patient was canceled due to insurance and patient did not receive conditioning treatment'* in the specify other reason data field.

If the infusion date is rescheduled, the Create Indication Form button on the Recipient tab may be used to receive a new Indication for CRID Assignment (2814) form.

Last modified: Mar 06, 2024

Recipient Transfer Tool

The Request for Recipient Transfer, is used when a recipient has left one center and transferred to a different center for treatment after having been reported at the previous center.

The Request for Recipient Transfer is completed in FormsNet3 by the data managers at the center the recipient is transferring FROM and the center the recipient is transferring TO.

After the transfer is processed, data managers at both the transferring FROM center and transferring TO center will receive a confirmation email.

Go to the Recipient tab > Assign CRID > Search/Edit CRID. Find the (original) CRID and click on the circle with the arrow to the left of the CRID to begin.
See the FormsNet3 Training Guide Initiating a Transfer for detailed instructions.

Links to Sections of Recipient Transfer Tool:

Section 1: Completed by transferring TO center
Section 2: Completed by transferring FROM center

Last modified: Mar 06, 2024

Section 1: Completed by transferring TO center

Section 1 of the recipient transfer tool is completed by the center where the recipient is transferring TO.

> ! The TO center and FROM center should be in contact with one another prior to completing the Recipient Transfer to ensure that both centers are referring to the same recipient and discuss reporting responsibilities with the transfer. If you are not able to reach the other center with the contact information FormsNet3^{SM} has provided, please submit a ticket to CIBMTR Center Support.

Confirmed patient with transferring FROM center:

Check the checkbox to indicate that the transferring TO center has confirmed the patient with the transferring FROM center.

Agreed upon effective date: (date the transferring TO center assumes responsibility for recipient)

This is the date the two centers agreed that the TO center will take responsibility for the reporting on the recipient. If there has been a subsequent infusion at the TO center, the agree upon effective date **must** be prior to the subsequent infusion date. Any of the dates below would be acceptable:

- The day the recipient was first seen at the TO center
- The date the recipient signed consent at the TO center
- The day before preparative regimen began
- The day before the infusion

It is most important that the date is **prior to any subsequent infusion** at the TO center to ensure the new forms come due at the correct center. Forms with an earliest complete date that are on or after the effective date will be moved to the transferring TO center. Forms with an earliest complete date before the effective date will remain at the transferring FROM center.

Was a duplicate CRID created at your center:

When discussing the transfer, the centers will have discovered whether the TO center has created a CRID for the recipient before realizing that a CRID already existed. This CRID will be merged with the original CRID by the CIBMTR CRC as part of the transfer process.

Indicate **Yes** or **No** if the transferring TO center created a duplicate CRID.

Duplicate CRID:

Enter the duplicate CRID number if Yes was reported in the previous question.

Reason for transfer:

Select the reason that the recipient is transferring to the new center.

- **Center Closed** – the recipient's original center is closing or has closed.
- **Center split / merged** – the center has either divided into two branches or has changed from a two-branch program to one single CIBMTR center.
- **Follow-up care** – the recipient will be receiving follow-up care at the TO center and a subsequent infusion is not planned at the time the transfer is being completed. Examples may include transferring due to patient moving out of state or changes related to insurance.
- **Subsequent infusion** – the recipient is receiving / has received a subsequent infusion at the TO center.

Date of subsequent infusion:

Enter the date of the subsequent infusion at the TO center using the YYYY/MM/DD format.

Data Manager agrees that their center will assume reporting responsibility:

Check the checkbox to indicate that the transferring TO center has agreed to assume reporting responsibilities.

Last modified: Jul 26, 2021

Section 2: Completed by transferring FROM center

Section 2 of the recipient transfer tool is completed by the center the recipient is transferring FROM.

> ! The TO center and FROM center should be in contact with one another prior to completing the Recipient Transfer to ensure that both centers are referring to the same recipient and discuss reporting responsibilities with the transfer. If you are not able to reach the other center with the contact information FormsNet3SM has provided, please submit a ticket to CIBMTR Center Support.

Confirmed patient with transferring TO Center:

Indicate yes if the patient has been confirmed with the transferring TO center. Indicate no if the FROM center has not been able to confirm the patient with the transferring TO center. If no is reported, a comment will be required to indicate why the patient has not been confirmed.

Agreed to effective date: (date the transferring TO center assumes responsibility for recipient)

Indicate yes if the effective date reported within the TO Center Data section is the date agreed upon by both centers. Indicate no if the effective date reported within the TO Center Data section is not the correct date agreed upon by both centers. If no is reported, enter the new effective date within the Proposed effective date field.

Data Manager agrees that reporting responsibility is transferring to TO center:

Check the checkbox to indicate that your center agrees that reporting responsibility will be moved to the transferring TO center.

Last modified: Jul 26, 2021

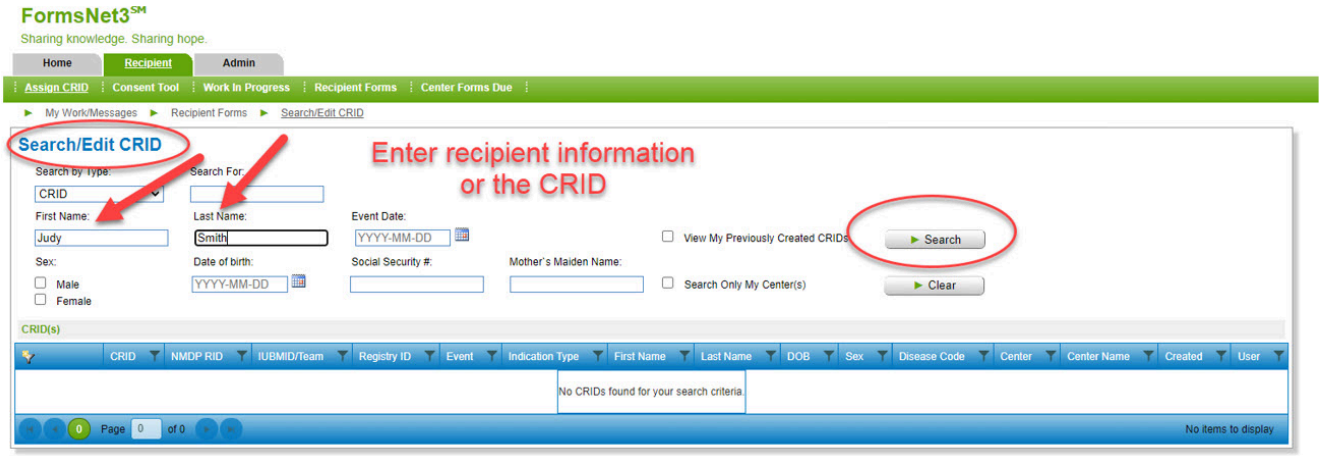
Recipient Transfer Best Practices

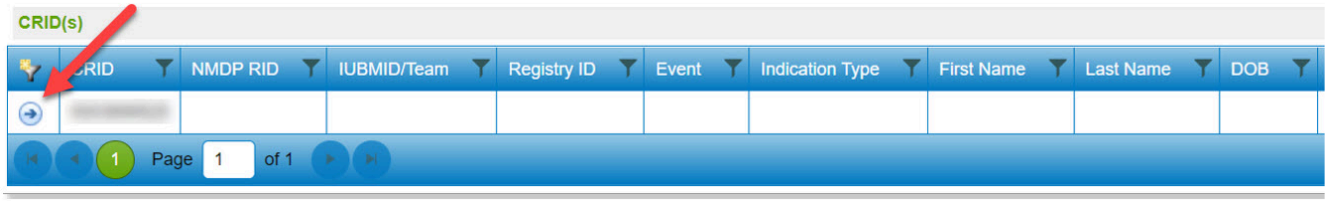
I have received a transfer request; how quickly do I need to respond?

- Please respond to a transfer request within two weeks. Requests will appear on the FormsNet3 homepage and via email notification. It is very important to not delay a transfer so that centers have sufficient time to complete the Pre-TED (2400) and Pre-TED Disease Classification (2402) forms for CPI.

What if there is a duplicate CRID at the new center?

- Search for the original CRID that needs to be transferred and click on the circle with the arrow icon to the left of the CRID to begin the transfer process.

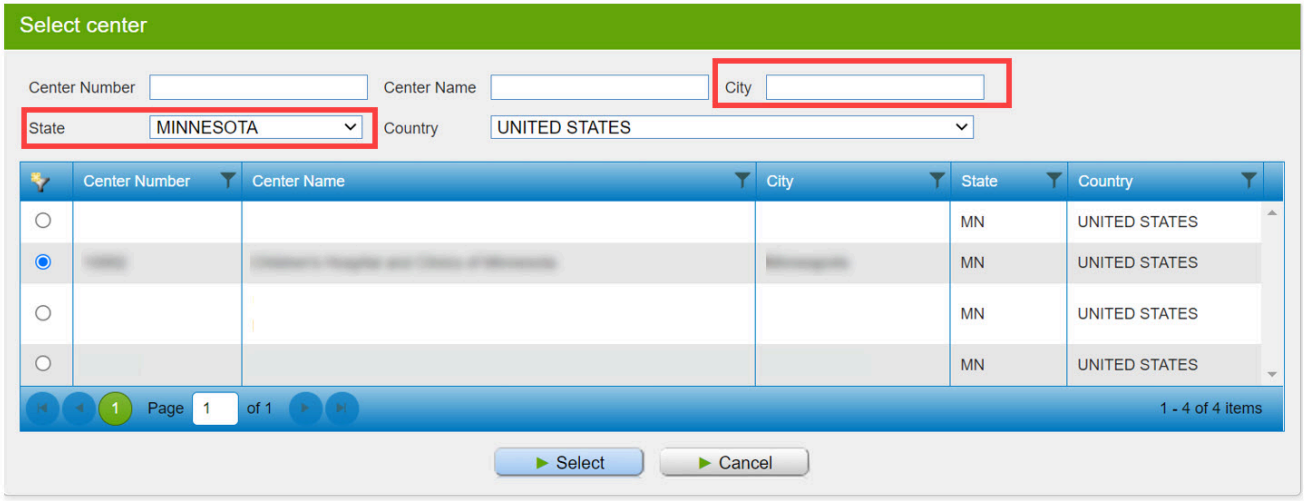




- When the patient has two CRIDs, always transfer the ORIGINAL CRID not the duplicate. The duplicate CRID will be added in the TO center's portion of the transfer tasks. CIBMTR staff will merge the CRIDs and finalize the transfer.
- If someone tries to transfer the duplicate CRID, contact the other center and cancel the transfer.

How can I get the contact information?

- You can find the other center if you know their city and state. You can search for the other center within the tool.



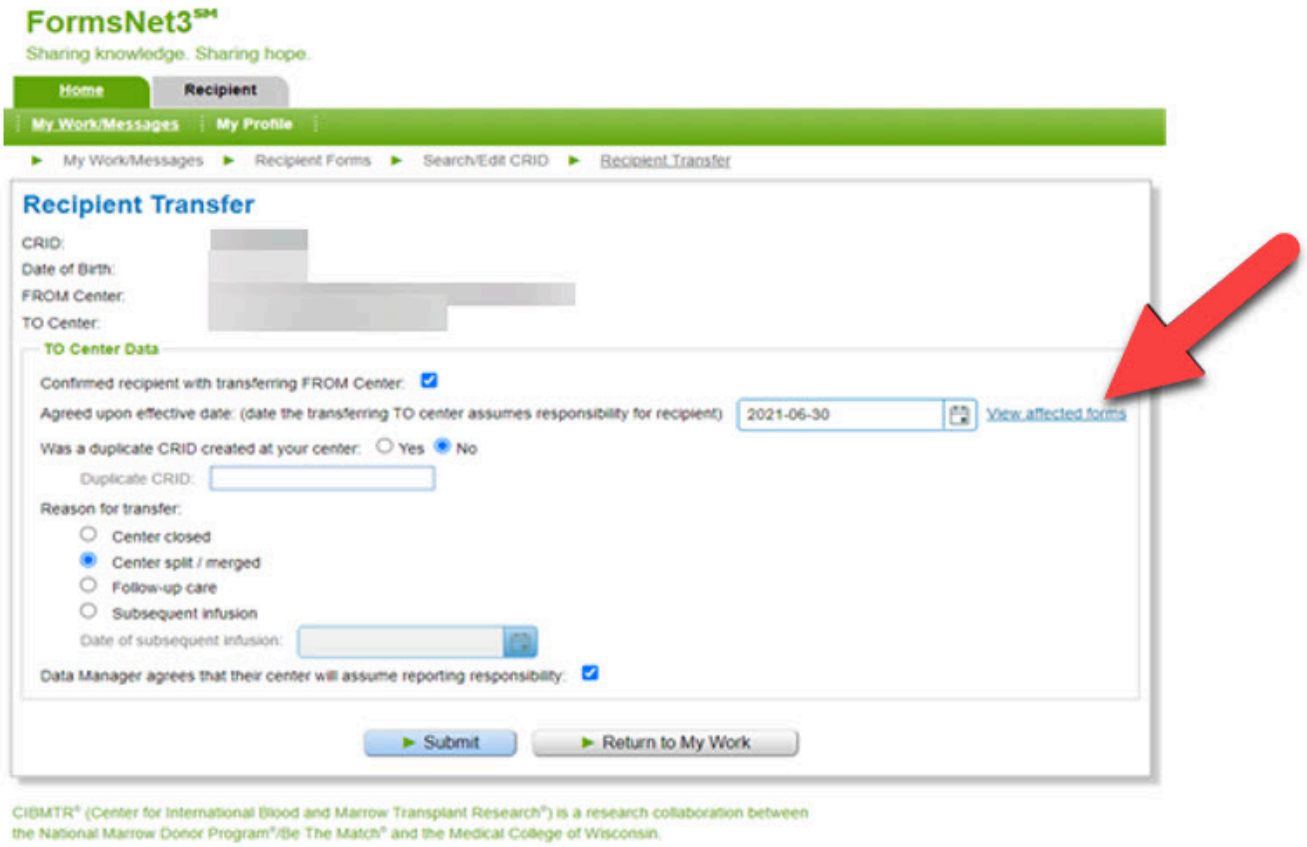
- Contact information for the other center will be sent to you by email from FormsNet3 once you have initiated the transfer.
- It is best practice to talk over the phone or via secure email to discuss the patient details, so you are verifying that this is indeed the same person. Make sure you are following your institution's policy on discussing the patient details, for example phone or secure email.

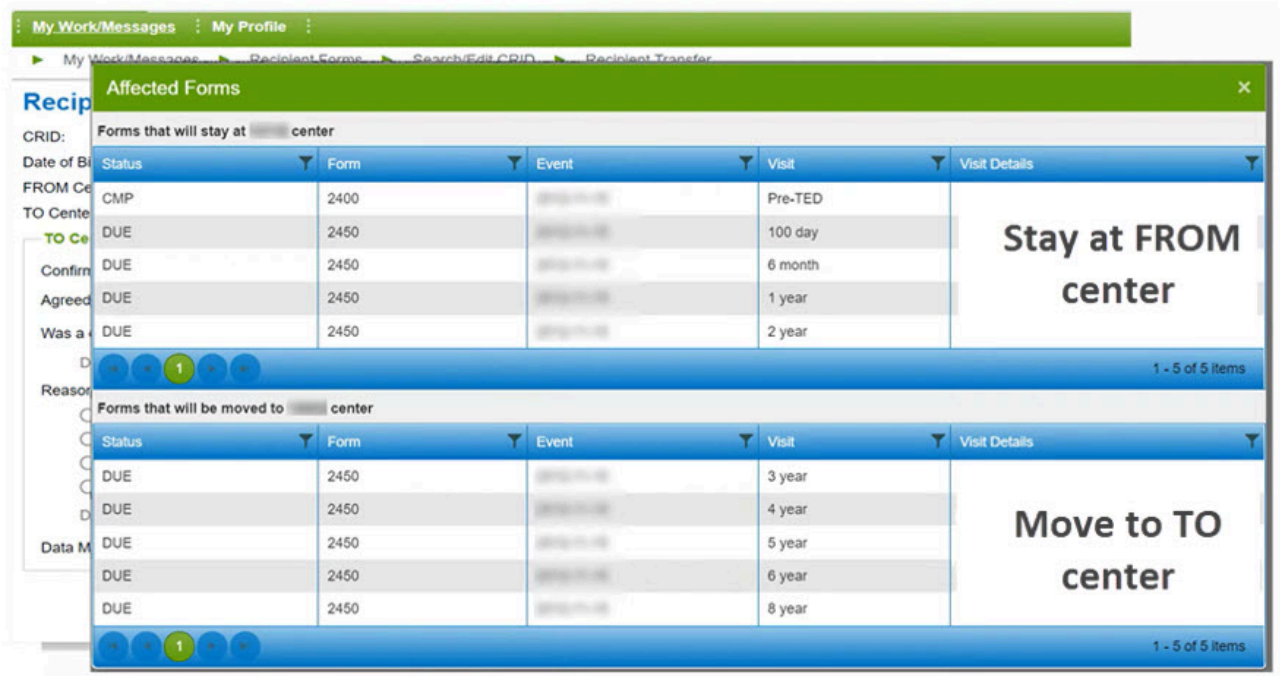
What if I am not sure it is the same patient?

- If you are not certain it is the same patient, you may not want to initiate a transfer prior to speaking to the other center. Please request contact information via CIBMTR Center Support.

How do I make sure the forms are at the right centers after the transfer?

- When in the process of initiating a transfer or accepting a transfer you will need to discuss the date that the new center will be taking over. This is very important as this date is what determines where the DUE forms transfer.
- The forms move based on the date listed under "Earliest" in the forms grid under the CRID. Forms before that date stay at the FROM center. Forms after that date move to the TO center. After choosing the date, use the blue "View Affected Forms" link next to the effective date to see which forms will move after the transfer. Either center can view the affected forms.

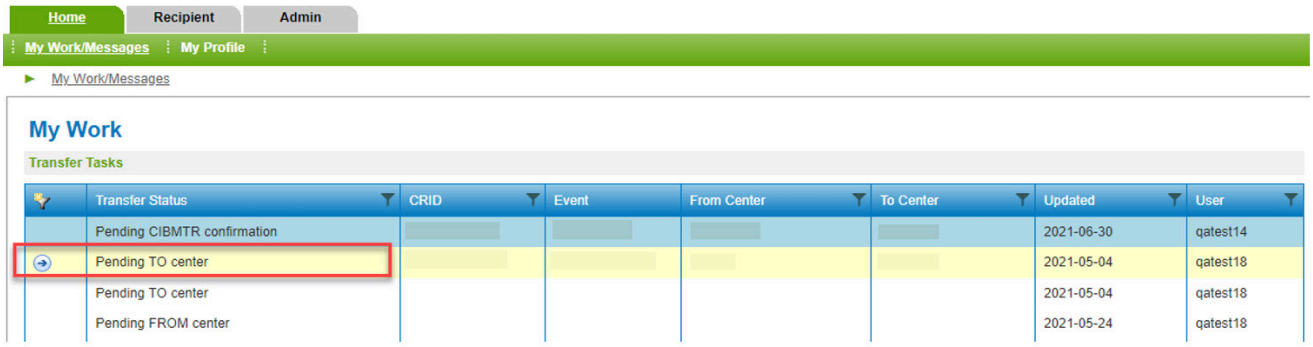




- After the transfer has been completed, please be sure to check that the forms due are at the correct center. This is very important for CPI, CTA and CVDR. Only the center that did the infusion should report that infusion on the 2400 and 2402 forms.
- If the FROM center doesn't agree to the effective date, they can propose an alternate date in their portion of the form, and they can add a reason for the denial or the proposed alternate date.

