August 2020 Newsletter

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Table of Contents:
Perspectives
Immunobiology Working Committee
Pediatric Cancer Working Committee
2021 TCT Meetings of ASTCT and CIBMTR
New Data Manager Onboarding
Tackling New Data Transmission Frontiers Together
Center-Specific Survival Analysis
BMT CTN in the Era of COVID-19
CIBMTR Survey Research Group Launches PRO Surveys
Health Services Research: Access to Cellular Therapy
Bioinformatics Research: New DPB1 and TCE Prediction Tools
Harmonizing Cellular Therapy Forms with EBMT
Sharing Research In Plain Language
Additional Research Datasets Available for Secondary Analysis
Our Supporters
Abbreviations

Perspectives: Are We Doing Enough?
By John Wingard, MD

Just when we thought things could not get worse, they did. The cold-blooded police killing of George Floyd with colleagues looking on. A Black man killed while jogging. An EMT killed in her bed. A man found sleeping in his car at a drive-through shot in the back by police. These recent atrocities in plain sight (during a time while all the distractions of everyday life were extinguished by the pandemic and economic meltdown) have made most of us rethink our assumptions about racial justice in the world we live in. These events call upon us to reflect on the chasm between what should be and what the reality of racial justice truly is. What actions have we taken now five years after churchgoers were killed in Charleston and after generations of racial injustice?

Last week I reviewed a grant. A prior reviewer had noted that the study would have limited significance since few minority subjects were to be recruited. My initial response was that clearly the reviewer was not a transplanter, since the
The demographic make-up of the study population was fairly typical of patients who undergo HCT. Upon further reflection, I realized how myopic my reaction was. The reviewer was touching on an essential truth that we transplant clinicians are uncomfortable facing.

Minorities are under-represented in those we take to transplant. This is true now, and it has always been true. More than two decades ago, we studied quality of life in HCT survivors randomly selected from North American centers reporting to the CIBMTR. Completing the enrollment demographic table for the progress report, I realized Black participants were woefully under-represented. We needed to rethink our recruitment strategy.

Over the years, the CIBMTR has conducted numerous studies to characterize ethnic and Black disparities in HCT. We have learned much about this problem. Blacks are less likely to get to HCT, less likely to get a well-matched donor, have a lower chance to survive HCT, and face less robust social networks for support through the transplant process. The hurdles for equal access for minorities and the poor are many and are now likely worsening with the pandemic.

It all too often seems that barriers are beyond our control. Certainly, each of our centers have unique challenges—and opportunities for progress. The patients at my center have high rates of poverty, poor access to primary care, high rates of advanced disease at diagnosis, and high rates of social vulnerability. Far too many do not get to transplant at my center. Our state's Medicaid program caps the number of reimbursed hospital days each year. A typical AML patient uses up all the annual benefits, leaving no coverage for transplant, until the benefits recharge the following year. Medicaid patients without days left or those without coverage were not allowed to proceed to HCT, unless they were in remission at the next anniversary. Was this just, I asked? That argument had little sway. An economic argument had more traction: Treating multiple relapses was more costly to the institution than proceeding to transplant (with the added benefit of offering a chance for cure rather than a relentless pathway to death). The institution changed policy. Now I ask myself: What have I done lately at my center to advance progress?

Is our HCT community doing enough to address issues of racial disparities? Are we giving sufficient voice to concerns of the poor and minorities in our local communities and among our professional societies? Are we giving sufficient priority to studies that gain deeper insights about the contributors to poor access to information and advocacy and make positive change? Are we making meaningful efforts to recruit minorities to our clinical trials? Are we asking our policymakers to fund ways to improve access? For change to occur, each of us individually should speak up and act. Our HCT organizations are starting discussions and initiatives. Please add your voice, lend your support, and volunteer to make our HCT community stronger and better able to serve the needs of all our patients.

The grant reviewer reminded me that I had become complacent with an uncomfortable truth; our patients and our communities deserve better.

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**Immunobiology Working Committee**

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**Committee Leadership**

**Co-Chairs:**
- Sophie Pazzesny, MD, PhD, Indiana University Hospital / Riley Hospital for Children, Indianapolis, IN
The Immunobiology Working Committee (IBWC) is the largest CIBMTR committee by study volume. The IBWC addresses scientific questions about the association between genetic factors and successful transplantation outcomes. The committee welcomes studies that assess genes and gene products of the major histocompatibility complex, natural killer cell repertoire, cytokine / proinflammatory cytokine and immune-response determinants, minor histocompatibility loci, and other genetic factors. The committee's studies also include comparisons of clinical outcomes from different donor types (e.g., mismatched related versus unrelated donors) and exploration of novel biostatistical and analytic approaches to investigate the impact of various HLA mismatches. In addition, the NMDP/Be The Match Research Sample Repository provides a unique resource for investigators conducting retrospective analyses of immune-response determinants and transplant outcomes. About 1/3 of the IBWC studies require sample testing. Currently, samples are available from more than 47,000 unrelated donor / cord blood-recipient pairs and 9,600 related donor pairs for whom complete clinical data have been collected and validated. Last year, the NMDP/Be The Match Research Sample Repository distributed more than 12,000 aliquots to investigators. Current inventory may be viewed and requests for samples may be submitted using the instructions on cibmtr.org.

