CIBMTR
CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

DATA MATTERS NEWSLETTER

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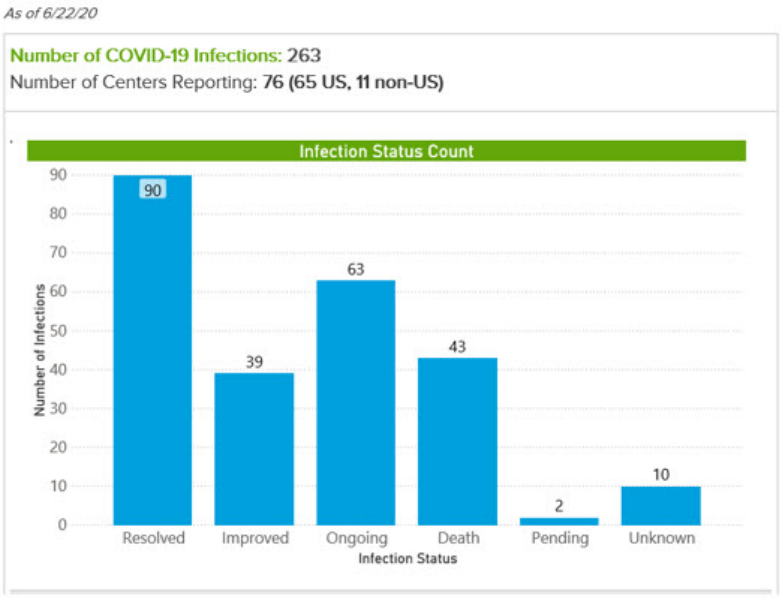
Volume 1, Issue 3

The Quarterly Data Matters Newsletter will be sent out in January, April, July, and October.

Please do not unsubscribe from this newsletter. This is the CIBMTR's means of keeping you updated about FormsNet3, Forms Revision, and Center Support updates.

Center Support Updates

Reporting COVID-19 Re-infection



As early as March 30, 2020, the CIBMTR was collecting data on COVID-19 infections for transplant and cellular therapy recipients. Initially collected outside of the FormsNet3 application, the Respiratory

Virus Post Infusion (2149) Form was launched in FormsNet3 as part of the Spring Release on May 8, 2020.

If your center is aware of COVID-19 infections that were not reported to the CIBMTR, please report those as soon as practical. The form is enabled for On-Demand reporting, so it is not necessary to wait until the next scheduled follow-up to report. For questions on how or what to report, submit a request via Service Now using the category specific to F2149 submissions.

CIBMTR.ORG/COVID19

The CIBMTR developed a webpage to disseminate high-level details on these infections. Updated each weekday, this site features a summary of infections reported, status of infections, and number of sites reported. There are also several charts available that describe the infections by recipient sex, recipient age, infusion type, time from infection to infusion, and infection by US region.

In addition to data, this site includes several reference materials:

- Instructions and FAQs for reporting
- Position Statement from CIBMTR and ASTCT regarding consenting patients during the pandemic
- Prioritization guidance for CIBMTR reporting / requests
- CPI suspension details
- Details on published and upcoming studies related to COVID-19
- Communication archive
- Links to additional content hosted by ASCTC and Be The Match

Reporting Tip

Many transplant centers have found it valuable to triage the completion of the CIBMTR Infusion Forms (F2006, F4003, F4006) to staff in their Stem Cell Processing Laboratory, rather than these forms being completed by Data Management staff. The lab staff are generally more familiar with the data being requested on those forms, both in what that data represents as well as where to find it. Centers who have opted to use this approach often have higher data quality and less outstanding forms as a result.

Your Center's Primary Contact can request center laboratory staff access to FormsNet3. Click **here** for further information.

Find FormsNet Training Resources **here**.

FormsNet3 Query Functionality

FormsNet3 Query functionality allows the CIBMTR to apply a data check to a specific field for missing or inconsistent data, for clarification

or documentation, or for requesting a paper/PDF correction for a FormsNet2-era form.

Queries may be initiated as a result of a data review for a CIBMTR Observational Study, to prepare a dataset for Transplant Center Specific Outcomes (TCSA), Center Volumes Data Report (CVDR), or the Cord Blood Outcomes reports, or as part of study management for an ongoing clinical trial. Because of this importance, queries should be reviewed and addressed within ***two weeks*** to ensure correct data are included in all datasets. Data corrected by query resolution will also be pushed to the Data Back to Centers (DBtC) tool on the CIBMTR Portal. Query functionality will greatly reduce the need for data corrections via email; however, email requests may still be required for more complex data correction requests.

How will sites know when queries have been placed on their data? Review the following:

In FormsNet3:

- Center Forms Due tool - select Status QRY to generate a list of all forms awaiting response.
- My Work - the landing page will list all open queries for your center

Weekly Email:

- Every Tuesday morning each center's Primary Data Contact will receive an excel file listing all forms with open queries, as well as the details of the request.