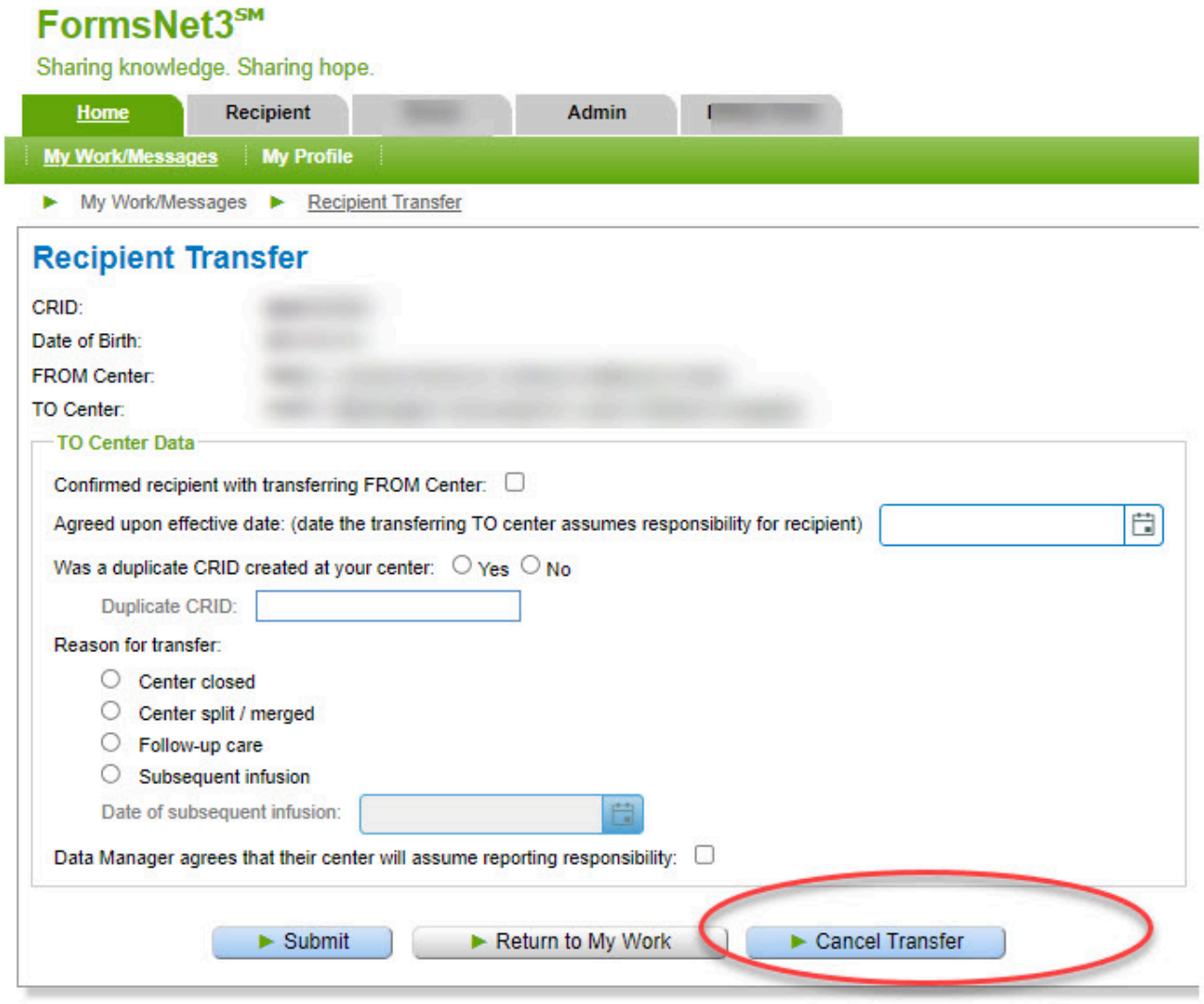
How can I tell what the next step is?

- In the Transfer Tasks on the home tab, you can tell who needs to take the next action.



What if something is incorrect and the transfer should not happen?

- If at any point you discover that the transfer should not happen, the transfer may be canceled by the TO center, the FROM center, or CIBMTR.



What if we completed a paper Form 2801?

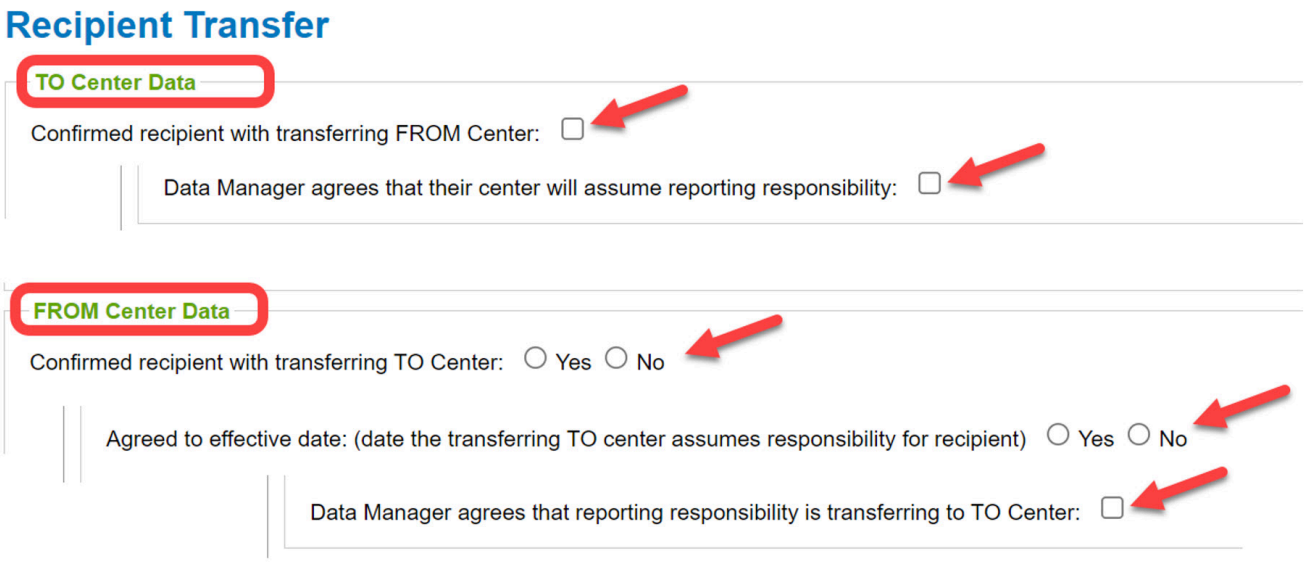
- The form 2801 has been replaced with the new Transfer Tool in FormsNet3. The paper form can no longer be processed. All transfers must be done in FormsNet3.

What if there is a form 2801 showing due at my center?

- If you have a Form 2801 that is showing due in the forms grid for more than two weeks, contact us via CIBMTR Center Support.

What if I cannot complete sign off on my section?

- Please check that you have answered all questions and selected an answer for each question about confirming with the other center and/or agreeing to the transfer. If the issue persists, contact us via CIBMTR Center Support.



What if the center that I need the CRID to be transferred FROM has closed?

- If the CRID belongs to a center that has been closed you will need to submit a CIBMTR Center Support ticket and let us know that you need assistance in getting the transfer completed.

What if the person I contacted to discuss CRID details has not responded?

- You will need to submit a CIBMTR Center Support ticket and let us know if you are having trouble contacting the other center. We will assist you in identifying an alternate contact.

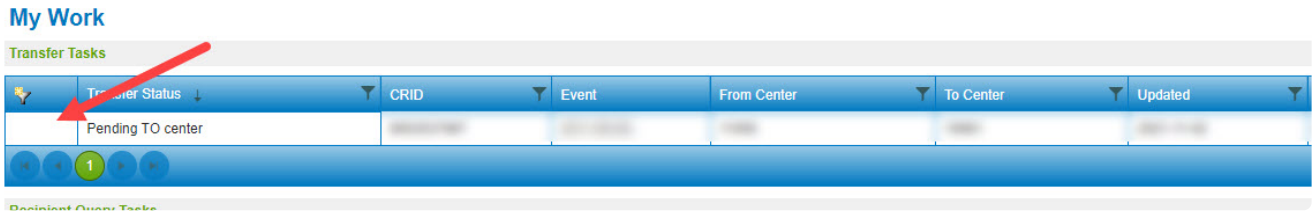
What if I have not received a response from the other center after initiating a transfer?

- Submit a CIBMTR Center Support ticket and let us know that the other center has not responded. Please include the contact information you used for the other center, (name, phone number, and email address.) We will assist you in identifying an alternate contact.

I am missing the transfer icon so I am not able to select the CRID

- If the transfer icon is not available in the transfer tasks, it means that the transfer is pending the other

center. When you are supposed to take action, the transfer icon will appear to the left of the CRID in the Transfer Tasks section on the Home tab.



Last modified: Dec 16, 2022

Data Collection and Quality

CIBMTR, in collaboration with the worldwide hematopoietic cell transplantation community, developed appropriately organized forms to capture a standard set of data elements for all transplant recipients. These forms are revised as needed to match the evolving science and medical advances in cellular therapy research to ensure that the most relevant data are collected.

Form Submission

CIBMTR encourages centers to submit forms electronically through either FormsNet3 or AGNIS. These electronic submission mechanisms allow for immediate validation of data allowing centers to correct or validate data prior to submission. When that is not possible, we accept a paper version of the form.

To view any of the forms in their paper format click here.

Section Updates:

Date	Topic	Add/ Remove/ Modify	Description
9/27/ 2021	Current Form Revision	Modify	Updated the date of the Winter Release to reflect October 29, 2021
7/28/ 2021	Primary Disease and Disease Forms Due	Modify	Updated each primary disease and disease inserts generated, if on CRF track
7/16/ 2021	Correcting Historical Data	Modify	Review of format and information accuracy
7/14/ 2021	Forms 2004, 2005, and 2006	Modify	Updated the format of each table (e.g. Autologous, Autologous Cord Blood Units, etc)

Last modified: Nov 01, 2021

FormsNet3

More than 95% of data collected by the CIBMTR is submitted electronically via FormsNet3, a comprehensive electronic data capture system containing greater than 250 forms related to the capturing of HCT outcomes for donors and recipients.

The FormsNet3 application is CIBMTR's clinical research management system that brings together researchers from around the world to share data and knowledge used to answer questions critical to saving lives.

FormsNet3 provides enhanced features and functions, including user friendly site navigation, field level saving, auto-population, enabling/disabling of fields, and timely form processing.

How to Use the Application:

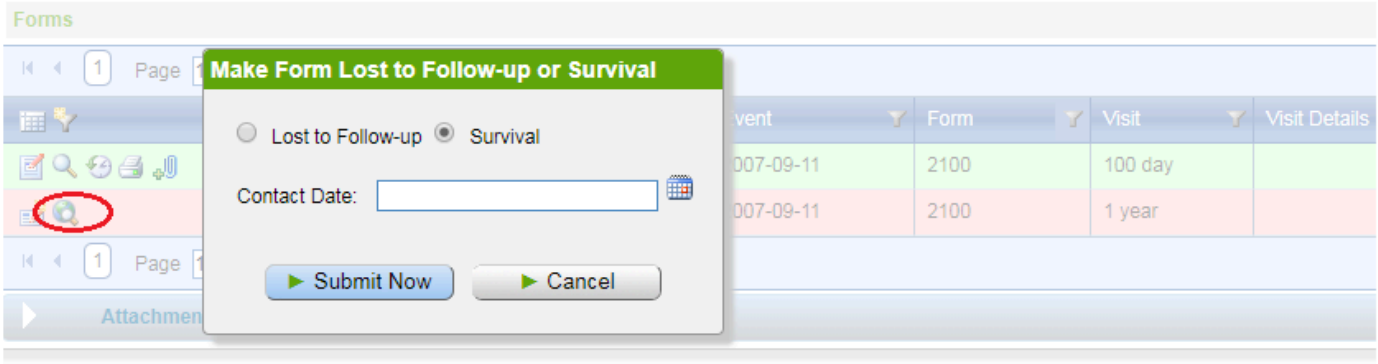
The FormsNet3 Training Guide is located here.

Last modified: Mar 08, 2024

Survival Form Status

When you have a patient that is further out from transplant, you know is alive and all efforts to obtain follow-up data on a patient have failed, you can report the recipient's latest alive date of contact, thus eliminating the need to override multiple questions to get forms to complete status.

This feature is located in the same location as the Lost to Follow-up (LTF) feature. Simply select if you are reporting Survival or LTF, then answer the applicable questions.



Additionally, the feature updates the corresponding disease inserts' form status to match the 2100 Form, (i.e. you only need to complete Survival or LTF once for the visit instead of on both forms).

Last modified: Jun 15, 2018

AGNIS

AGNIS® (A Growable Network Information System) is an open-source messaging system specifically designed to exchange hematopoietic cell transplant data using a secure, standards-based system.

Transplant centers can use AGNIS to retrieve and transmit form data, extracted directly from their own institution's database, directly to the FormsNet3 application using a secure and authenticated electronic data transmission system.

AGNIS gives centers an "enter once, use often" data capability by handling all subsequent distribution and synchronization between databases, including the CIBMTR database.

For information to access AGNIS and training, please see the AGNIS section on the CIBMTR website. Click here.

Last modified: Mar 08, 2024

How Forms Come Due

When first registering a patient with CIBMTR, the center must complete a CIBMTR Research ID (CRID) Assignment (2804) in FormsNet3, which generates a unique identifier for the patient. Once a CRID is assigned, the Consent Tool and Indication for CRID Assignment Form (2814) must be completed to report the consent status and indication. Depending on the indication reported, forms are added to the Forms Due list by FormsNet3, and must then be completed by the center.

Indication	Forms Due
HCT	Pre-TED (Form 2400) Disease Classification (Form 2402)
Cellular therapy (non-HCT)	Pre-CTED (Form 4000)
Marrow Toxic Injury	RITN Baseline Form (Form 5000) RITN Contact Form (Form 5001) RITN Follow-Up Form(s) (Form 5002)
Non-cellular therapy (e.g. chemotherapy, immunotherapy, etc.)	No additional data is required at this time. No forms required (Stop Here)

If the indication reported is Non-cellular therapy, no additional data is required at this time. For more information, see the Indication for CRID Assignment (2814) Form Instruction Manual.

If the indication reported was HCT, Cellular therapy (non-HCT), or Marrow toxic injury, refer to the sections specific to those indications for more information on CIBMTR forms due.

Indication and Pre-TED Forms

As of May 13, 2015, the CIBMTR requires centers to complete the Pre-TED Forms (Form 2400 and 2402) for all autologous transplant recipients, whether or not they consent to have their data used in research. The release of the revised CRID Assignment Form (Form 2804) and new Indication Form (Form 2814) in FormsNet3 on May 12, 2015 supported this change.

Last modified: Mar 06, 2024

HCT

When the indication is reported as HCT for the patient's first event, or an HCT is reported on an HCT or cellular therapy follow-up form, the Pre-TED Forms 2400 and 2402 will be the first to come due. Once the Pre-TED forms are complete and the data are processed, the selection algorithm determines if the patient will follow the CRF or TED track.

If the patient is autologous and did not give consent to submit data to the research database and is not participating in a study protocol requiring data to be submitted, **no additional forms are required**.

Autologous patients that did not give consent to the research database but **are** participating in specific study protocols will be assigned to the CRF track while enrolled in the study.

For all other patient types, follow the appropriate track below:

TED track – Click here to see the Visio flowchart for how forms come due.

CRF track – Click here to see the Visio flowchart for how forms come due.

Last modified: Mar 06, 2024

Forms 2003, 2004, 2005, 2006, 4003

Gene Therapy Product (Form 2003)
Infectious Disease Markers (Form 2004)
Confirmation of HLA Typing (Form 2005)
Hematopoietic Stem Cell Transplant (HCT) Infusion (Form 2006)
Cellular Therapy Product (Form 4003)

The following tables display how the 2004, 2005, and 2006 forms come due by donor types for HCT recipients.

The Forms 2003, 2004, 2005, 2006 and 4003 are generated based on the following:

- Form track (TED, CRF)
- HCT type (AUTO, ALLO_U, ALLO_R) **Reported on the F2814*
- Donor type (NMDP, Non-NMDP, HLA type) **Reported on the F2400*
- Product type (PBSC, BM, CBU) **Reported on the F2400*
- Consent to Research Repository (Yes, No, NA, Not approached) **Reported on the F2400*
- Was the donor previously used (Yes, No) **Reported on the F2400*

-If a Form 2005 has been completed for the recipient for a prior event date, another will not be made due.
-If the donor was used for a previous HCT or cellular therapy for the same recipient and 2005s were not captured for the donor and/or recipient, form(s) will be made due.
-In the case of cellular therapies occurring post-HCT, where the same donor is used from the prior HCT, no Form 2005s are required.
-A Form 2004 is required for each product type from a single donor.
-If you have any questions or think a form has been made due in error, please create a ticket in CIBMTR Center Support

Last modified: Mar 06, 2024

Autologous

For each Autologous instance,

	Form 2003 (Gene Therapy)	Form 2004	Form 2005	Form 2006 or 4003
TED or CRF track Genetically modified = yes	X			X (F4003 only)
TED or CRF track Product Type = Cord Blood Units Genetically modified = no				X (for each product)
CRF track Genetically modified = no				X (for each product)
TED track Genetically modified = no				

✻ On the Pre-TED (F2400), questions will determine the number of F2006 and/or F4003 generated.
A. 'Specify number of products infused from this donor'
B. 'Specify number of these product intended to achieve hematopoietic engraftment'
If A and B are equal, then FN3 will generate the number of F2006s reported in B.
If A and B are not equal, this indicates a co-infusion and data will be reported on both the F2006 (the number reported in B) and F4003 (the difference between A and B).

Last modified: Mar 31, 2022

Allo- NMDP Donor

For each NMDP Donor instance, regardless of:

- HCT type (ALLO_U, ALLO_R)
- Product Type (PBSC, BM, CBU)
- Form Track (TED, CRF)
- F2400 ‘Was this donor used for any prior HCTs’ (Yes, No)

a F2006 will come due.

On the Pre-TED (F2400), questions will determine the number of F2006 and/or F4003 generated.
A. ‘Specify number of products infused from this donor’
B. ‘Specify number of these product intended to achieve hematopoietic engraftment’
If A and B are equal, then FN3 will generate the number of F2006s reported in B.
If A and B are not equal, this indicates a co-infusion and data will be reported on both the F2006 (the number reported in B) and F4003 (the difference between A and B).