For studies that examine the clinical role of the immune system in transplantation and do not require complete high-resolution HLA typing data and / or samples, the CIBMTR can provide clinical data on more than 48,000 HLA-identical siblings, 10,500 other-related, and 56,000 unrelated donor transplants. The IBWC currently lists 24 studies in progress, some in collaboration with other research organizations such as the International Histocompatibility Working Group and EBMT. Examples of ongoing studies include investigation of epigenetic changes prior to transplant KIR content, algorithms for identifying non-permissive HLA mismatches, and the role of ultra-high-resolution HLA matching in addition to classical studies of HLA-associations with outcomes, including in haploidentical related transplants using post-transplant cyclophosphamide. The IBWC has a strong publication record with 60 manuscripts published since 2015. The complete list of IBWC publications is available online.

The success of the committee depends on vibrant scientific interactions, new ideas and testable hypotheses, and participation by individuals with different perspectives and scientific backgrounds; therefore, the IBWC encourages investigators to submit new and bold proposals. Study proposals may be submitted year-round at cibmtr.org. Working committee meetings convene annually at the TCT Meetings of ASTCT and CIBMTR, although other venues for interaction are also available. All investigators with an interest in immunology, immunobiology, and human genetics should feel welcome to become actively involved with this committee or to contact one of the chairs or a member of the scientific staff to learn more or to discuss your research ideas and proposals. We look forward to chatting with you and seeing you at our meetings!

The TCT® Trademark belongs to the Cardiovascular Research Foundation, ASTCT, CIBMTR, MCW, NMDP, the 2019, 2020, and 2021 TCT Conferences and materials are NOT affiliated with or sponsored by Cardiovascular Research Foundation.
Scientific Director:
- Muna Gayed, MD, Emory University School of Medicine, Atlanta, GA
- Kirk Schultz, MD, British Columbia Children’s Hospital and Research Institute, Vancouver, BC, Canada

Statistical Director:
- Mary Eapen, MD, MS, Medical College of Wisconsin, Milwaukee, WI

The Pediatric Cancer Working Committee provides scientific oversight for allogeneic and autologous HCT studies of pediatric and adolescent cancer. We have increased our effort to improve the committee's visibility amongst pediatric transplant physicians as well as the Cooperative group meetings and to encourage involvement of junior investigators. In 2020, a study led by Muna Gayed, MD, MSc, and Carline L. Klitko, MD, successfully developed and validated a disease risk score (pediatric DRI) for pediatric patients with acute myeloid and lymphoblastic leukemia. This pediatric DRI stratified children with acute myeloid leukemia into four risk groups and acute lymphoblastic leukemia, into three risk groups for prognostication. The components of the risk score differ from the adult DRI with the pediatric DRI incorporating minimal residual status into its risk score assignment.

The success of our committee depends on new ideas and testable hypotheses as well as participation by individuals with different perspectives and scientific backgrounds. We encourage investigators with an interest in evaluating transplantation issues that impact pediatric cancer to propose studies via the "How to Propose a Study" webpage. If you would like, please contact the co-chairs to discuss your study's hypothesis and feasibility prior to a formal submission.

Return to Top

2021 TCT Meetings of ASTCT and CIBMTR

By Tia Hcuseman

Will the TCT Meetings of ASTCT and CIBMTR take place in 2021?

The TCT Meetings of ASTCT and CIBMTR team is proceeding with preparations for the TCT Meetings of ASTCT and CIBMTR scheduled for February 10-14, 2021, and is committed to providing an outstanding program developed by the Scientific Organizing Committee. The health and safety of our attendees, speakers, and staff is our top priority, so we are preparing for various options should a face-to-face conference not be possible. Please check the home site periodically for updates.

Scientific Program Topics
- Acute GVHD: Therapies for new targets
- Cellular therapies: New platforms and targets
- Chronic GVHD: Mechanisms and new therapies
- Creating solutions through international collaboration: Lessons learned during the COVID-19 pandemic
- Gene therapy for non-malignant diseases
- Immunotherapy in myeloma
- NK cellular therapies
- Oxygen sensing
- T-Cells: Biology to therapeutics
- Transplantation and cell therapy during pandemics
- The microbiome and transplant outcomes
- The impact of COVID-19 on the global transplant community
- Pediatric BMT
- ...and more

Plus: Mortimer M. Bortin Lecture, E. Donnall Thomas Lecture, late-breaking abstracts, CIBMTR Working Committee meetings, ASTCT Special Interest Groups, and Meet-the-Professor sessions. Along with these state-of-the-art educational offerings, industry-supported satellite symposia, product theaters, and exhibitors will broaden the spectrum of presentations even further.