Submit questions specific to the query process to the **CIBMTR Center Support**, using the ECF/Queries category. This will ensure your question is directed to the Data Quality team for resolution.

Forms Completion Request

We Need Your Help!

To honor our commitment to providing high-quality stem cell products to patients during the coronavirus (COVID-19) pandemic, the CIBMTR **needs your help**. As more and more HCT products are being cryopreserved due to commercial flight limitations, courier restrictions, as well as to ensure these cells are available when needed, the CIBMTR is hoping to assess the effects of the cryopreservation process on these life-saving cells.

Therefore, the CIBMTR is requesting that centers complete HCT Product and Infusion (2006) Forms within **30 days** of infusion for **all** transplants which utilized a cryopreserved product of any source (i.e., autologous, allogeneic – related, allogeneic – unrelated). **This is a temporary change from the general reporting guidelines which request these data be submitted within 60 days of infusion.** However, timely review of these data is critical and may help inform clinical care.

Email reminders may be sent for applicable F2006s that are not completed within 30 days post-infusion. These requests will not impact your standing with any other CIBMTR initiatives (i.e., CPI, TCSA, etc.).

Please contact **HubandSpoke@NMDP.org** with any questions, concerns, or feedback.

CPI Updates

Recipient CPI

Due to the COVID-19 pandemic, CIBMTR suspended CPI requirements for all product types (Allogeneic Related, Allogeneic Unrelated, Autologous, and Cellular Therapy (CT) infusions, if CT infusions are applicable to your center). It is currently impossible to predict the impact of this situation on future CPI requirements; we will continue to communicate with you as the situation develops.

For US Centers, please note, during this time, your center must still have current IRB documents (renewal letters and consents) on file with NMDP.

For NON-US centers, please note, during this time your center must still have a signed Data Transmission Agreement (DTA) or updated Master Healthcare Data and Sample Submission Agreement (MHA) on file with NMDP.

CPI reports will still be emailed on the same schedule to assist centers with monitoring their completion rates and other CPI requirements.

During this time, please prioritize the submission of the Respiratory Virus Post - Infusion Form (2149) and forms for recipients on studies, especially BMT CTN, as well as the Consecutive Transplant Audit (CTA).

Donor CPI (Phase IV)

CPI Updates ending June 30th, 2020:
20 Donor Centers --- 100%
20 in Good Standing
67 Collection Centers ---- 100%
67 in Good Standing
84 Apheresis Centers --- 100%
84 in Good Standing

Upcoming Form Releases

CIBMTR member centers use FormsNet3℠ to electronically submit data. FormsNet3℠ can be used alone or it can be used in conjunction with AGNIS®, a second application that transmits data from your center's own database to FormsNet3℠.

Anticipated Release – Summer (July) 2020

Forms
2030 R3 – Sickle Cell Disease Pre-Infusion Data
2130 R3 – Sickle Cell Disease Post-Infusion Data
2543* R1 – Gemtuzumab Ozogamicin (Mylotarg™) Supplemental

**indicates new form*

In addition to the forms listed above, CIBMTR has now defined a hard stop in reporting when multiple genetically modified cellular therapies and HCTs require follow-up forms. This new functionality has been implemented to reduce center reporting burden and redundancies when reporting 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). See details under "Forms Scheduled for Release in FormsNet3" **here** for further information.

For more information about the upcoming release or to comment on current form revisions, please contact **cibmtr-form-feedback@NMDP.ORG**.

CIBMTR Forms Instruction Manual Updates

New manual releases
Manuals for the following forms will be released on July 24th, 2020.

Sickle Cell Disease Pre-Infusion Form (2030)
Sickle Cell Disease Post-Infusion Form (2031)
Gemtuzumab Ozogamicin Supplemental Study Form (2543)

CIBMTR Forms Instruction Manual Updates
Several CIBMTR Forms Instruction Manual updates are currently in progress. The primary goal of manual updates is to increase clarification around a reporting instruction, update the instruction to capture necessary data and provide additional reporting examples to assist data management staff in reporting accurate data. In an effort to increase transparency in manual updates, each Data Matters Newsletter includes recent updates in the manual to review. In addition, the **Historical Manual Updates** section of the Forms Instruction Manual will be undergoing revision to more clearly outline manual updates and reporting instruction changes.

Pre-TED Disease Classification (2402) Form
Q1 - 2: *Primary disease for HCT / Cellular Therapy – Reporting instructions clarification*

The CIBMTR data collection forms capture disease assessments at multiple timepoints before and after transplant. If the indication for HCT / Cellular Therapy is relapsed / progressive disease, and the previous infusion was reported to the CIBMTR, only disease assessments performed at disease relapse / progression and after need to be reported. In this case, for the "at diagnosis" timepoint, only report assessments performed at the time of relapse / progression (prior to the initiation of therapy). Some pre-infusion forms on the Case Report Form (CRF) track have different reporting rules, depending on whether a pre-infusion CRF had been previously completed for the recipient. Carefully review the Disease-Specific CRF manuals for additional information.