Last modified: Mar 08, 2024

Allo_Unrelated Donor (Non-NMDP)

For each Non-NMDP Unrelated instance,

	Form 2004	Form 2005	Form 2006 or 4003
CRF track Was the donor used for a prior HCT = yes	X		X (For each product)
CRF track Was the donor used for a prior HCT = no	X	X (Donor) X (Recipient)	X (For each product)
TED track Product type = PBSC, BM Consent for Research Repository = No/NA/Not Approached Was the donor used for a prior HCT = no		X (Donor) X (Recipient)	
TED track Product type = PBSC, BM Consent for Research Repository = No/NA/Not Approached Was the donor used for a prior HCT = yes	X		
TED track Product type = PBSC, BM Consent for Research Repository = yes Was the donor used for a prior HCT = no	X	X (Donor) X (Recipient)	X (For each product)
TED track Product type = PBSC, BM Consent for Research Repository = yes Was the donor used for a prior HCT = yes	X		X (For each product)
TED track Product type = CBU Was the donor used for a prior HCT = no	X	X (Donor) X (Recipient)	X (For each product)
TED track Product type = CBU Was the donor used for a prior HCT = yes	X		X (For each product)

On the Pre-TED (F2400), questions will determine the number of F2006 and/or F4003 generated.
A. 'Specify number of products infused from this donor'
B. 'Specify number of these product intended to achieve hematopoietic engraftment'
If A and B are equal, then FN3 will generate the number of F2006s reported in B.
If A and B are not equal, this indicates a co-infusion and data will be reported on both the

F2006 (the number reported in B) and F4003 (the difference between A and B).

Last modified: Mar 31, 2022

Allo_Related Donor (Non-NMDP)

For each Related Donor instance, where F2400 'Was this donor used for any prior HCTs' = No

Related Donor type: Syngeneic (monozygotic twin) or HLA-Identical Sibling

	Form 2004	Form 2005	Form 2006 or 4003
CRF track	X	X (Recipient)	X (For each product)
TED track Consent for Research Repository = yes	X	X (Recipient)	X (For each product)
TED track Consent for Research Repository = No/NA/Not Approached			

Related Donor type: HLA-mismatched or HLA-matched

	Form 2004	Form 2005	Form 2006 or 4003
CRF track	X	X (Donor) X (Recipient)	X (For each product)
TED track Consent for Research Repository = yes	X	X (Donor) X (Recipient)	X (For each product)
TED track Consent for Research Repository = No/NA/Not Approached		X (Donor) X (Recipient)	

For each Related Donor instance, where F2400 'Was this donor used for any prior HCTs' = Yes

	Form 2004	Form 2005	Form 2006 or 4003
CRF track	X		X (For each product)
TED track Product type = PBSC, BM Consent for Research Repository = yes	X		X (For each product)
TED track Product type = CBU	X		X (For each product)

On the Pre-TED (F2400), questions will determine the number of F2006 and/or F4003 generated.

A. ‘Specify number of products infused from this donor’
B. ‘Specify number of these product intended to achieve hematopoietic engraftment’
If A and B are equal, then FN3 will generate the number of F2006s reported in B.
If A and B are not equal, this indicates a co-infusion and data will be reported on both the F2006 (the number reported in B) and F4003 (the difference between A and B).

Last modified: Mar 31, 2022

Additional Forms

Data reported on CIBMTR forms may trigger additional forms to come due. Examples of these forms include, but are not limited to

- Infection forms (e.g. Fungal Infection Forms 2046/2146)
- Study specific forms (e.g. 2500 series)
- Veno-Occlusive Disease/Sinusoidal Obstruction Syndrome Supplemental Form 2553

Additionally, there are several forms that are used by the center as needed, and submitted to CIBMTR. Examples include, but are not limited to

- Delayed / Canceled HCT Form (Form 2008)
- Request for Recipient Transfer (Form 2801)

For more information on how to complete these forms, see the Forms Instruction Manual, or contact CIBMTR Center Support.

Last modified: Mar 08, 2024

Creating Unscheduled Forms

All data reporting to CIBMTR is managed through the FormsNet3 application. Although most CIBMTR data collection forms are automated in the FormsNet3 system, there are cases where needed form(s) may not come due as expected. To ensure timely reporting, the following instructions may be used to create an unscheduled form in these circumstances. Please note, unscheduled forms should only be created when needed, and only if CIBMTR communications detail that this mode of action may be required. An example is reporting COVID-related information pertaining to an infection that does not coincide with an applicable follow-up form (example: 1 year form completed 1/1/2020 and patient diagnosed with COVID-19 on 7/1/2020. Since the 2 year follow-up form would not be required until around January 2021, the Respiratory Virus Post-Infusion Data (2149) Form will need to be created as an unscheduled form).

Unscheduled Form Instructions:

1. Log into the FormsNet3 application
2. Select the **Recipient** tab from the application's menu bar
3. Ensure "CRID" is selected in the **Search by Type** field
4. Enter the applicable CRID and hit **Search**
5. Under the **Recipient Information** section (immediately below the search field), locate the applicable infusion event. This should be the most recent infusion (i.e., bottom-most infusion row)

Last modified: Mar 06, 2024

Marrow Toxic Injury

When the indication is reported as marrow toxic injury, the RITN Baseline Form 5000, RITN Contact Form 5001, and RITN Follow-Up Forms will come due.

Note: Marrow toxic injury should only be reported as an indication by participating Radiation Injury Treatment Network centers in the event of a radiation incident.

For more information on RITN, click here, or contact CIBMTR Center Support.

Click here to see the Visio flowchart for how forms come due.

Last modified: Feb 10, 2022

Cellular Therapy

When the indication is reported as Cellular therapy (non-HCT) for the patient's first event, or a post-HCT cellular therapy is reported on an HCT follow-up form, the Cellular Therapy Pre-CTED Form 4000 will come due. Once completed and the data is processed, FormsNet3 will add additional forms based on whether the product was genetically modified and if the infusion was post-HCT.

> ✱ Reporting of cellular therapy infusions to CIBMTR remains voluntary. Reporting of commercially available cellular therapy product infusions (i.e. Kymriah®, Yescarta™, Tecartus™, Breyanzi™, Abecma®, Carvykti™) is strongly encouraged.

The following sub-sections are available for Cellular Therapy:

- Cell Therapy Training Resources
- CIBMTR Guidance Document for Reporting Autologous Cellular Therapies
- Cell Therapy Reporting Preferences
- Cell Therapy Reporting Levels
- Cell Therapy Reporting Tracks and Follow-Up Schedules
- How Forms Come Due
    - Cell Therapy, Stand-Alone
    - Co-Infusion
    - Post-HCT Cellular Therapy
    - Combined Follow-Up Scenarios (HCT + CT (genetically modified))
        - HCT -> CT
        - CT -> HCT
        - 3+ Events
- Common Cell Therapy Related Questions

Last modified: Mar 06, 2024

Cell Therapy Training Resources

CIBMTR Portal

- Click HERE to access the Portal (https://portal.cibmtr.org/)
- Click on the "**Training & eLearnings**" tile

Resources Available on the CIBMTR Portal

- Self-Guided New Data Manager Onboarding: The Center for International Blood & Marrow Transplant Research (CIBMTR) is pleased to offer self-guided onboarding training for new Data Managers. This course will provide you with all of the e-learnings and information about data submission requirements of CIBMTR and field knowledge, as well as suggested weekly timelines for completing all of your self-guided learning materials. Within this training, you will find content specific to Cellular Therapy.
- eLearnings: There are 6 eLearnings in the Cellular Therapy Series

Cell Therapy Forms Instruction Manuals

- Click HERE to access the Cellular Therapy Manuals
  - The sections of the manual provide instructions for completing the Pre-Cellular Therapy Essential Data (4000) form, Pre-Cellular Therapy Baseline Data (4001) form, Cellular Therapy Product (4003) form, Cellular Therapy Infusion (4006) form, Post-Cellular Therapy Essential Data (4100) form and Post-Cellular Therapy Follow-Up (4101) form.

Last modified: Mar 06, 2024

CIBMTR Guidance Document for Reporting Autologous Cellular Therapies

Please consider the following guidance when determining whether to report a cellular therapy to CIBMTR. The scope of this document covers autologous cellular therapies only.

Reporting autologous cellular therapy data to CIBMTR

Reporting of autologous cellular therapy data to CIBMTR remains voluntary at this time, with the exception of cellular therapy received after an allogeneic HCT. Reporting of the infusion date is strongly encouraged and form completion remains voluntary.

Consent status for Cellular Therapy

CIBMTR encourages centers to approach all patients for consent to participate in the Observational Research Database. When a patient consents to participate in the Observational Database, their data are stored in the CIBMTR's Observational Research Database and may be used for research. The primary purpose of the Observational Research Database is to have a comprehensive source of data that can be used to study cellular therapy and hematopoietic cellular transplantation (HCT). The consent form applies to both HCT and cellular therapy. Per CIBMTR, a patient only needs to be consented once to participate in the Observational Research Database, however, you should follow the guidance of your local IRB. The most recent consent status reported to CIBMTR is the consent applied to the entire patient record.

Below are the scenarios describing when autologous cellular therapy data can be collected in the context of patient consent for research:

1. **Autologous cellular therapy**: For any cellular therapy (e.g., CAR T-cells) that uses an autologous donor/product and is given as a stand-alone therapy (not associated with an HCT)
    a. Reporting these infusions is voluntary at this time. When consent for research is not obtained, these infusions can be reported to CIBMTR, but there will be limited data collection.
    b. If consent for research is later obtained for a subsequent infusion, cellular therapy infusions that occurred prior to obtaining consent to participate in the Observational Database are not be required to be retroactively reported.
    c. CT REMS report tool: infusions can be reported without research consent if the center is utilizing CIBMTR's CT REMS report to support their REMS reporting needs in meeting the requirements for the commercially available CAR-T products. This tool provides the data in the appropriate format for REMS submission by the center. These data will not be used for research.
2. **Autologous cellular therapy given after HCT**: for any cellular therapy infusion (e.g. co-infusion, DCI, CAR-T) given after a patient has already had an HCT, please follow the table below for requirements:

First Infusion Type	Consent for research obtained for HCT	Second Infusion Type	Consent for research obtained for CT	Report the CT event occurred?	Complete the F4000 series?	How to Report
AUTO HCT	Yes	AUTO cell therapy	Yes / Not Approached (prior consent status is valid)	Yes	Voluntary	CT infusion reported on appropriate HCT follow up to trigger F4000
			Declined	Yes	No	CT infusion reported on appropriate HCT follow up, but F4000 would be made NRQ
	No		Yes	Yes	Voluntary	Create new Indication F2814 to trigger F4000
			No / Not approached	No	No	Do not report to CIBMTR
ALLO HCT	Yes		Yes / Not Approached (prior consent status is valid)	Yes	Voluntary	CT infusion reported on appropriate HCT follow up to trigger F4000
			Declined	Yes	No	CT infusion is reported on HCT follow up, but F4000 would be made NRQ
	No		Yes	Yes	Voluntary	CT infusion reported on appropriate HCT follow up to trigger F4000
			No / Not approached	Yes	No	CT infusion is reported on HCT follow up, but F4000 would be made NRQ

Last modified: Mar 06, 2024

Cell Therapy Reporting Preferences

Cell therapy reporting preferences took effect in July 2022 and are used to determine how forms come due.

> ✻ Donor Lymphocyte Infusions (DLIs) are not included as a type of cellular therapy for the purpose of reporting preference. As of September 2022, DLIs are no longer reported on the cellular therapy forms.

Do Not Perform

Site does not perform any cellular therapy infusions, only HCT

- Other types of Donor Cellular Infusion (DCIs), but excluding DLIs, should be considered as cellular therapy infusions
- **Note:** This status will not prevent cellular therapy forms from being made due if a cellular therapy infusion is reported. If a cellular therapy infusion is reported, rules for the research level will be followed.

Perform Do Not Report

Site is performing cellular therapies (i.e. CAR-T, VSTs, CTLs, DCIs), but no infusions are submitted to CIBMTR

- Other types of Donor Cellular Infusion (DCIs), but excluding DLIs, should be considered as cellular therapy infusions
- **Note:** This status will not prevent cell therapy forms from being made due if a cellular therapy infusion is reported. If a cellular therapy infusion is reported, rules for the Research level will be followed.

Research Level

All TYPES of cellular therapy infusions that are performed at the site are submitted to CIBMTR

- This includes all commercially available products, investigator studies, and clinical trial infusions
- CIBMTR has an embargo request for clinical trial and study data. A job aid is available on the CIBMTR Portal.

CIBMTR Research Database consent status will be considered for determining what forms come due:

- If CIBMTR Research Database consent is **'yes'**, then all forms come due as expected
- If CIBMTR Research Database consent is **'no'**, then only the F4000/2402 will come due

REMS Level

ONLY commercially available cellular therapy product infusions are submitted to CIBMTR

- Examples include Kymriah®, Yescarta®, Tecartus™, Breyanzi™, Abecma®, Carvykti™

For the commercially available products, all forms, including 15 years of follow up, come due as expected regardless of consent status.

Data are made available in the DBtC application CT REMS report to support a centers REMS reporting needs in meeting the requirements for the commercially available CAR-T products. This tool provides the data in the appropriate format for REMS submission by the center. These data will not be used for research.

This status will not prevent forms from being made due for non-commercially available products.

- If non-commercially available products are reported, CIBMTR Research Database consent status will be considered for determining what forms come due
    - If CIBMTR Research Database consent is **'yes'**, then all forms come due as expected
    - If CIBMTR Research Database consent is **'no'**, then only the F4000/2402 will come due

If you would like to change the cellular therapy reporting preference for your center or have questions about which reporting preference has been chosen, please submit a ticket via CIBMTR Center Support.

Last modified: Mar 06, 2024

Cell Therapy Reporting Levels

Beginning July 2023, new TED and CRF reporting levels for cellular therapy were created to reduce the burden of data collection. TED and CRF reporting levels are determined by the **center reporting preference** and **infusion details**.

> ! Cell therapy reporting levels are **not** a center level attribute like HCT reporting. Each cell therapy infusion will be randomized separately.

TED Level Reporting Forms	CRF Level Reporting Forms
4000	4000
4003	4001
4006	4003
4100	4006
2402	4100
3500	4101
2900	2402 + disease forms (when applicable)
	3500
	3501
	2900

Toxicities on F4100

All toxicities will be present on the F4100; however, they will enable based on TED vs CRF reporting.

TED Level Reporting Forms	CRF Level Reporting Forms
CRS (Y/N) + diagnosis date + symptoms + resolution date	Therapy for CRS
MAS/HLH-like toxicities (Y/N) + diagnosis date + resolution date	Therapy for MAS/HLH-like toxicities, splenomegaly, confirmation by BMBx, lab values
Neurotoxicity (Y/N) + cognitive assessment + neurotoxicity manifestation parent list, details on cerebral edema, depressed level of consciousness, motor neuron disease, movement disorder, seizure, speech impairment	Therapy for neurotoxicity + details on cerebrovascular accident, cognitive impairment, personality change, other

	Hypogammaglobulinemia, tumor lysis syndrome, other toxicity, grade 3/4 organ toxicity, lab values

Last modified: Aug 01, 2023

Cell Therapy Reporting Tracks and Follow-Up Schedules

Beginning in July of 2023, a reporting track will now be set for all cell therapy CRIDs reported to CIBMTR. The track will be set by the center reporting preference and infusion type.

> ✻ TED vs CRF reporting for cellular therapy was launched in the Summer 2023 release. It is determined by the center reporting preference and infusion details; it is not a center level attribute like HCT reporting.

There are five cellular therapy reporting tracks.

15 Year Follow-Up (CRF)

- Applies to commercially available CAR-T PASS studies currently accruing, BMT CTN studies, genetically modified products (other than CAR-T) either stand alone or post-HCT, and registry partners
- **Follow-up schedule:** 100 day – 15 years
- **Forms:** F4000, F4001, F4003, F4006, F4100, F4101, F2402 + disease forms (when applicable)

Standard Follow-Up (TED)

- Applies to commercially available CAR-T PASS studies that are currently accruing but CIBMTR research database consent is not obtained, commercially available CAR-T products no longer part of a PASS study, non-commercial CAR-T products, and stand-alone non-genetically modified cell therapy infusions without a history of HCT
- **Follow-up schedule:** 100d – 6yr, 8yr, 10yr, 12yr, 14yr
- **Forms:** F4000, F4003, F4006, F4100, F2402

100-Day Only Follow-Up

- Applies to post-HCT non-genetically modified cell therapy infusions (excludes Donor Lymphocyte Infusions (DLIs))
- **Follow-up schedule:** 100-day only
- **Forms:** F4000, F4003, F4006, single F4100 at 100d, F2402 + disease forms (when applicable)

CTRM

- Applies to cell therapy infusions for regenerative medicine indications (cardiovascular disease, musculoskeletal disorder, neurologic disease, ocular disease, pulmonary disease) and genetically modified cellular therapy products (not CAR-T) when the center reporting preference is Do not perform/Perform do not report/Research
- **Follow-up schedule:** None
- **Forms:** F4000, F4003, F4006

No Follow-Up

- Applies when consent to CIBMTR Research Database has not been obtained for commercially available CAR-T products no longer part of a PASS study, other genetically modified cellular therapy products, and non-genetically modified cellular therapy products
- **Follow-up schedule:** None
- **Forms:** F4000 + F2402

TED (Standard & 100-Day Only)	CRF (15 years)	CTRM	No Follow-Up
Commercial CAR-T on study, no consent, REMS/RGL center (Standard Follow-Up TED)	Commercial CAR-T on study (15 years)	Indication = Cardiovascular disease, Musculoskeletal disorder, Neurologic disease, Ocular disease, Pulmonary disease	Commercially available CAR-T products no longer part of a PASS study without consent
Commercial CAR-T not on study (Standard Follow-Up TED)	BMT CTN	Non-commercial genetically modified non-CAR-T products	Genetically modified cellular therapy products other than CAR-T
Non-commercial CAR-T products (Standard Follow-Up TED)	Genetically modified products (other than CAR-T) either stand alone or post-HCT		Non-genetically modified cellular therapy products
Stand-alone non-genetically modified cell therapy infusions without a history of HCT (Standard Follow-Up TED)	Commercial CAR-T not on study (Standard Follow-Up CRF)		
Post-HCT non-genetically modified cell therapy infusions (100 day only)			

Commercial CAR-T = Kymriah®, Yescarta®, Tecartus™, Abecma®, Breyanzi™, Carvykti™

If forms did not come due as expected, or you have questions on the forms that did come due, please submit a ticket via CIBMTR Center Support.