Tracks – New This Year!

To improve the attendee experience with the overall TCT Meetings of ASTCT and CIBMTR agenda, parallel meetings are now known as "tracks." Confirmed tracks include administrative directors, advanced practice professionals, BMT CTN
coordinators and investigators, clinical research professionals / data management, IT and informatics, nursing, pediatrics, and pharmacists.

Abstracts and Registration
The abstract submission site will open late summer / early fall. On line registration and housing will open in the fall of this year.

Support Opportunities and Additional Information
Please direct questions regarding support opportunities at the 2021 TCT Meetings of ASTCT and CIBMTR to the TCT Meetings of ASTCT and CIBMTR Conference Office: TCTMeeting@mcw.edu.

We look forward to seeing you!

Join the conversation: #TCTM21

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New Data Manager Onboarding

LET US HELP ONBOARD YOUR NEW DATA MANAGER

We are here to help you educate your staff

JOIN US FOR OUR FIRST

NEW DATA MANAGER VIRTUAL ONBOARDING

SEPTEMBER 2020

Open to data managers with less than six months of experience at your center. Data managers must attend all sessions to participate.

Click HERE for more information, cost, and registration

The CIBMTR often receives requests for assistance with new data manager onboarding. We offered our first in-person new data manager onboarding class this past February at the TCT Meetings of ASTCT and CIBMTR. In addition, at the parallel Clinical Research Professionals / Data Management Conference, CIBMTR Data Operations announced it would offer in-person new data manager onboarding every six months (February and August).

Due to the ongoing COVID-19 pandemic and subsequent travel restrictions, CIBMTR Data Operations cannot offer an in-person class this August. Instead, we will offer VIRTUAL interactive training classes via Webex over seven days throughout September 2020.

The classes are open to individuals with 6 months or less experience at their center as a data manager. The virtual classes include interactive training in our...
Tackling New Data Transmission Frontiers Together
By Gina Fischer

Pilot Partner Sites Begin Testing New Ways of Transmitting Data to the CIBMTR

The CIBMTR recently announced seven Pilot Partner Sites readying to test new methods of sending data electronically to the CIBMTR with the goal of reducing the administrative burden for centers to submit their data to the CIBMTR.

Four guiding principles were applied when designing the prototype to send data electronically to the CIBMTR:

1. Meet the data where it resides, such as an electronic medical record or a research database
2. Enlist data standards according to how data is structured to collect it
3. Enlist technical standards (e.g. LOINC, SNOMED, etc.) to move the data to the CIBMTR
4. Minimize center level effort required to use the prototype

"This is a pivotal moment. This is where the design and development comes together and we begin prototype testing with the Pilot Partner Sites," said Kristina Bloomquist, the CIBMTR Data Transformation Initiative Business Lead.

"We are encouraged by the interest expressed by sites to be pioneers in re-thinking how we exchange data so that we can reduce the administrative burden to collect and send data to CIBMTR," said Bridget Wakaruk, CIBMTR Data Transformation Initiative Senior Relationship Manager.

To-date, Pilot Partner Sites prepared to begin prototype testing include:

- Children’s Healthcare of Atlanta, Inc.
- Children’s Hospital Colorado
- Duke Cancer Institute at Duke University Medical Center
- The Ohio State University Comprehensive Cancer Center, James Cancer Hospital and Solove Research Institute
- Oregon Health & Science University
- Moffitt Cancer Center
- Sarah Cannon Blood Cancer Network

The Data Transformation Initiative Community
Fostering an ongoing exchange. Join us to learn more.

Many transplant centers, unable to commit to the pilot at this time, expressed a preference to stay knowledgeable of the initiative’s progress and plans. In response, the CIBMTR Data Transformation Initiative established a community group. The group meets monthly—providing relevant updates on the initiative, educating about technical aspects of the new model, and fostering a community environment to exchange information and ideas helping to inform future decisions for both transplant centers and the initiative.

Contact Information
Interested in learning more? Curious about getting involved? Email DT@ndpc.org. We look forward to hearing from you.

Center-Specific Survival Analysis
By Carol Dzieysh

The SCTOD contract requires the CIBMTR to annually conduct an analysis of one-year survival rates at each transplant center in the US. The results are also made available to the public at bethematch.org/tcdirectory/search.