Q23, Q50, Q77, Q115, Q134, Q153: *Were tests for molecular markers performed?* – Reporting instructions changed from previous version of manual

Molecular markers for disease refer to specific genetic sequences which are believed to be associated with the recipient's primary disease. Historically, if molecular methods of assessments were performed by chromosomal microarray, these results could be reported in the molecular section(s) of the Pre-TED Disease Classification (2402) Form. However, questions capturing molecular marker results are intended to capture molecular abnormalities identified by molecular methods. Additional testing methods, such as FISH and chromosomal microarray, may identify molecular abnormalities but should not be reported in the molecular section. Any abnormalities identified by karyotyping, FISH, or chromosomal microarray should only be reported in the cytogenetic section of the Pre-TED Disease Classification (24202) Form. This change applies when reporting molecular assessments on the Form 2402 (AML, ALL, MDS, MPN, and Multiple Myeloma sections) as well as the Post-TED (2450) Form.

Waldenstrom's Macroglobulinemia
Response Criteria – Reporting instructions clarification

The response criteria options for Waldenstrom's Macroglobulinemia (WM) do not correspond to the option values listed on the current version of the Pre-TED Disease Classification (2402) Form. As a result, clarification was added on the WM Response Criteria on how to report the pre-HCT disease status.

Appendix N: Drug Classification – New Appendix

A new appendix was added and lists various drug classifications, a short description, and examples.

For more information about the management of the CIBMTR Forms Instruction Manual or to comment on the current manual, please contact: **CIBMTRFormsManualComments@nmdp.org**

Education and Training

New Data Manager Virtual Onboarding

CIBMTR has received many requests over the years for new data manager onboarding. We offered our first in person new data manager onboarding class this past February at The TCT | Transplantation & Cellular Therapy Meetings. In addition, at the parallel The Clinical Research Professionals/Data Management Conference, CIBMTR Data Operations announced it would be offering in-person new data manager onboarding every six-months (February and August).

Due to COVID-19 and travel restrictions, CIBMTR Data Operations cannot offer an in-person class this August. Instead, we will be offering interactive classes VIRTUALLY via Webex Trainings over seven days throughout the month of September 2020.

The class is open to individuals with 6 months or less experience at their center as a data manager. The virtual classes include interactive training in our FormsNet3 training environment along with topics that are pertinent to new data managers to submit quality data. Click **HERE** for more information, cost, and registration.

eLearnings: New and Updated

Recently updated and new eLearnings
The following training modules have been updated or added to the CIBMTR website:

Updated
HLA eLearning:
The content of this eLearning will focus on when and how to report on Form 2005; plus provide instruction on reading laboratory reports for form reporting accuracy.

- **HLA Reporting: Confirmation of HLA Typing - (Form 2005)**

Myeloma eLearnings:
Multiple Myeloma disease status reporting can be challenging, due to the numerous patient assessments performed throughout the disease course. This module is intended to provide basic information about the

pathophysiology of myeloma and the assessments used to evaluate myeloma, as well as strategies for organizing key assessments.

- **Multiple Myeloma 101 - part 1 “Understanding the Basics and Relevant Assessments”**

This module is intended to help understand how those assessments determine appropriate disease status for CIBMTR reporting based on the international myeloma working group (IMWG) criteria.

- **Multiple Myeloma 101 - part 2 “Reporting Myeloma Disease Status”**

New

Cellular Therapy eLearnings:

An overview of how the CIBMTR cellular therapy data collection forms come due, and a description of the reporting schedules.

- **Cellular Therapy Forms Submission: How Forms Come Due**

A description of donor cellular infusions (DCI) / donor lymphocyte infusions (DLI), how they differ from HCT, and how to complete the cellular therapy forms.

- **Cellular Therapy Reporting: What Distinguishes a DCI / DLI from HCT and How to Report Them**

Explanation of what types of cellular therapy infusions should be reported to CIBMTR.

- **Submitting Cellular Therapy Data to the CIBMTR**

An overview of the CIBMTR cellular therapy data collection forms and what they captured.

- **An Overview of Cellular Therapy Forms**

MDS and MPN Reporting eLearnings:

This module is intended to provide basic information about the pathophysiology of MDS and MDS/MPN, help identify and organize the key assessments used to track MDS and MDS/MPN, and understand how those assessments determine appropriate disease status for CIBMTR reporting.

- **MDS and MDS / MPN Reporting**

This module is intended to provide basic information about the pathophysiology of MPN, help identify and organize the key assessments used to track MPN, and understand how those assessments determine appropriate disease status for CIBMTR reporting.

- **MPN Reporting**

Donor, Apheresis, and Collection Center Updates

For more information click **here**.

For Donor Centers

This summer the NMDP will be updating the material on the BeTheMatchClinical.org website. This will entail a comprehensive review of materials and will span over three months. The expected completion date is 9/1/2020.

About the Network Section. This section of our health care professional's website provides our network partners access to operational information, tools and resources to help serve hematopoietic cell transplant patient and donors.

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