Last modified: Mar 06, 2024

How Forms Come Due

There are four scenarios for how cellular therapy forms come due:

1. Cellular therapy, stand alone (no HCT forms)
2. Co-infusion (with HCT)
3. Post-HCT cellular therapy (not genetically modified)
4. Post-HCT cellular therapy (genetically modified)

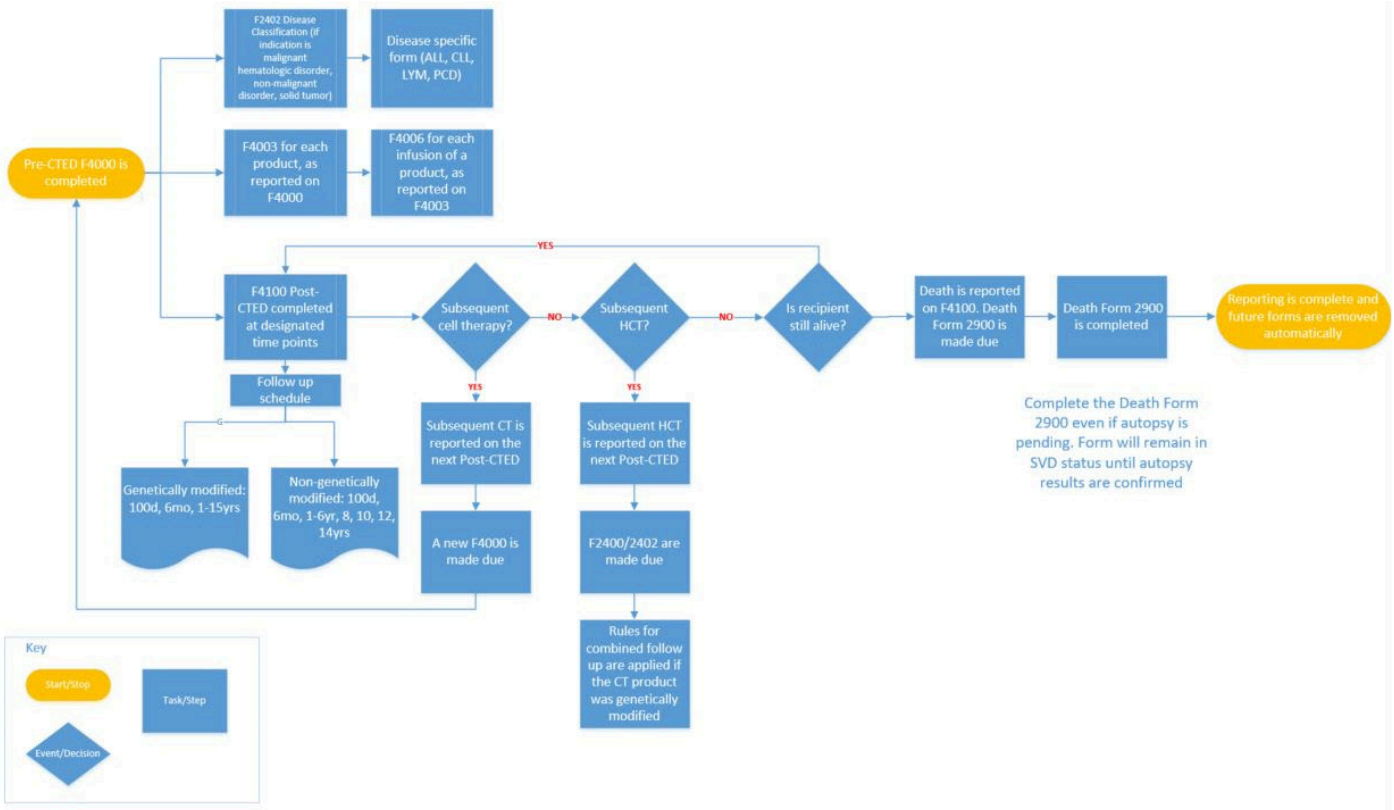
Continue to view the cellular therapy scenarios to determine what forms will come due.

Last modified: Sep 23, 2022

Cell Therapy, Stand-Alone (No HCT Forms)

Please review CIBMTR Guidance Document for Reporting Autologous Cellular Therapies to determine if the cellular therapy should be reported to CIBMTR.

This Visio flowchart shows how forms come due when the indication is Cellular Therapy (no HCT forms due).

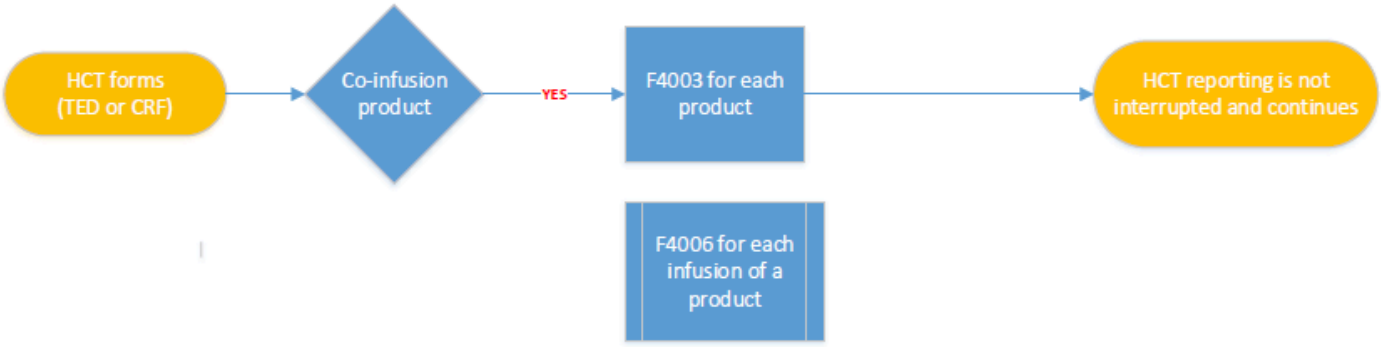


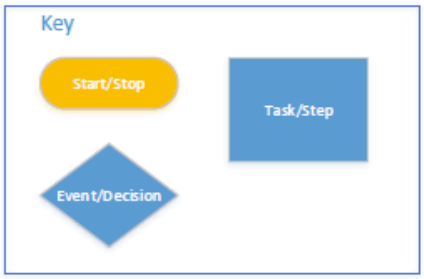
Last modified: Mar 06, 2024

Co-Infusion (with HCT)

Please see Appendix D: How to Distinguish Infusion Types for a definition of co-infusion.

This Visio flowchart shows how forms come due when there is a co-infusion.

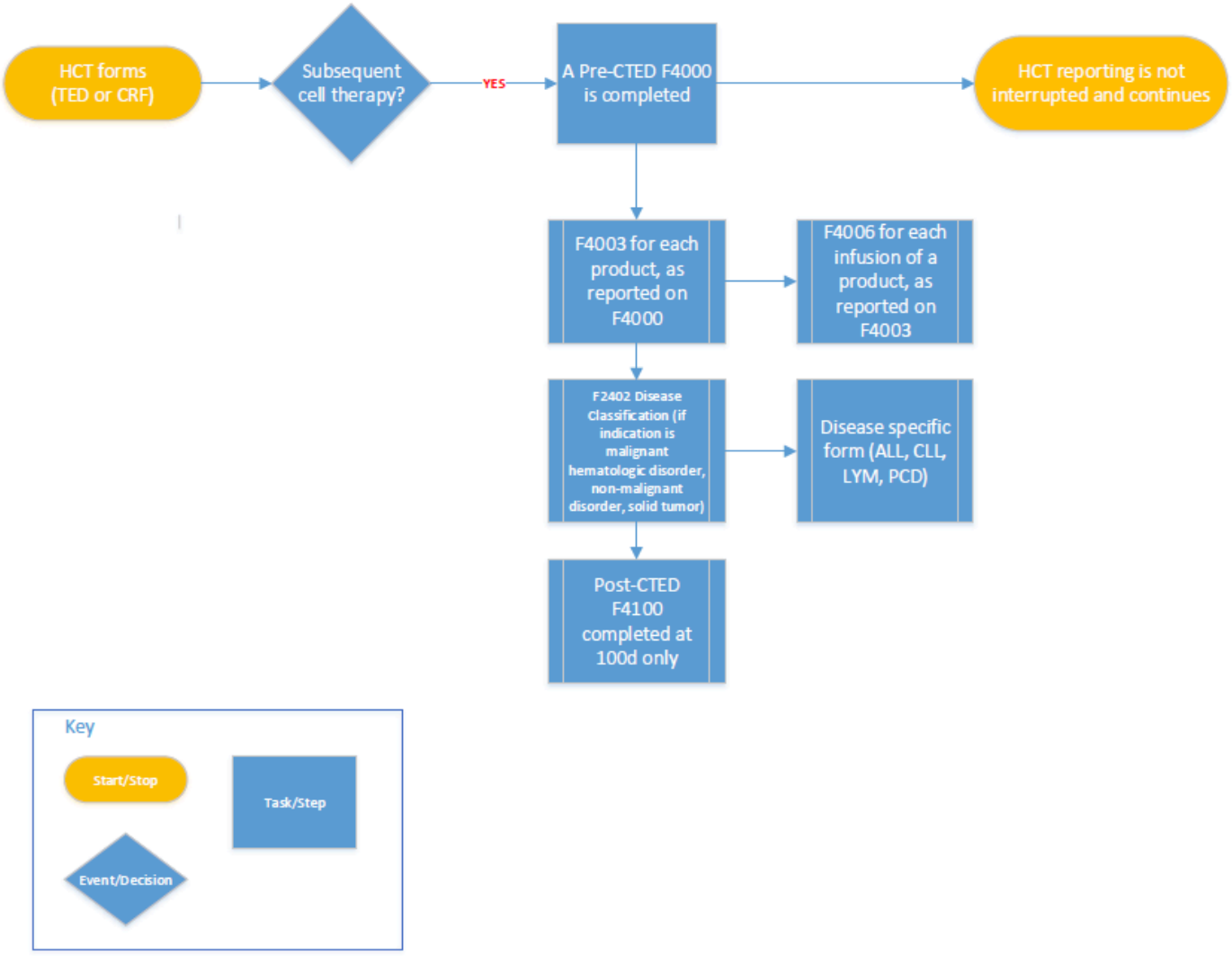




Last modified: Feb 21, 2023

Post-HCT Cellular Therapy (Not Genetically Modified)

This Visio flowchart shows how forms come due when the infusion is Post-Transplant Cellular Therapy (does not include DLIs).



Last modified: Jul 28, 2023

Combined-Follow Up Scenarios (HCT + CT (Genetically Modified))

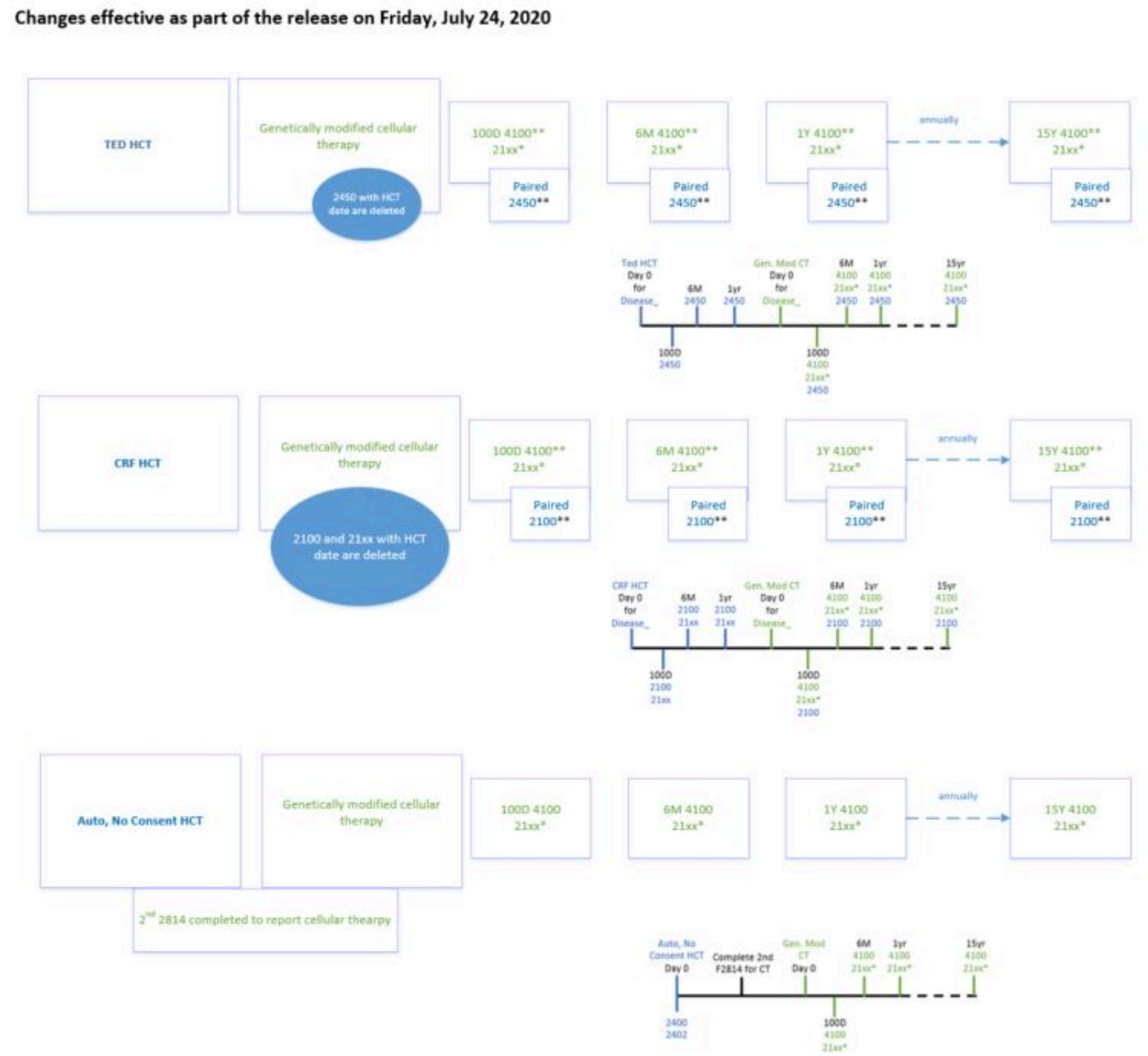
As of the Summer 2020 Release, CIBMTR implemented a hard stop when reporting multiple genetically modified cellular therapies and HCTs that require follow-up forms. This new functionality has been implemented to reduce center reporting burden and redundancies when having to report multiple cellular therapy and HCT events for a single patient.

Instead of having two sets of forms due at different timepoints, all applicable follow-up forms will be due at the same timepoints moving forward (i.e. Forms 2450+4100 or 2100+4100). **Duplicate questions on the paired forms will be disabled in identified reporting scenarios, listed in each subpage.** Defined hard stops in addition to the custom enabling and disabling will streamline follow-up reporting when a patient receives infusions for multiple indications with overlapping time periods.

Last modified: Jul 28, 2023

HCT --> CT

This Visio flowchart shows how forms come due when the HCT is first and there is combined follow up for the subsequent cellular therapy.



Questions disabled on HCT and CT forms

Question	F4100	F2450 (when TED level HCT	F2100 (when CRF level HCT
Subsequent HCT/CT	Disabled		

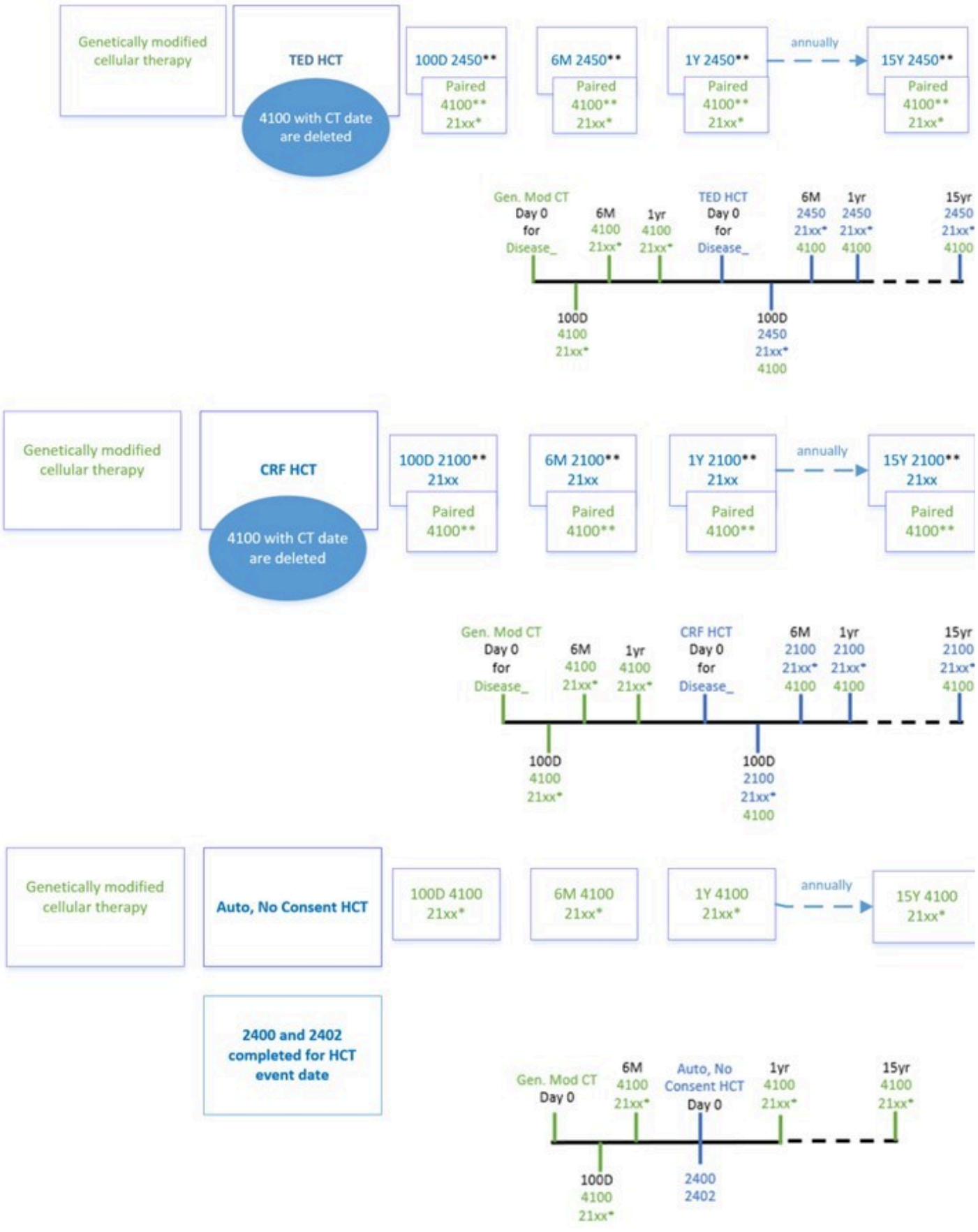
Best response to CT	Disabled when disease form present		
Relapse	Disabled when disease form present	Disabled when disease form present	Disabled when disease form present
GVHD	Disabled		
Initial ANC recovery		Disabled	Disabled
Initial platelet recovery		Disabled	Disabled
Infection Prophylaxis		N/A	Disabled
Infection		Disabled	Disabled
COVID vaccine		Disabled	Disabled
New malignancy		Disabled	Disabled
Disease assessment at time of best response		Disabled when disease form present	
Post-HCT therapy		Disabled when disease form present	
Intervention		Disabled when disease form present	
Current disease status		Disabled when disease form present	

Last modified: Sep 23, 2022

CT --> HCT

This Visio flowchart shows how forms come due when the cellular therapy is first and there is combined follow up for the subsequent HCT.

Changes effective as part of the release on Friday, July 24, 2020

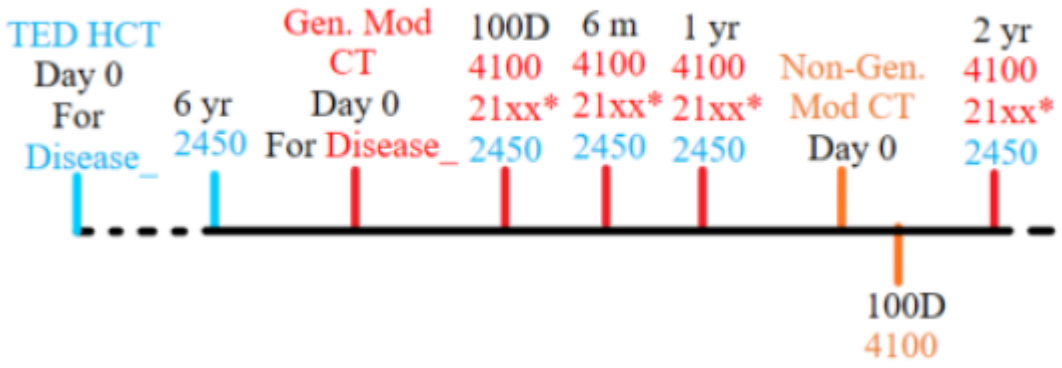


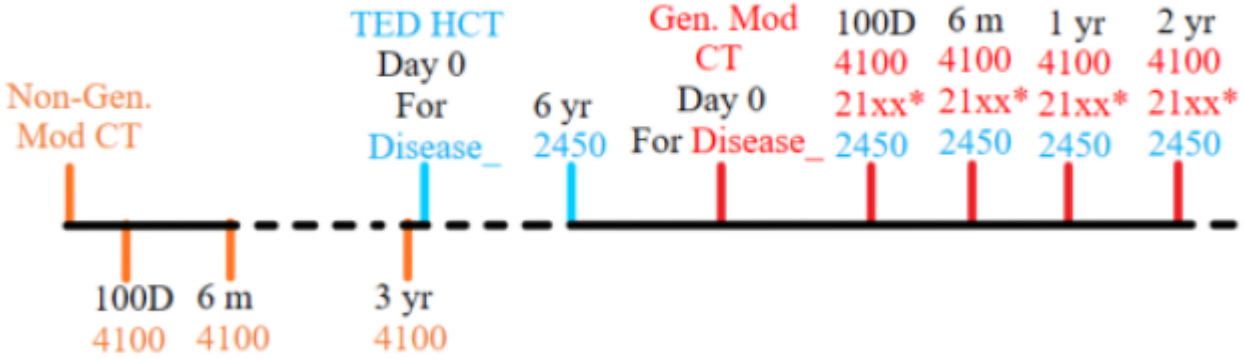
Question	F4100	F2450 (when TED level HCT	F2100 (when CRF level HCT)
Subsequent HCT/CT	Disabled		
Best response to CT	Disabled when disease form present		
Peripheral Blood Count Recovery	Disabled		
Relapse	Disabled when disease form present	Disabled when disease form present	
GVHD	Disabled		
Current hematologic findings			Disabled
Infection		Disabled	Disabled
New malignancy		Disabled	Disabled
Disease assessment at time of best response		Disabled when disease form present	
COVID vaccine		Disabled	Disabled
New malignancy		Disabled	Disabled
Post-HCT therapy		Disabled when disease form present	
Relapse		Disabled when disease form present	Disabled when disease form present
Intervention		Disabled when disease form present	
Current disease status		Disabled when disease form present	
Pregnancy			Disabled

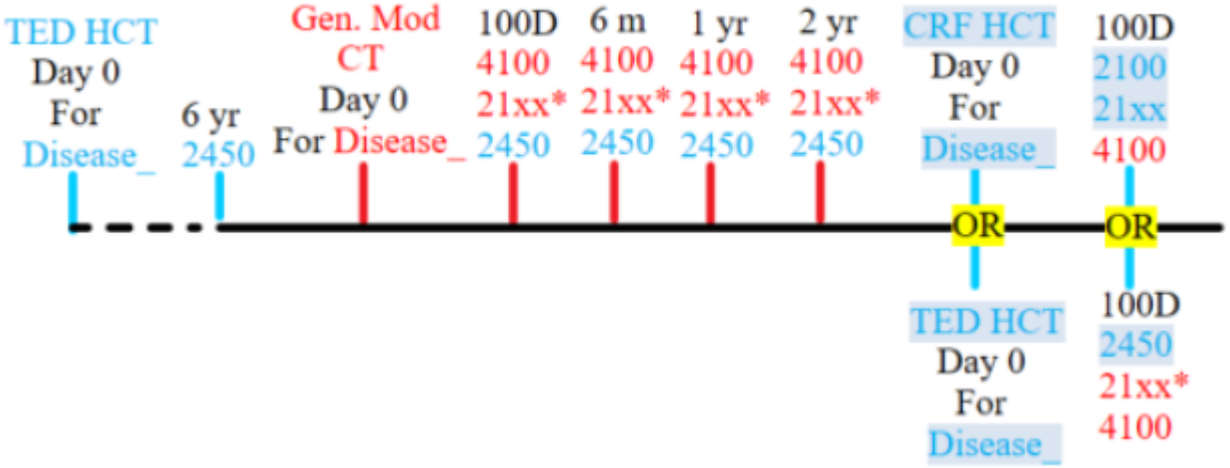
Last modified: Sep 23, 2022

3+ events

These flowcharts show how forms come due when the recipient receives three or more infusions.







Last modified: Sep 23, 2022

Common Cell Therapy Related Questions

The recipient had a CAR-T infusion followed by an HCT. I see cell therapy forms with the HCT event date, is this correct?

What you are seeing is “combined follow-up”. The intent of “combined follow-up” (when a recipient receives both an HCT and genetically modified CT) is to collect both the HCT and CT outcomes data. To achieve this, instead of creating a new ‘universal form’, CIBMTR took the existing forms and combined, or paired them together, to create a “data package”. Instead of completing the HCT and CT forms according to different event dates and having staggered reporting periods, forms have now been combined under the most recent infusion, which is why you see the F4100s with the most recent event date.

The F4100s should cover the same reporting period as the associated F2450/2100s. The reporting periods are now counted from the HCT date. The contact date on the F4100 should match the F2450/2100, but the F4100 will capture the CT specific data that does not exist on the F2450/2100. For the sections of the forms that are the same, they are disabled on either the F2450/2100 or F4100.

There is an eLearning about combined follow-up available on the CIBMTR Portal. Log in and click on the tile for “Training &eLearnings.” The video eLearning is titled “Combined Follow-Up: HCT and Cellular Therapy”. This video is short and will describe the intent as well as show examples.

There is also a page in the Data Management Guide that has illustrations of different scenarios.

The recipient had a CAR-T infusion followed by an HCT. I see HCT forms with the cell therapy event date, is this correct?

What you are seeing is “combined follow-up”. The intent of “combined follow-up” (when a recipient receives both an HCT and genetically modified CT) is to collect both the HCT and CT outcomes data. To achieve this, instead of creating a new ‘universal form’, CIBMTR took the existing forms and combined, or paired them together, to create a “data package”. Instead of completing the HCT and CT form according to different event dates and having staggered reporting periods, forms have now been combined under the most recent infusion, which is why you see the F2450/2100 with the most recent event date.

The F2450/2100s should cover the same reporting period as the associated F4100. The reporting periods are now counted from the CT date. The contact date on the F2450/2100 should match the F4100, but the F2450/2100 will capture the HCT specific data that does not exist on the F4100. For the sections of the forms that are the same, they are disabled on either the F2450/2100 or F4100.

There is an eLearning about combined follow-up available on the CIBMTR Portal. Log in and click on the tile for “Training &eLearnings.” The eLearning is titled “Combined Follow-Up: HCT and Cellular Therapy”. This video is short and will describe the intent and show examples.

There is also a page in the Data Management Guide that has illustrations of different scenarios.

Can our center be set to TED track only for cell therapy?

TED/CRF level reporting for CT is not a center level attribute like HCT reporting. It is determined by your center's reporting preference and infusion details. Each infusion will randomize separately.

Why have the follow-up forms not been removed after a death was reported?

Possibly a prior form was updated after the death was reported or a glitch occurred. First try and open the F4100 that reported the death and resubmit. The system should then remove the forms. Additionally, check to ensure that the date of death of the F2900 is the same as the date of contact on the F4100.

When can I create a new F2814 to report an infusion?

There are only 2 instances where a F2814 should be created.

- A new CRID reporting the first infusion
- An auto HCT where consent = No and there are no follow-up forms to report a subsequent infusion.

How do I report "bridging therapy"?

If a line of therapy starts before leukapheresis, but ends after leukapheresis, does it count as bridging therapy?

- No, bridging therapy is any new therapy that starts after leukapheresis. The intent is important as bridging therapy is meant to control a disease that is progressing while the product is being manufactured.

If a line of therapy contains both systemic and radiation therapy for which the systemic therapy starts before leukapheresis, but the radiation therapy starts after leukapheresis, does the radiation therapy count as bridging therapy while the systemic therapy does not, even though they are considered one line?

- If it was given to control the disease prior to infusion, then yes. If it was given for example in myeloma to alleviate pain, then no. The intent is important when determining if therapy is considered bridging.

In an opposite scenario, if a line of therapy contains both systemic and radiation therapy for which the radiation therapy starts before leukapheresis, but the systemic therapy starts after leukapheresis, does the systemic therapy count as bridging therapy, while the radiation therapy does not, even though they are considered being one line?

- Same as above.

Reporting bridging therapy on disease forms:

- Consolidation (if there was no prior relapse)
- Treatment for disease relapse (continuation of therapy for prior relapse)
- Maintenance (intrathecal chemo, but for ALL only and would be very rare)

Do I need to report a cell therapy infusion that was done at a different institution?

The subsequent CT should be reported on the appropriate follow-up form, which will make the F4000 come due. Your center is not responsible for reporting the CT done at a different center. You can attempt to transfer the CRID in FormsNet3^{SM}. If the patient will continue to be seen at your center, the other center can then transfer the CRID back after reporting the CT. If the center rejects the transfer and will not be reporting on the CT, then you can submit a request to make the F4000 NRQ.

Instructions for initiating a transfer are found in the FormsNet3^{SM} Training Guide

When I attempt to change the disease form status to LTF/SUR it gives me an error message “Access not allowed.”

First try making the F4100 LTF. The disease form status will automatically change when the F4100 is made LTF/SUR.

Last modified: Jul 28, 2023

Correcting Historical Data

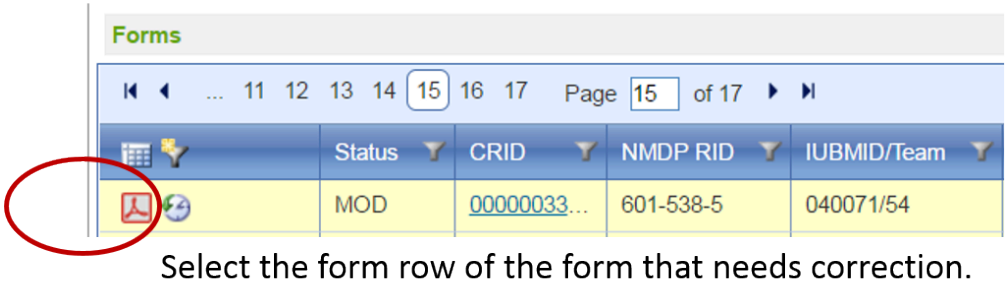
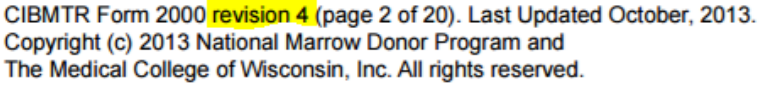
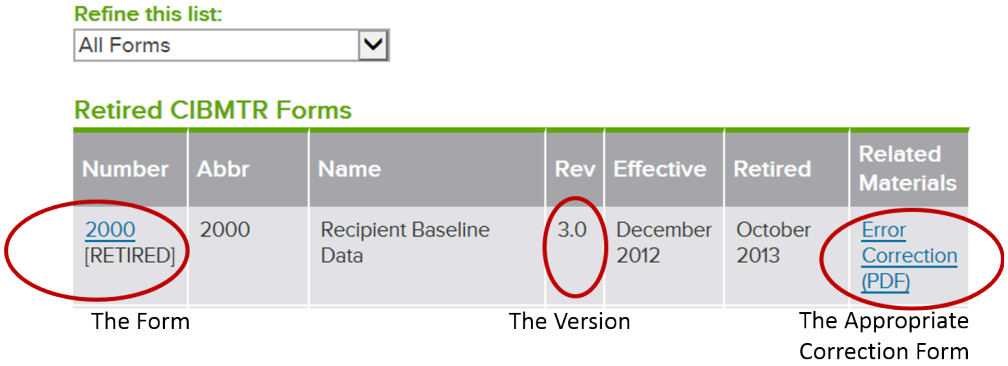
With the release of FormsNet3, all corrections to Legacy Data (submitted prior to FormsNet2) and FormsNet2 forms that aren't FormsNet3 editable, need to be sent via Paper Error Corrections.

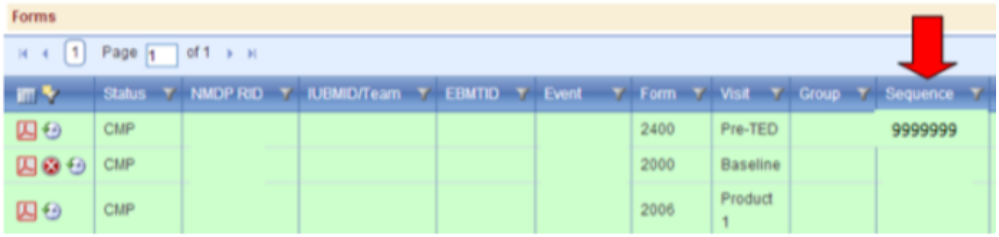
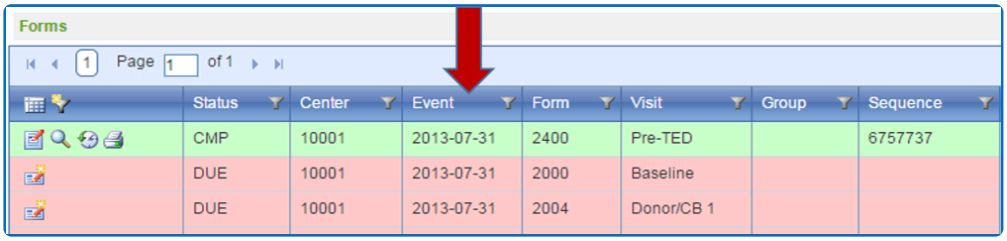
Data entered into FormsNet3 (since 12/4/12) or on FormsNet3 editable FormsNet2 forms should be corrected in FormsNet3.

Last modified: Mar 08, 2024

FormsNet2 Paper EC Process

Error corrections for FormsNet2 versions of the forms are available on the Retired Forms page of CIBMTR's website. Please make sure to use the correct version of the form that was completed for all FormsNet2 documents. The question number and sometimes entire questions may be different depending on the version of the form used.

To Find the Appropriate Form	Select the PDF symbol of the form that needs correction from the first column of the **Forms Grid** 
To Find the Form Version	Look to the bottom of the form's page 
To Find the Error Correction Form	From the Retired Forms webpage, on the same row, select the form, and the version, on the far right column is the Error Correction form. 
To Find the Sequence Numbers	In the **Recipient Forms** tab, the Forms Due Grid displays the sequence number for each form. This number is used by data entry to assure corrections are made to the right form.

	 Forms Page 1 of 1 Status / NMDP RID / IUBMID/Team / EBMTID / Event / Form / Visit / Group / Sequence CMP / 2400 / Pre-TED / 9999999 CMP / 2000 / Baseline CMP / 2006 / Product 1 **Note**: The CRID Assignment Form 2804 does not have a sequence number, so this field should be left blank on the banner.
To Find the Infusion Date	The infusion date is located in the 'Event' column. Be aware which infusion the form was submitted for, if there are more than one for the patient  Forms Page 1 of 1 Status / Center / Event / Form / Visit / Group / Sequence CMP / 10001 / 2013-07-31 / 2400 / Pre-TED / 6757737 DUE / 10001 / 2013-07-31 / 2000 / Baseline DUE / 10001 / 2013-07-31 / 2004 / Donor/CB 1

Last modified: Mar 08, 2024

Legacy Error Corrections

How to make changes to Legacy Data

“Legacy data” are data submitted to CIBMTR or NMDP before the FormsNet2 application became available on December 3, 2007. If you need to make changes to data that were submitted to the legacy databases, please send an error correction to document the change.

You only need to send the page that has the information on it that needs to be changed. For all corrections, please indicate “LEGACY ERROR CORRECTION” on the page so we know where to find the data that you are changing.

The procedures to follow are different depending on whether corrections are being made to NMDP or CIBMTR forms.

NMDP forms

Blank Error Correction pages for NMDP forms are available on the Retired Forms page of CIBMTR’s website.

- Follow the instructions on Completing the Error Correction Form
- The sequence number from the legacy forms is not available in FormsNet3. This may be left blank and a CRC will add this for you.

IBMTR / ABMTR forms

For IBMTR / ABMTR forms, if you need to change data on a previously submitted old version IBMTR form (002 Core or earlier), please copy the original page of the old form and indicate “LEGACY ERROR CORRECTION” on the top of the page. Please cross out the original answer, and record the correct answer and circle it. Please initial and date your changes and send to your assigned campus. If the original CIBMTR form is not available, you may create a CIBMTR Center Support ticket containing the following information:

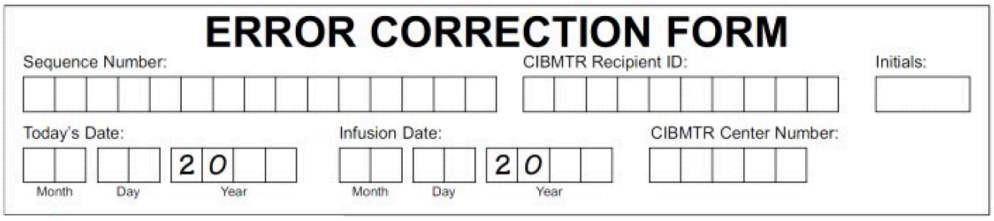
- Old IBMTR Team #
- Recipient IUBMID #
- Date of Birth
- Date of HCT that the correction pertains to
- Which form is being corrected and the Question Number
- A clear explanation of the change that needs to be made

Note: If you submitted NMDP data to both organizations, you do not need to submit corrections to both campuses. Send the corrections to CIBMTR Center Support. They will ensure that the information is changed in the legacy databases and in FormsNet if applicable.

Last modified: Mar 07, 2024

Completing Error Correction Forms

The banner box needs to be completed for each page.



1. Provide the Sequence Number from the original form
2. Provide the CRID, Infusion Date, and Center Number
3. Today's Date – is the date you are completing the EC
4. Provide your initials in the 'Initials' box to indicate that you are approving the change

You only need to complete the questions on the form where updates to the data are required. It is helpful to highlight these changes with an arrow or circle, especially if the change is small. Be aware, a change to one question may result in other questions needing to be answered or deleted. Only the page(s) with data changes need to be sent.

Submit the form via the CIBMTR Center Support. (FormsNet3 Technical Request > Queries/Error Corrections)

Last modified: Oct 17, 2022

Primary Disease and Disease Forms Due

This section is useful for determining which disease inserts should be completed for the disease reported on a recipient's Disease Classification Form 2402. The disease insert should appear in FormsNet for those on the CRF track after the Pre-TED Form 2400 and Disease Classification Form 2402 are submitted, and for cellular therapy patients once the Pre-CTED Form 4000 and Disease Classification Form 2402 are submitted. No disease inserts are due for those on the TED reporting track.

Last modified: Jul 16, 2021

Acute myelogenous leukemia (AML or ANLL)

Disease Subtype(s)	HCT Disease Inserts required	Cellular Therapy Disease Inserts required
AML with recurrent genetic abnormalities • AML with t(9;11) (p22.3;q23.3); MLLT3-KMT2A (5) • AML with t(6;9) (p23;q34.1); DEK-NUP214 (6) • AML with inv(3) (q21.3;q26.2) or t(3;3) (q21.3;q26.2); GATA2, MECOM (7) • AML (megakaryoblastic) with t(1;22) (p13.3;q13.3); RBM15-MKL1 (8) • AML with t(8;21); (q22; q22.1); RUNX1-RUNX1T1 (281) • AML with inv(16)(p13.1;1q22) or t(16;16)(p13.1; q22); CBFB-MYH11 (282) • APL with PML-RARA (283) • AML with BCR-ABL1 (provisional entity) (3) • AML with mutated NPM1 (4) • AML with biallelic mutations of CEBPA (297) • AML with mutated RUNX1 (provisional entity) (298) • AML with 11q23 (MLL) abnormalities (i.e., t(4;11), t(6;11), t(9;11), t(11;19)) (284) • AML with myelodysplasia – related changes (285) • Therapy related AML (t-AML) (9)	Forms 2010 & 2110	No disease inserts required

AML, not otherwise specified • AML, not otherwise specified (280) • AML, minimally differentiated (286) • AML without maturation (287) • AML with maturation (288) • Acute myelomonocytic leukemia (289) • Acute monoblastic / acute monocytic leukemia (290) • Acute erythroid leukemia (erythroid / myeloid and pure erythroleukemia) (291) • Acute megakaryoblastic leukemia (292) • Acute basophilic leukemia (293) • Acute panmyelosis with myelofibrosis (294) • Myeloid sarcoma (295) • Myeloid leukemia associated with Down syndrome (299)	Forms 2010 & 2110

Last modified: Jun 27, 2017

Acute lymphoblastic leukemia (ALL)

Disease Subtype(s)	HCT Disease Inserts required	Cellular Therapy Disease Inserts required
B-lymphoblastic leukemia / lymphoma • B-lymphoblastic leukemia / lymphoma, NOS (B-cell ALL, NOS) (191) • B-lymphoblastic leukemia / lymphoma with t(9;22)(q34.1;q11.2); BCR-ABL1 (192) • B-lymphoblastic leukemia / lymphoma with t(v;11q23.3); KMT2A rearranged (193) • B-lymphoblastic leukemia / lymphoma with t(1;19)(q23;p13.3); TCF3-PBX1 (194) • B-lymphoblastic leukemia / lymphoma with t(12;21)(p13.2;q22.1); ETV6-RUNX1 (195) • B-lymphoblastic leukemia / lymphoma with t(5;14)(q31.1;q32.3); IL3-IGH (81) • B-lymphoblastic leukemia / lymphoma with Hyperdiploidy (51-65 chromosomes) (82) • B-lymphoblastic leukemia / lymphoma with Hypodiploidy (<45 chromosomes) (83) • B-lymphoblastic leukemia / lymphoma, BCR-ABL1-like (provisional entity) (94) • B-lymphoblastic leukemia / lymphoma, with iAMP21 (provisional entity) (95) • T-cell lymphoblastic leukemia / lymphoma (precursor T-cell ALL) (196) • Early T-cell precursor lymphoblastic leukemia (provisional entity) (96) • Natural killer (NK)- cell lymphoblastic leukemia / lymphoma (provisional entity) (97)	Form 2011 & 2111	Form 2011/2011

Last modified: Jul 28, 2021

Acute Leukemias of Ambiguous Lineage and Other Myeloid Neoplasms

Disease Subtype(s)	HCT Disease Inserts required	Cellular Therapy Disease Inserts required
• Blastic plasmacytoid dendritic cell neoplasm (296) • Acute undifferentiated leukemia (31) • Mixed phenotype acute leukemia (MPAL) with t(9;22)(q34.1;q11.2); BCR-ABL1 (84) • Mixed phenotype acute leukemia with t(v;11q23.3); KMT2A rearranged (85) • Mixed phenotype acute leukemia, B/myeloid, NOS (86) • Mixed phenotype acute leukemia, T/myeloid, NOS (87) • Other acute leukemia of ambiguous lineage or myeloid neoplasm (88)	Forms 2010 & 2110	No disease insert required

Last modified: Jun 27, 2017

Chronic myelogenous leukemia (CML)

Disease Subtype(s)	HCT Disease Inserts required	Cellular Therapy Disease Inserts required
Not Applicable	Forms 2012 &2112	No disease insert required

Last modified: Jul 28, 2021

Myelodysplastic (MDS)

Disease Subtype(s)	HCT Disease Inserts required	Cellular Therapy Disease Inserts required
• Atypical chronic myeloid leukemia (aCML), BCR-ABL1 (1440) • Chronic myelomonocytic leukemia (CMMoL) (54) • Myelodysplastic syndrome / myeloproliferative neoplasm, unclassifiable (69) • MDS / MPN with ring sideroblasts and thrombocytosis (MDS / MPN-RS-T) (1452) • Myelodysplastic syndrome (MDS), unclassifiable (50) • Myelodysplastic syndrome with isolated del(5q) (66) • Myelodysplastic syndrome with multilineage dysplasia (MDS-MLD) (64) • Myelodysplastic syndrome with single lineage dysplasia (MDS-SLD) (51) • Refractory cytopenia of childhood (68) **Myelodysplastic syndrome with excess blasts (MDS-EB)** • MDS with excess blasts-1 (MDS-EB-1) (61) • MDS with excess blasts-2 (MDS-EB-2) (62) **Myelodysplastic syndrome with ring sideroblasts (MDS-RS)** • MDS-RS with single lineage dysplasia (MDS-RS-SLD) (1453) • MDS-RS with multilineage dysplasia (MDS-RS-MLD) (1454)	Forms 2014 & 2114	No disease inserts required

Disease Subtype(s)	HCT Disease Inserts required	Cellular Therapy Disease Inserts required
• Juvenile myelomonocytic leukemia (JMML/JCML)(no evidence of Ph1 or BCR/ABL)(36)	Forms 2015 & 2115	No disease insert required

Last modified: Jul 28, 2021

Myeloproliferative Neoplasms (MPN)

Disease Subtype(s)	HCT Disease Inserts required	Cellular Therapy Disease Inserts required
• Chronic neutrophilic leukemia (165) • Chronic eosinophilic leukemia, not otherwise specified (NOS) (166) • Essential thrombocythemia (58) • Myeloproliferative neoplasms (MPN), Unclassifiable (60) • Polycythemia vera (PCV) (57) • Primary myelofibrosis (PMF) (167)	Forms 2057 & 2157	No disease inserts required

Disease Subtype(s)	HCT Disease Inserts required	Cellular Therapy Disease Inserts required
• Myeloid / lymphoid neoplasms with PDGFRA rearrangement (1461) • Myeloid / lymphoid neoplasms with PDGFRB rearrangement (1462) • Myeloid / lymphoid neoplasms with FGFR1 rearrangement (1463) • Myeloid / lymphoid neoplasms with PCM1-JAK2 (1464) **Mastocytosis** • Cutaneous mastocytosis (CM) (1465) • Systemic mastocytosis (1470) • Mast cell sarcoma (MCS) (1466)	No disease insert required	No disease insert required

Last modified: Jul 28, 2021

Other Leukemia

Disease Subtype(s)	HCT Disease Inserts required	Cellular Therapy Disease Inserts required
• Chronic lymphocytic leukemia (CLL), NOS (34) • Chronic lymphocytic leukemia (CLL), B-cell / small lymphocytic lymphoma (SLL) (71)	Form 2013 & 2113	Form 2013 & 2113
• Hairy cell leukemia (35) • Hairy cell leukemia variant (75) • Monoclonal B-cell lymphocytosis (76)	No disease insert required	No disease insert required
• Prolymphocytic leukemia (PLL), NOS (37) • PLL, B-cell (73) • PLL, T-cell (74)	Form 2013 & 2113	Form 2013 & 2113
• Other leukemia, NOS (30) • Other leukemia (39)	Form 2010 & 2110	No disease insert required

Last modified: Jul 28, 2021

Hodgkin Lymphoma

Disease Subtype(s)	HCT Disease Inserts required	Cellular Therapy Disease Inserts required
• Nodular lymphocyte predominant Hodgkin lymphoma (155) • Lymphocyte-rich (151) • Nodular sclerosis (152) • Mixed cellularity (153) • Lymphocyte depleted (154) • Hodgkin lymphoma, NOS (150)	Form 2018 & 2118	No disease inserts required

Last modified: Jun 27, 2017

Non-Hodgkin Lymphoma

Disease Subtype(s)	HCT Disease Inserts required	Cellular Therapy Disease Inserts required
B-cell neoplasms • ALK+ large B-cell lymphoma (1833) • B-cell lymphoma, unclassifiable, with features intermediate between DLBCL and classical Hodgkin lymphoma (149) • Burkitt lymphoma (111) • Burkitt-like lymphoma with 11q aberration (1834) • Diffuse, large B-cell lymphoma- Activated B-cell type (non-GCB) (1821) – Go to question 382 • Diffuse, large B-cell lymphoma- Germinal center B-cell type (1820) – Go to question 382 • Diffuse large B-cell Lymphoma (cell of origin unknown) (107) • DLBCL associated with chronic inflammation (1825) • Duodenal-type follicular lymphoma (1815) • EBV+ DLBCL, NOS (1823) • EBV+ mucocutaneous ulcer (1824) • Extranodal marginal zone B-cell lymphoma of mucosal associated lymphoid tissue type (MALT) (122) • Follicular, mixed, small cleaved and large cell (Grade II follicle center lymphoma) (103) • Follicular, predominantly large cell (Grade IIIA follicle center lymphoma) (162) • Follicular, predominantly large cell (Grade IIIB follicle center lymphoma) (163) • Follicular, predominantly large cell (Grade IIIA vs IIIB not specified) (1814) • Follicular, predominantly small cleaved cell (Grade I follicle center lymphoma) (102) • Follicular (grade unknown) (164) • HHV8+ DLBCL, NOS (1826) • High-grade B-cell lymphoma, with MYC and BCL2 and/or BCL6 rearrangements (1831) • High-grade B-cell lymphoma, NOS (1830) • Intravascular large B-cell lymphoma (136) • Large B-cell lymphoma with IRF4 rearrangement (1832) • Lymphomatoid granulomatosis (1835) • Mantle cell lymphoma (115)	Forms 2018 & 2118	Forms 2018 & 2118

• Nodal marginal zone B-cell lymphoma (± monocytoid B-cells) (123) • Pediatric nodal marginal zone lymphoma (1813) • Pediatric-type follicular lymphoma (1816) • Plasmablastic lymphoma (1836) • Primary cutaneous DLBCL, leg type (1822) • Primary cutaneous follicle center lymphoma (1817) • Primary diffuse, large B-cell lymphoma of the CNS (118) • Primary effusion lymphoma (138) • Primary mediastinal (thymic) large B-cell lymphoma (125) • Splenic B-cell lymphoma/leukemia, unclassifiable (1811) • Splenic diffuse red pulp small B-cell lymphoma (1812) • Splenic marginal zone B-cell lymphoma (124) • T-cell / histiocytic rich large B-cell lymphoma (120) • Waldenstrom macroglobulinemia / Lymphoplasmacytic lymphoma (173) • Other B-cell lymphoma (129) **T-cell / NK cell neoplasms** • Adult T-cell lymphoma / leukemia (HTLV1 associated) (134) • Aggressive NK-cell leukemia (27) • Anaplastic large-cell lymphoma (ALCL), ALK positive (143) • Anaplastic large-cell lymphoma (ALCL), ALK negative (144) • Angioimmunoblastic T-cell lymphoma (131) • Breast implant–associated anaplastic large-cell lymphoma (1861) • Chronic lymphoproliferative disorder of NK cells (1856) • Enteropathy-type T-cell lymphoma (133) • Extranodal NK / T-cell lymphoma, nasal type (137) • Follicular T-cell lymphoma (1859) • Hepatosplenic T-cell lymphoma (145) • Indolent T-cell lymphoproliferative disorder of the GI tract (1858) • Monomorphic epitheliotropic intestinal T-cell lymphoma (1857) • Mycosis fungoides (141) • Nodal peripheral T-cell lymphoma with TFH phenotype (1860) • Peripheral T-cell lymphoma (PTCL), NOS (130) • Primary cutaneous acral CD8+ T-cell lymphoma (1853) • Primary cutaneous CD4+ small/medium T-cell lymphoproliferative disorder (1854) • Primary cutaneous CD8+ aggressive epidermotropic cytotoxic T-cell lymphoma (1852) • Primary cutaneous CD30+ T-cell lymphoproliferative disorders [Primary cutaneous anaplastic large-cell lymphoma (C-ALCL), lymphoid papulosis] (147) • Primary cutaneous γδ T-cell lymphoma (1851)		

• Sezary syndrome (142) • Subcutaneous panniculitis-like T-cell lymphoma (146) • Systemic EBV+ T-cell lymphoma of childhood (1855) • T-cell large granular lymphocytic leukemia (126) • Other T-cell / NK-cell lymphoma (139) **Post transplant lymphoproliferative disorders (PTLD)** • Classical Hodgkin lymphoma PTLD (1876) • Florid follicular hyperplasia PTLD (1873) • Infectious mononucleosis PTLD (1872) • Monomorphic PTLD (B- and T-/NK-cell types) (1875) • Plasmacytic hyperplasia PTLD (1871) • Polymorphic PTLD (1874)		

Last modified: Jul 20, 2022

NHL-Waldenstrom

Disease Subtype(s)	HCT Disease Inserts required	Cellular Therapy Disease Inserts required
• Waldenstrom macroglobulinemia / Lymphoplasmacytic lymphoma (173)	Forms 2019 & 2119	No disease insert required

Last modified: Jun 27, 2017

Multiple Myeloma/Plasma Cell Disorder (PCD)

Disease Subtype(s)	HCT Disease Inserts required	Cellular Therapy Disease Inserts required
• Multiple myeloma (178) • Multiple myeloma-light chain only (186) • Multiple myeloma non-secretory (187) • Plasma cell leukemia (172) • Solitary plasmacytoma (no evidence of myeloma) (175) • Smoldering myeloma (180) • Amyloidosis (174) • Osteosclerotic myeloma / POEMS syndrome (176) • Monoclonal gammopathy of renal significance (MGRS) (1611) • Other plasma cell disorder (179)	Form 2016 & 2116	No disease insert required

Last modified: Jul 28, 2021

Solid Tumors

Disease Subtype(s)	HCT Disease Inserts required	Cellular Therapy Disease Inserts required
• Breast cancer (250)	No disease insert required	No disease insert required
• Lung, small cell (202) • Lung, non-small cell (203) • Lung, not otherwise specified (230)	No disease insert required	No disease insert required
• Germ cell tumor, extragonadal (225) • Testicular (210)	Form 2022/2122	No disease insert required
• Ovarian (epithelial) (214)	No disease insert required	No disease insert required
• Bone sarcoma (excluding Ewing family tumors) (273) • Ewing family tumors of bone (including PNET) (275) • Ewing family tumors, extraosseous (including PNET) (276) • Fibrosarcoma (244) • Hemangiosarcoma (246) • Leiomyosarcoma (242) • Liposarcoma (243) • Lymphangio sarcoma (247) • Neurogenic sarcoma (248) • Rhabdomyosarcoma (232) • Synovial sarcoma (245) • Soft tissue sarcoma (excluding Ewing family tumors) (274)	Form 2024/2124	No disease insert required
• Central nervous system tumor, including CNS PNET (220) • Medulloblastoma (226)	Form 2025/2125	No disease insert required
• Neuroblastoma (222)	Form 2026/2126	No disease insert required
• Head / neck (201) • Mediastinal neoplasm (204) • Colorectal (228) • Gastric (229) • Pancreatic (206) • Hepatobiliary (207)	No disease insert required	No disease insert required

• Prostate (209) • External genitalia (211) • Cervical (212) • Uterine (213) • Vaginal (215) • Melanoma (219) • Wilm tumor (221) • Retinoblastoma (223) • Thymoma (231) • Other solid tumor (269) • Solid tumor, not otherwise specified (200)		
• Renal cell (208)	No disease insert required	No disease insert required

Last modified: Jul 28, 2021

Aplastic Anemia

Disease Subtype(s)	HCT Disease Inserts	Cellular Therapy Disease Inserts
• Acquired severe aplastic anemia, not otherwise specified (301) • Acquired AA secondary to chemotherapy (313) • Acquired SAA secondary to hepatitis (302) • Acquired AA secondary to immunotherapy or immune effector cell therapy (314) • Acquired SAA secondary to toxin / other drug (303) • Acquired amegakaryocytosis (not congenital) (304) • Acquired pure red cell aplasia (not congenital) (306) • Other acquired cytopenic syndrome (309)	Forms 2028 & 2128	No disease insert required

Last modified: Jul 28, 2021

Inherited Bone Marrow Failure Syndromes

Disease Subtype(s)	HCT Disease Inserts	Cellular Therapy Disease Inserts
• Diamond-Blackfan anemia (pure red cell aplasia) (312) • Dyskeratosis congenita (307) • Severe congenital neutropenia (including Kostmann syndrome) (460) • Shwachman-Diamond (305)	Forms 2028 & 2128	No disease insert required
• Fanconi anemia (311)	Form 2029 & 2129	No disease insert required

Last modified: Jun 10, 2022

Hemoglobinopathies

Disease Subtype(s)	HCT Disease Inserts	Cellular Therapy Disease Inserts
• Sickle cell disease (356)	Forms 2030 & 2130	No disease insert required
• Transfusion dependent thalassemia (360) • Other hemoglobinopathy (359)	No disease insert required	No disease insert required

Last modified: Jul 28, 2021

Disorders of the immune system

Disease Subtype(s)	HCT Disease Inserts	Cellular Therapy Disease Inserts
• Adenosine deaminase (ADA) deficiency / severe combined immunodefiency (SCID)(401) • Absence of T and B cells SCID (402) • Absence of T, normal B cell SCID (403) • Omenn syndrome (404) • Reticular dysgenesis (405) • Bare lymphocyte syndrome (406) • Other SCID (419) • SCID, not otherwise specified (410) • Ataxia telangiectasia (451) • HIV infection (452) • DiGeorge anomaly (454) • Common variable immunodeficiency (457) • Leukocyte adhesion deficiencies, including GP180, CD-18, LFA and WBC adhesion deficiencies (459) • Neutrophil actin deficiency (461) • Cartilage-hair hypoplasia (462) • CD40 ligand deficiency (464) • Other immunodeficiencies (479) • Immune deficiency, not otherwise specified (400)	Forms 2031 & 2131	No disease insert required

Disease Subtype(s)	HCT Disease Inserts	Cellular Therapy Disease Inserts
• Chediak-Higashi syndrome (456) • Griscelli syndrome type 2 (465) • Hermansky-Pudlak syndrome type 2 (466) • Other pigmentary dilution disorder (469)	Forms 2056 & 2156	No disease insert required
• Chronic granulomatous disease (455)	Forms 2055 & 2155	No disease insert required
• Wiskott-Aldrich syndrome (453)	Forms 2033 & 2133	No disease insert required
• X-linked lymphoproliferative syndrome (458)	Forms 2034 & 2134	No disease insert required

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Inherited abnormalities of platelets

Disease Subtype(s)	HCT Disease Inserts	Cellular Therapy Disease Inserts
• Congenital amegakaryocytosis / congenital thrombocytopenia (501)	Forms 2035 & 2135	No disease insert is required
• Glanzmann thrombasthenia (502) • Other inherited platelet abnormality (509)	No disease insert required	No disease insert required

Last modified: Jun 27, 2017

Inherited disorders of metabolism

Disease Subtype(s)	HCT Disease Inserts	Cellular Therapy Disease Inserts
• Osteopetrosis(malignant infantile osteopetrosis) (521)	Forms 2036 & 2136	No disease insert required
Leukodystrophies • Metachromatic leukodystrophy (MLD) (542) • Adrenoleukodystrophy (ALD) (543) • Krabbe disease (globoid leukodystrophy) (544)	Forms 2037 & 2137	No disease insert required
• Lesch-Nyhan (HGPRT deficiency) (522) • Neuronal ceroid lipofuscinosis (Batten disease) (523) **Mucopolysaccharidosis** • Hurler syndrome (IH) (531) • Scheie syndrome (IS) (532) • Hunter syndrome (II) (533) • Sanfilippo (III) (534) • Morquio (IV) (535) • Maroteaux-Lamy (VI) (536) • β-glucuronidase deficiency (VII) (537) • Mucopolysaccharidosis (V) (538) • Mucopolysaccharidosis, not otherwise specified (530) **Mucolipidoses** • Gaucher disease (541) • Niemann-Pick disease (545) • I-cell disease (546) • Wolman disease (547) • Glucose storage disease (548) • Mucolipidoses, not otherwise specified (540) **Polysaccharide hydrolase abnormalities** • Aspartyl glucosaminidase (561) • Fucosidosis (562) • Mannosidosis (563) • Polysaccharide hydrolase abnormality, not otherwise specified (560) • Other inherited metabolic disorder (529) • Inherited metabolic disorder, not otherwise specified (520)	Forms 2038 & 2138	No disease insert required

Last modified: Jul 28, 2021

Histiocytic disorders

Disease Subtype(s)	HCT Disease Inserts	Cellular Therapy Disease Inserts
• Hemophagocytic lymphohistiocytosis (HLH) (571)	Form 2039 & 2139	No Disease Insert Required
• Langerhans cell histiocytosis (histiocytosis-X) (572)	Form 2040 & 2140	No Disease Insert Required
• Hemophagocytosis (reactive or viral associated) (573) • Malignant histiocytosis (574) • Other histiocytic disorder (579) • Histiocytic disorder, not otherwise specified (570)	No Disease Insert Required	No Disease Insert Required

Last modified: Jun 27, 2017

Autoimmune diseases

Disease Subtype(s)	HCT Disease Inserts	Cellular Therapy Disease Inserts
Multiple sclerosis • Multiple sclerosis (602)	Form 2043 & 2143	No disease insert required
Connective tissue diseases • Systemic sclerosis (scleroderma) (607)	Form 2044 & 2144	No disease insert required
Arthritis • Rheumatoid arthritis (603) • Psoriatic arthritis / psoriasis (604) • Juvenile idiopathic arthritis (JIA): systemic (Stills disease) (640) • JIA: oligoarticular (641) • JIA: polyarticular (642) • JIA: other (643) • Other arthritis (633) **Connective tissue diseases** • Systemic lupus erythematosis (SLE) (605) • Sjögren syndrome (608) • Polymyositis / dermatomyositis (606) • Antiphospholipid syndrome (614) • Other connective tissue disease (634) **Vasculitis** • Wegener granulomatosis (610) • Classical polyarteritis nodosa (631) • Microscopic polyarteritis nodosa (632) • Churg-Strauss (635) • Giant cell arteritis (636) • Takayasu (637) • Behcet syndrome (638) • Overlap necrotizing arteritis (639) • Other vasculitis (611) **Other neurologic autoimmune disease** • Myasthenia gravis (601) • Other autoimmune neurological disorder (644) **Hematologic autoimmune disease** • Idiopathic thrombocytopenic purpura (ITP) (645) • Hemolytic anemia (646) • Evan syndrome (647) • Other autoimmune cytopenia (648)	No disease insert required	No disease insert required

Bowel disease • Crohn's disease (649) • Ulcerative colitis (650) • Other autoimmune bowel disorder (651) **Metabolic** • Diabetes mellitus type 1 (660) **Other** • Other autoimmune disease (629)		

Last modified: Jul 28, 2021

Quarterly Form Revision Schedule

The following forms are currently being revised/developed. Check back for new forms, and updates to the anticipated release dates.
Full details regarding the revisions (e.g. new questions, modified questions, removed questions) are located on the CIBMTR Portal. {Training & eLearning > Job Aids > FormsNet3 Quarterly Releases}

Next Quarterly Release: July 26, 2024

Spring 2024 (April 19, 2024)

Forms	Notes
F2402r8 Disease Classification Form	

Winter 2024 (January 26, 2024)

Forms	Notes
F2542r2 Mogamulizumab (Poteligeo) Supplemental Data Collection Form	

Fall 2023 (October 27, 2023)

Forms	Notes
F2100r9 Post-HSCT Data Form	
F2103r1 Gene Therapy Persistence Form	NEW Form

Summer 2023 (July 28, 2023)

Forms	Notes
F4000r10 Pre-Cellular Therapy Essential Data Form	
F4001r1 Pre-Cellular Therapy Baseline Data Form	NEW Form
F4100r9 Post-Cellular Therapy Essential Data Form	
F4101r1 Post-Cellular Therapy Follow-Up Form	NEW Form

Spring 2023 (April 21, 2023)

Forms	Notes
No form revisions	—

For more information about the forms, or revision schedule, please open a ticket via CIBMTR Center Support >Form Revision.

Last modified: Apr 19, 2024

Monthly Maintenance Items for FormsNet3

Each month the FormsNet3 team makes updates to validations, question enabling/disabling and form generation.
The monthly maintenance updates are tentatively scheduled for the 4th Friday of the month.

April 2024 (released April 19, 2024)

Form_Revision	Question	Type of Change	Current	New	Rationale for Change
F2100 r9	Q245-249	Validation (Modify)	Covid-19 vaccine questions must be answered	Questions disabled	Burden reduction, no longer collecting data
F2400 r10	Q87-94	Validation (Modify)	Covid-19 infection and vaccine questions must be answered	Questions disabled	
	Q95	Modify (Floating Text)	Is there a history of mechanical ventilation (*excluding COVID-19 (SARS-CoV-2)*)?	Is there a history of mechanical ventilation?	
F2450 r7	Q49-55	Validation (Modify)	Covid-19 infection and vaccine questions must be answered	Questions disabled	
F4000 r10	Q81-90	Validation (Modify)	Covid-19 pre-exposure drugs, infection and vaccine questions must be answered	Questions disabled	
F4100 r9	Q183-189	Validation (Modify)	Covid-19 pre-exposure drugs and vaccine questions must be answered	Questions disabled	

F2003 r1	Q13 and 20	Validation (Modify)	Questions must be answered	If and only if Q1 = other, then Q13 and Q20 must be answered	Burden reduction
F2037 r3	Q54	Smart Navigation	If Q54 = normal, then go to Q57	If Q54 = normal, then go to Q55	Data quality improvement, gadolinium information being collected
	Q55	Validation (Modify)	If and only if Q54 = abnormal, then Q55 must be answered	If Q54 is answered, then Q55 must be answered	
F2137 r3	Q37	Smart Navigation	If Q36 = normal, then go to Q39	If Q36 is answered, then go to Q37	Data quality improvement, gadolinium information being collected
		Validation (Modify)	If and only if Q36 = abnormal, then Q37 must be answered	If Q36 is answered, then Q37 must be answered	
F2100 r9	Q140, 389, 390, 393, 395, 399 and 400	Validation (Modify)	Question validations based on patient's current age	Question validations based on patient's age at date of contact reported on follow-up form	Data quality improvement, prevent errors if correcting old data
F2110 r4	Q104	Modify (Floating Text)	No floating text	Floating text added to indicate when each answer option should be selected	Eliminate reporting confusion
		Validation (Add)		If Q51, Q63, Q70, Q80, Q87 = no, then Q104 must be no	
F2111 r4	Q95	Modify (Floating Text)	No floating text	Floating text added to indicate when each answer option should be selected	Eliminate reporting confusion
		Validation (Add)		If Q48, Q54, Q61, Q71, Q78 = no, then Q95 must be no	
F2114 r4	Q172	Modify (Floating Text)	No floating text	Floating text added to indicate when each answer option should be selected	Eliminate reporting confusion
		Validation (Add)		If Q88 = not answered or no or not applicable and Q94 = not answered or no and Q100, Q109, Q118, Q137, Q144, Q148 = no, then Q172 must be no	

F2157 r1	Q203	Modify (Floating Text)	No floating text	Floating text added to indicate when each answer option should be selected	Eliminate reporting confusion
		Validation (Add)		If Q105 = no or not applicable and Q111, Q117, Q130, Q139, Q167, Q174, Q178 = no, then Q203 must be no	

March 2024 (released March 22nd, 2024)

Form_Revision	Question	Type of Change	Current	New	Rationale for Change
F4006 r6	Q33	Validation (Add)	Q33 (Specify start date) must be between date of product infusion and date of product infusion +2 days.	Q33 (Specify start date) must be greater than or equal to event date	Allows for a broader date range to be reported
F2003 r1	Q3-5	Validation (Modify)	If and only if Q2 = Gene Therapy product ID, then Q3 must be answered. If and only if Q2 = Batch number, then Q4 must be answered. If and only if Q2 = Lot number, then Q5 must be answered.	If Q2 contains Gene Therapy product ID, then Q3 must be answered. If Q2 contains Batch number, then Q4 must be answered. If Q2 contains Lot number, then Q5 must be answered.	Fixing previously incorrect validations to work as initially intended

February 2024 (released February 23rd, 2024)

Form_Revision	Question	Type of Change	Current	New	Rationale for Change
F2402 r7	Q415	Validation (Modify)	If Q413 is multiple myeloma then Q415 may contain any combination of heavy and light chain options	If and only if Q413 is answered as multiple myeloma then Q415 must contain only heavy chain **OR** only light chain options. Will receive error if both heavy and light chain options are reported together	Prevent contradicting information from being reported

F2100 r9	Q121 and 191	Modify (Floating Text)	Brand names listed next to drug options	Brand names no longer listed next to drug options. Only generic drug names are listed on form	Eliminate reporting confusion

January 2024 (released January 26th, 2024)

Form_Revision	Question	Type of Change	Current	New	Rationale for Change
F2402 r7	Q469-501	Validation (Modify)	Q469-501 are required for Thalassemia	Q469-501 will still be required for Thalassemia. Q469-474, 477-494 & 499-501 will be answered for Sickle Cell Disease	These questions will now be required for both Thalassemia and Sickle Cell Disease (previously only required for Thalassemia)
F2030 r3	Q28-29, 38-40, 41-46	Validation (Modify)	If Q27 = yes, then Q28 must be answered. Q38 & Q41 must be answered	Q28, 38 & 41 no longer need to be answered	Because these questions are now answered on F2402 (see above revision), they will be disabled on F2030 to avoid duplicate reporting
F2402 r7	Q93-101, 169-177	Validation (Modify)	MRD questions are disabled	MRD questions are enabled AML: Q93-95 & 99-101 ALL: Q169-171 & 175-177	For AML and ALL, these MRD questions are now required to be answered

December 2023 (released December 8th, 2023)

Form_Revision	Question	Type of Change	Current	New	Rationale for Change
F2100 r9	Q209-211	Validation (Add)	Questions required only for recipients with acute or chronic GVHD	Questions required for all ALLO recipients regardless of GVHD status	Information required for all ALLO patients
F2100 r9	Q348-349	Validation (Modify)	Active questions	Inactive questions	No longer collecting data *Note: If questions were previously answered, data will be removed from form*

F2116 r5	Q110-141	Validation (Add)	If Q4 = yes, must answer Q110-141	Will not need to re-answer Q110-141	Burden reduction
F2116 r5	Q228 and Q230	Validation (Modify)	Questions must always be answered	If Q1 = AMYL or MRGS **OR** Q2 contains AMYL or MGRS, then Q228 and 230 must be answered	Only captured at baseline for AMYL or MGRS and should only be captured for same diseases at follow-up *Note: If questions were previously answered for data that is not AMYL or MGRS, data will be removed from form*
F2014/2114, F2016, F2028/ 2128, F2057/ 2157		Validation (Modify)	Karyotype ISCN string field does not exist	Karyotype ISCN string field added	Expanding functionality

November 2023 (released November 17th, 2023)

Form_Revision	Question	Type of Change	Current	New	Rationale for Change
F2100 r9	Q317	Validation (Modify)	If cardiac impairment/ disorder = arrhythmia or pericarditis, then Q317 must be answered	If cardiac impairment/ disorder = arrhythmia, pericarditis or cardiomyopathy, then Q317 must be answered	Cardiomyopathy has been added as a cardiac impairment/disorder that, when reported, makes Q317 required
F2402 r7	Q92 & Q168	Validation (Modify)	If disease status = 1CR, 2CR, or GE3CR, then number of cycles of induction therapy required to achieve 1st CR must be answered	If disease status = 1CR, then number of cycles of induction therapy required to achieve 1st CR must be answered	A disease status that is anything but 1CR implies the disease is more aggressive. Thus, only patients in 1CR should have this question answered
F2116 r5	Q30	Validation	If Q1 =	If Q1 = MGRS or Q2	Previous validations were

		(Modify)	amyloidosis, MGRS or other PCD **OR** Q2 contains amyloidosis or MGRS, then Q30 must be answered If Q4 or Q7 = no, then Q30 must be answered	contains MGRS and Q4 = no **OR** Q1 = amyloidosis or Q2 contains amyloidosis and Q7 = no, then Q30 must be answered	combined into a single validation to prevent contradicting validations and incorrect errors occurring for users
F2116 r5	Q32	Validation (Modify)	If Q1 = amyloidosis, MGRS, other PCD **OR** Q2 = amyloidosis or MGRS, then Q32 must be answered If Q4 or Q7 = no, then Q32 must be answered	If Q1 = MGRS or Q2 contains MGRS and Q4 = no **OR** Q1 = amyloidosis or Q2 contains amyloidosis and Q7 = no, then Q32 must be answered	Previous validations were combined into a single validation to prevent contradicting validations and incorrect errors occurring for users
F2400 r10	Q61	Validation (Modify)	If Q45 contains single cord blood unit or Q44 = allogeneic, unrelated and Q55 is not answered, then Q61 must be answered	If Q45 contains single cord blood unit and Q53 = no **OR** Q44 = allogeneic, unrelated and Q45 contains any (BM, PBSC, Other) and Q55 is not answered, then Q61 must be answered	Cord blood units facilitated through NMDP are not required to answer the Cord Blood Bank, this question is now optional. **Note**: optional fields will appear enabled, but there will not be a validation error if it is left blank

October 2023 (released October 27, 2023)

Form_Revision	Question	Type of Change	Current	New	Rationale for Change
F2402 r6	Q18, 45, 72, 110, 129, 148,	Validation (Add)	ISCN validations do not exist	ISCN validations added	Support AGNIS centers using 2402r6

	213, 250, 301, 358, 436				

September 2023 (released September 22, 2023)

No updates to communicate.

August 2023 (released August 25, 2023)

Form_Revision	Question	Type of Change	Current	New	Rationale for Change
F2100 r7-8 F2149 r1 F2900 r4-5 F4100 r5-9		Events and Actions	If COVID-19 (SARS-CoV-2) infection is reported F2149 comes due	F2149 will not come due	Data no longer being collected except for BMT CTN 2101 study
F2149 r1		Events and Actions	On-demand capability enabled	On-demand capability removed, CIBMTR will add form manually	Data no longer being collected except for BMT CTN 2101 study

July 2023 (released July 28, 2023)

Form_Revision	Question	Type of Change	Current	New	Rationale for Change
F2000 r6	Q115	Validation (Modify)	If country of primary residence is EQUAL to any (AS, GU, MP, PR, US, UM, VI) then household income must be answered	Household income question will be disabled for all	To coincide with cell therapy form updates and reduce reporting burden
F4000, F4100, F4003, F4006, F4101		Option group (add and modify)		Afamitresgene autoleucel added to cell therapy product list and Orvacabtagene autoleucel removed from cell therapy product list	Changes in availability/ production of cell therapy products

F2400 r10	Q19	Option group (add)		Four COG studies added to the dropdown list. These include: COG AALL1732, COG AAML1831, COG APAL2020SC (PedAL) and COG ASCT2031	Updating list to include additional studies
F2400 r10 and F4000 r10	Q17 (F2400) and Q9 (F4000)	Option group (modify)	Study sponsor list includes “RCI BMT”	“RCI BMT” has been changed to “CIBMTR CRO Services”	Change in sponsor name
F2400 r10 and 2003 r1	Q79 (2400) and Q1 (2003)	Option group (add)	Only option for gene therapy product name is “other name”	New options for gene therapy products added. Product options include: Betibeglogene autotemcel (Zynteglo®), Elivaldogene autotemcel (Skysona®), Exagamglogene autotemcel and Other name (specify)	Updating list to add gene therapy product names

June 2023 (released June 23, 2023)

Form_Revision	Question	Type of Change	Current	New	Rationale for Change
F2010, F2011, F2014, F2016, F2018, F2057			CT is reported as a prior line of therapy	CT is no longer reported as prior line of therapy	Consistency between HCT and CT reporting

May 2023 (released May 19, 2023)

Form_Revision	Question	Type of Change	Current	New	Rationale for Change
F2450r7 / F2100r4-8	Q16 (F2450) / Q18 (F2100)	Validation (Add)	“Not Applicable” available as answer option	“Not Applicable” will NOT be allowed to be reported for 6M, 1Y, and 2Y reporting periods	Consistency with ANC data capture update in April
F4100r8/9	Q180 and 187 (r8) / Q153 and 160 (r9)	Validation (Modify)	If current treatment path is equal to 2, questions must be answered	Disabled for combined follow-up when 2nd event is HCT	Burden reduction

F2450r7 / 2011r8	Q67 (F2450) / Q65 (F2100)		Answer option reads “PCR (includes quantitative, real time, and fluorescent multiplex)”	Option PCR changed to “Single nucleotide polymorphisms (SNPs) (includes quantitative PCR, real-time PCR, sequencing, other)”	Updated for more inclusive data capture

April 2023 (released April 21, 2023)

Form_Revision	Question	Type of Change	Current	New	Rationale for Change
F2400 r10	Q135	Validation (Add)	No option available to report “none”	“None” available as answer option	Allows “None” as answer without requiring override error code
F2400 r10	Q21	Validation (Modify)	If recipient is participating in a clinical trial AND Study Sponsor = Other Sponsor OR Study ID = BMT CTN 1903, then NCT ID must be answered	NCT ID required for all clinical trials	All clinical trials will report NCT ID. Exception: RCI BMT studies with no NCT ID – reporting NCT ID will be optional in this case

February 2023 (released February 24, 2023)

Form_Revision	Question	Type of Change	Current	New	Rationale for Change
F2600 r5 / r6		Validation (Modify)	If HCT = allo unrelated AND product type is BM or PBSC, then GRID must be answered	If HCT = allo unrelated AND product type is BM or PBSC OR HCT = allo related and NMDP product, then GRID must be answered	Include allo related NMDP product infusions

January 2023 (released January 27, 2023)

Form_Revision	Question	Type of Change	Current	New	Rationale for Change
F2100 r8	Q136	Validation (Modify)	Disabled for the 100 day visit	Enabled for both acute and chronic GVHD	Allows capture of GVHD that persists across infusions

December 2022 (released December 9, 2022)

Form_Revision	Question	Type of Change	Current	New	Rationale for Change
F2013 r3	Q3	Validation (Modify)	If subsequent transplant or cell therapy, then Q3 is disabled	Q3 must be answered for every transplant and cell therapy (regardless if subsequent or first)	Provides disease status at latest assessment
F2900 r5		Events & Actions	If primary cause of death = COVID-19 OR contributing cause of death contains COVID-19, then a F2149 comes due	As of November 2022, F2149 will not come due for TED track (except those enrolled in CTN 2101 study)	F2149 is no longer collected for TED track
F2000 r6	Q80	Validation (Modify)	No decimal place available when entering dosing weight	One decimal place available when entering dosing weight	Exact dosing weight necessary to capture data accurately, especially in pediatric patients

Last modified: Apr 19, 2024

NMDP Forms

Last modified: Jan 27, 2023

Adverse Event and Product Complaint Reporting

NMDP requires transplant centers to report all qualifying recipient adverse events and/or product complaint events on all recipients of cellular product that we facilitate. FormsNet3 is a system used by the Event Reporting System (ERS) to capture information about recipient adverse events and product complaints.

The Event Reporting System provides a single mechanism for transplant centers to report adverse events and product complaints to NMDP, thus simplifying the process for centers and saving centers time and resources. Investigations of adverse events and product complaints can also be initiated more quickly by Transplant Medical Services and Quality Systems because the electronic forms systematically collect all pertinent information upfront. In addition, the Event Reporting System enhances the NMDP's ability to comply with all reporting obligations we have to regulatory and funding agencies such as the FDA and HRSA.

For training resources, form samples (F3001, F3003, F3010) and instructions, please refer to the NMDP Network Website.

Last modified: Mar 05, 2024

Genetic Mutation Reporting

NMDP has implemented a protocol consent change and is introducing a standardized way to report genetic mutations detected in donor-derived cells.

Historically, the process to report findings has not been outlined and occurs on a case-by-case basis. By standardizing this reporting process, we will now be able to:

- Respond to the results of next-generation sequencing technology for disease surveillance
- Notify donors about the process
- Have donors opt in at workup if they want to be notified about genetic changes of unknown significance
- The Transplant Medical Services team will notify donors, regardless of opt in status, of any/all medically actionable genetic changes with known significance.

Genetic mutations may be identified during post-donation marrow and/or peripheral blood genetic testing. In such cases, the transplant center is expected to report any genetic mutations found in their recipients that may be donor-derived back to the NMDP. Transplant centers will submit findings through the CIBMTR FormsNet3 application via the Genetic Mutation Report intake form, Form 3004. This form is available as of 1/20/2023 by generating an 'on-demand' form. For steps on how to create an on-demand form, please see the 'Create an Unscheduled Form' page within the FormsNet3 Training Guide.

The links below provide training on the new Genetic Mutation Reporting process for transplant centers:

On-demand recording link
RISE training module link
Form Instructions can be found HERE

Contact Information

- For help with how to answer the questions after reviewing the training materials, please reach out to the NMDP Transplant Medical Services team at tms@nmdp.org
- For questions about potential donor-derived findings, form submissions, or any additional guidance please email geneticmutations@nmdp.org
- For technical issues regarding this form, please create a CIBMTR Center Support ticket

Last modified: Mar 08, 2024

Corporate Studies and Registries

There are two lists related to CIBMTR Corporate Studies and Registries that are sent via email

- Forms Due List
- Forms Completion List

These are automatically sent to current Primary Data Managers and staff we've been asked to copy on correspondence sent to the primary data manager role. If your center is not receiving this report, your primary data manager may submit a CIBMTR Center Support ticket to request assistance with the distribution list including adding staff members to the distribution list.

> ! Make sure to include CIBMTRReports@NMDP.ORG in your Safe Senders list to ensure these emails make it to your inbox.

Last modified: Dec 05, 2022

Forms Due List

CIBMTR Corporate Studies and Registries Forms Due List

The Corporate Studies and Registries Forms Due List is automatically sent each Tuesday via email. If you have questions about forms in these reports, contact CIBMTR Center Support.

Your center will receive this list if there are any forms DUE for any study. The table will contain one row per form due for the studies that your center is participating in. Forms will be listed if the due date is past or within seven days of the run date.

These forms are a subset of forms due for CPI. Completing these forms by the form due date will lower the forms due in the next CPI trimester. The form due date is the date by which CIBMTR expects to receive the data whenever possible. Forms for a study are expected to be completed by the form due date to ensure all required data are available for analysis.

Run Date: 08/30/2022 05:00:28 AM

Study Forms Due Report

STUDY	CCN	CRID	IUBMID_TEAMID	Birth Year	Event Date	Infusion Type	Product Type	Primary Disease	Form	Visit	Sequence Number	Form Status	Due Date
10-CMS-MDS						ALLO_U	PBSC	MDS	2006	Product 1		DUE	09/04/2022
RLTD_TX						ALLO_R	PBSC	NHL	2118	1 year		DUE	06/03/2022
RLTD_TX						ALLO_R	PBSC	NHL	2450	1 year		DUE	06/03/2022
RLTD_TX						ALLO_R	PBSC	NHL	4100	1 year		DUE	06/03/2022
RLTD_TX						ALLO_R	PBSC	ALL	2450	1 year		DUE	08/15/2022
SC17-08						UNK		NHL	2118	1 year		DUE	06/03/2022
SC17-08						UNK		NHL	2450	1 year		DUE	06/03/2022
SC17-08						UNK		NHL	4100	1 year		DUE	06/03/2022
SC20-03						UNK		NHL	2118	100 day		DUE	05/27/2022
SC20-03						UNK		NHL	2118	6 month		DUE	08/30/2022
SC20-03						UNK		NHL	4100	100 day		DUE	05/27/2022
SC20-03						UNK		NHL	4100	6 month		DUE	08/30/2022

Definitions

Run Date

Indicates the date and time the report was generated. Times listed are U.S. Central Time, not necessarily the centers local time. There may be a delay between the report generation and when it is distributed to transplant centers. Use the Center Forms Due feature in FormsNet for a real-time listing of what forms are outstanding.

Study Name

Indicates the CIBMTR study number. There will be one row per form for that study. A study may have multiple rows for as many forms as there are due.

Recipient details

CRID, IUBMID/Team ID, Birth year and Event date are all provided to help identify the correct recipient.

Infusion details

There is a column for Infusion Type, Product type, and Primary disease.

Form details

Form ID, visit, sequence number, form status and due date are provided for each form. The table will contain any form past due and due within 7 days of the run date.

Last modified: Jun 02, 2023

Forms Completion List

CIBMTR Corporate Studies and Registries Forms Completion List

The Corporate Studies and Registries Forms Completion List is automatically sent the first Tuesday of the month via email. If you have questions about forms in these reports, contact CIBMTR Center Support.

Your center will receive this email if there is at least one CRID enrolled in a study. The table will contain one row per study if your center is participating in multiple studies.

This report does not contain any CRIDs or Form IDs. It is meant to be paired with weekly study forms due list. You can also create a forms due list using the FormsNet3 Center Forms Due tool.

Run Date: Aug 2, 2022 3:30 AM

Dear CIBMTR Data Manager,

No response is required, this email serves as a monthly update on study progress. If your center has reported a CRID that meets study eligibility requirements, regardless of whether the infusion was performed at your center, you will receive this update. CIBMTR greatly appreciates your participation in these studies and your constant support of completing study forms.

Please forward this message to applicable staff at your center.

The table below shows form completion status for your center for each study where at least one CRID is enrolled. Form completion is a key component to study analysis. **Any form that is greater than 30 days past due should be prioritized for completion.**

This report does not contain any CRIDs or Form IDs. It is meant to be paired with monthly study forms due list. You can also create a forms due list using the FormsNet3 Center Forms Due tool.

Form Completion Summary

CCN	STUDY	COHORT_NAME	CMP	NOT DUE	SUR	LTF	NRQ	< 30 DAYS PAST DUE	30 - 60 DAYS PAST DUE	> 60 DAYS PAST DUE
[redacted]	CS20-36	Liso-cel	28	158	0	0	0	2	0	2
[redacted]	10-CMS-MDS	MDS Control	769	410	0	14	1	1	4	4
[redacted]	SC17-08	NHL	22	56	0	0	0	0	0	0
[redacted]	SC16-06	Primary	11	0	0	0	0	0	0	0
[redacted]	SP16-02	Primary	4	0	0	0	0	0	0	0
[redacted]	CS20-36	Ide-cel	19	45	0	0	0	0	0	0
[redacted]	10-CMS-MDS	MDS Case	15	28	0	0	0	0	0	0

Definitions

Run Date

Indicates the date and time the report was generated. Times listed are U.S. Central Time, not necessarily the center's local time. There may be a delay between the report generation and when it is distributed to transplant centers. Use the Center Forms Due feature in FormsNet for a real-time listing of what forms are outstanding.

Study and Cohort Name

Indicates the CIBMTR study number. There will be one row per study. If the study has multiple cohorts (arms), it will be listed under cohort name. For studies with a single cohort it is listed as 'primary'.

Form status

Forms considered complete (CMP)	AUD – Audited form
	CMP – Completed form
	LCK – Locked form (not external edits allowed)
	PND – Center's response to a query is pending review by CIBMTR
	QRY – Form has an outstanding query
Forms considered not due (NOT DUE)	DUE – Form has not been started, and has a due date in the future
SUR, LTF, NRQ	SUR – Center indicated no clinical data known, but survival status provided
	LTF – Form was exempted because patient is lost to follow-up
	NRQ – Form was exempted by CIBMTR
Forms considered Incomplete	ERR – Form has an outstanding validation error
	SVD/MOD – Form has been edited, but not submitted to CIBMTR
	DUE – Form has not been started
• <30 days past due	The due date for the form has passed and is less than 30 days from the report run date
• 30-60 days past due	The due date for the form has passed and is 30-60 days from the report run date
• >60 days past due	The due date for the form has passed and greater than 60 days from the report run date

Last modified: Dec 05, 2022

Cell Therapy Corporate Studies

Questions regarding any of the below studies should be submitted via CIBMTR Center Support

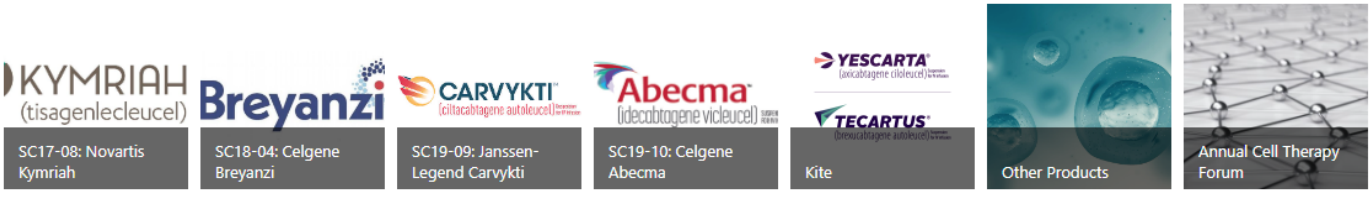
Current CIBMTR Cell Therapy Studies

Company	Novartis	Kite	Kite	BMS/Celgene	BMS/Celgene	BMS/Celgene	Janssen/Legend
Product Name	Kymriah	Yescarta	Tecartus	Breyanzi	Abecma	n/a	Carvykti
Scientific Name	Tisagenlecleucel	Axicabtagene ciloleucel	Brexucabtagene autoleucel	Lisocabtagene maraleucel	Idecabtagene vicleucel	Non-conforming Liso-cel and Ide-cel	Ciltacabtagene autoleucel
Other Name	CTL019	KTE-C19	KTE-X19	JCAR017	BB2121	JCAR017 & BB2121	BCMA
FDA Approval Date	8/30/2017 (DLBCL) 5/27/22 (FL)	10/18/2017	7/24/2020 (mantle cell) 10/1/2021 (ALL)	2/5/2021	3/26/2021	n/a	2/28/2022
Disease	LYM ALL	LYM FL	Mantle cell LYM ALL	LYM	MM	LYM MM	MM
LD Therapy	Flu + Cy	Flu + Cy	Flu + Cy	Flu + Cy	Flu + Cy	Flu + Cy	Flu + Cy
Lines of Prior Therapy	2 or more lines of systemic therapy	2 or more lines of systemic therapy	2 or more lines of systemic therapy	2 or more lines of systemic therapy	2 or more lines of systemic therapy	4 or more lines of systemic therapy	4 or more lines of systemic therapy
Study ID	SC17-08	SC17-07	CS20-03	SC18-04	SC19-10	CS20-36	SC19-09
PC	Gretchen Koenigs	Jaime Santi	Jaime Santi	Sarah Lesniewski	Sarah Lesniewski	Sarah Lesniewski	Gretchen Koenigs
Accrual Goal	2500 (1500 LYM) (1000 ALL)	1500 FL	500 500	1000 (500 B-cell) +200 MCL	1000	No cap	1000
Package Insert	https://www.fda.gov/media/107296/download	https://www.fda.gov/media/108377/download	https://www.fda.gov/media/140409/download	https://www.fda.gov/media/145711/download	https://www.fda.gov/media/147055/download	n/a	https://www.fda.gov/media/156560/download
Reporting Guide?	Yes	FAQ	FAQ	Yes	Yes	Yes	Yes

Enrollment into these cellular studies is done when the product name is reported on the F4000. No additional consent is required. These studies fall under the current CIBMTR Research Database consent form, which include HCT and cell therapy language.

Additional reporting guides are available for some of these studies. These contain extra information that is product specific and not part of the Forms Instruction Manuals. These reporting guides can be requested via CIBMTR Center Support and are available on the CIBMTR portal.

There is additional training on the CIBMTR Portal. There are recordings of the site initiation meeting and copies of the reporting guides.



Last modified: Mar 08, 2024

Online Training

Educational opportunities are continually being developed as part of our commitment to improving data quality and providing resources for data managers for data reporting to the CIBMTR.
CIBMTR Training has implemented eLearning modules for easily accessible training which is available whenever needed (24/7). For a look at our course menu and immediate access, visit the CIBMTR Portal in the Training & eLearning tile.

Last modified: Feb 10, 2022

Acronyms

AA: African American
ABil: Acute biphenotypic leukemias
AC: apheresis center
ACCME: Accreditation Council for Continuing Medical Education
AFA: Anti-fungal agent
AGNIS: A Growable Network Information System
ALL: Acute lymphoblastic leukemia, acute lymphocytic leukemia
AML: Acute myelogenous leukemia, acute myeloid leukemia
ANC: Absolute neutrophil count
ARC : American Red Cross
ASBMT: American Society for Blood and Marrow Transplantation
ASH: American Society of Hematology
ASHI: American Society for Histocompatibility and Immunogenetics
BBMT: Biology of Blood and Marrow Transplantation
BMDW: Bone Marrow Donors Worldwide
BMT: Blood and marrow transplant / bone marrow transplant
BMT CTN: Blood and Marrow Transplant Clinical Trials Network
CBB: Cord blood bank
CBU: Cord blood unit
CC: Collection center
CDC: Centers for Disease Control and Prevention
CHTC: Certified Hematopoietic Transplant Coordinator
CIBMTR: Center for International Blood and Marrow Transplant Research
CLL: Chronic lymphocytic leukemia
CML: Chronic myelogenous leukemia, chronic myeloid leukemia
CMV: Cytomegalovirus
CPI: Continuous Process Improvement
CRF: Comprehensive Report Forms
CRM: Customer Relationship Management
CT: Confirmatory (HLA) Testing
CY: Calendar year
DC: Donor center
DNA: Deoxyribonucleic Acid
DX: Diagnosis
EBMT: European Society for Blood and Marrow Transplantation
FA: Fanconi anemia
FACT: Foundation for the Accreditation of Cellular Therapy
FMLA: Family and Medical Leave Act
FSA: Flexible Spending Account
FY: Fiscal year
GAO: U.S. Government Accountability Office
GVHD: Graft-versus-host disease

GVL: Graft versus leukemia, graft-versus-leukemia effect
GVM: Graft versus malignancy, graft-versus-malignancy effect
HCT: hematopoietic cell transplant
HHS: (The Department of) Health and Human Services
HIPAA: Health Insurance Portability and Accountability Act of 1996
HIV/AIDS: human immunodeficiency virus/acquired immunodeficiency syndrome
HLA: Human leukocyte antigen
HRSA: Health Resources and Services Administration
HTLV: human T-cell lymphotropic virus
IDMs: infectious disease markers
IRB: Institutional Review Board
IT: Information Technology
MDS: Myelodysplastic syndromes
MM: Multiple myeloma
MPD: Myeloproliferative disorder
NCI: National Cancer Institute
NHL: Non-Hodgkin lymphoma
OHRP: Office for Human Research Protections
OHSRP: Office of Human Subjects Research Protections
OMB: Office of Management and Budget
OPA: Office of Patient Advocacy (used only in HRSA contract)
PHPS: Patient and Health Professional Services
PBSC: Peripheral blood stem cell
RC: recruitment center
RITN: Radiation Injury Treatment Network
SCD: Sickle cell disease
SCTOD: Stem Cell Therapeutic Outcomes Database
STAR: Search, Tracking and Registry (System)
SCID: Severe combined immunodeficiency disease
TC: Transplant center
TED: Transplant Essential Data
TX: Transplant / treatment (avoid due to ambiguity)
WHO: World Health Organization
WMDA: World Marrow Donor Association

Last modified: Jun 26, 2017

Quick Links

CIBMTR and NMDP

AGNIS
NMDP Official Website
CIBMTR Website
Forms Instruction Manual
Retired Manuals
Traxis
Adding/Removing Center Personnel
Data Collection Forms List
Retired Forms List
CIBMTR Portal

Additional Resources:

Bone Marrow Donors Worldwide
HRSA – Bone Marrow and Cord Blood Donation and Transplantation
HHS – Informed Consent
Blood & Marrow Transplant Information Network
Foundation for the Accreditation of Cellular Therapy
Good Clinical Practices
Laboratory – Volume Unit Converter
Laboratory – GlobalRPh Converter
National Cancer Institute

Last modified: Mar 05, 2024

Contact Us

- NMDP Service Desk at (612) 362-3411 or (800) 526-7809 Ext. 3411
- Submit a question and/or issue via CIBMTR Center Support, our customer service portal
    - If you do not have an account for CIBMTR Center support, please email centersupport@nmdp.org to create a ticket

> ! Note: emailing a question or request typically takes longer than submitting a support ticket directly to CIBMTR Center Support as the emails are not automatically sent to the appropriate subject-matter experts.

Last modified: Feb 03, 2023