In March 2020, the CIBMTR began collecting additional information related to COVID-19 infection in cellular therapy recipients. These data will be useful as the
CIBMTR evaluates approaches to accommodate the impacts of the pandemic in the Center-Specific Survival Analysis. The report that will be issued this year (2020) includes patients transplanted between 2016 and 2018 and is not affected by COVID-19.

**BMT CTN In the Era of COVID-19**

*By Amy Foley, MA*

The BMT CTN team continues to evaluate the impact of the COVID-19 pandemic and adjust course as needed, such as:

- Shipping study drugs directly to study participants
- Providing study participants with ship from home kits for stool and urine samples
- Incorporating remote monitoring visits
- Modifying study databases to collect COVID-19 related data and leveraging the CIBMTR database to obtain COVID-19 infection data
- Revising statistical analysis plans

As of July 1, all temporarily suspended BMT CTN studies are now open to accrual. There are 12 current studies in the following areas: Sickle cell disease (2); GVHD (2, and a companion biomarkers protocol); lymphoma (2); severe aplastic anemia; stem cell donor source; prognostic assessment in older adults; multiple myeloma; and multiple sclerosis. For information on these trials, visit bmtctn.net.

The BMT CTN team is documenting all areas of COVID-19 impact. Over the next months, we will assess which practices implemented due to the pandemic may provide future value beyond the pandemic; these practices may allow patients greater flexibility, decrease burden on site staff, and increase overall efficiencies and cost savings for the Network.

In the meantime, in the midst of the continued uncertainty, we hope that you, your families, and your patients stay safe and healthy.

**About the BMT CTN**

The CIBMTR shares administration of the BMT CTN Data and Coordinating Center with NMDP/Be The Match and The Emes Company. Together, these three organizations support all BMT CTN activities.

To receive up-to-date information about BMT CTN studies, meetings, and news:

- Like us on Facebook: facebook.com/BMTCN
- Follow us on Twitter: twitter.com/BMTCN (@BMTCN)

**CIBMTR Survey Research Group Launches PRO Surveys**

*By Deborah Mattila*

The CIBMTR Survey Research Group is excited to launch routine collection of patient-reported outcomes (PRO) surveys this summer! The NMDP IRB approved a protocol for routine PRO collection in July 2019. Bronwen Shaw, MD, PhD, is the Principal Investigator for this protocol. Deborah Mattila, Survey Research Group Manager, leads logistics and coordination.

Over the past year, Dr. Shaw and Ms. Mattila convened a task force composed of clinicians, patient advocates, and PRO experts to design a Core PRO survey instrument for adult HCT and CAR-T recipients and a schedule for PRO collection. The Core PRO survey includes PROMIS domains related to physical, mental, emotional, social and sexual health; the comprehensive score for financial toxicity (COST) measure; and occupational / school functioning and sociodemographic questions. The Core PRO instrument is administered in English or Spanish, either electronically or on paper (per subject request). The schedule includes surveys prior to treatment and then at day 100, day 180, 1 year, and annually post-treatment.

The CIBMTR Survey Research Group centrally manages patients enrolled in the protocol for collection of PRO data. When patients sign consent to the CIBMTR Research Database, giving permission for the CIBMTR to contact them, the center provides patient contact information in FormsNet3. A Survey Research Group
member then contacts the patient by phone to describe the protocol, answer questions, and obtain verbal permission to send the PRO data collection consent form. The staff member then sends both the consent form and baseline PRO survey to the patient and tracks completion. A Survey Research Group member sends post-treatment PRO surveys to patients and follows-up with non-responders by phone and email. The PRO data collected under this protocol are available in the CIBMTR Research Database for future studies. At this time, the Survey Research Group is also working on a mechanism to return the PRO data to centers (with explicit patient consent).

Routine collection of Core PRO surveys launched this summer at four centers based on interest in the protocol, geographic diversity, and ability to adjust workflows related to FormsNet3 data management for the pilot. Over the next year, Dr. Shaw and the staff members of the Survey Research Group will track patient response rates; respond to logistical concerns; and plan expansion to other centers, pediatric patients, and additional languages.

We look forward to sharing accrual and response rates in future newsletters! Please contact Deborah Mattila at dmattila@nmdp.org with any questions about the protocol for collection of PRO data.

Health Services Research: Access to Cellular Therapy

By Jaime Freussler, MS; Christa Meyer, MS; Lih-Wen Mau, PhD, MPH; Tatiana Muppidi, PhD; Meggan McCann, MPH

The Health Services Research team collaborates with multiple stakeholders to conduct research that increases access to cellular therapy. The team is currently working on completing multiple studies, with manuscripts under development. Two of these studies, include:

- A recent collaboration with researchers at the University of Virginia resulted in a study using Virginia Cancer Registry and CIBMTR data to determine access to transplant for patients with AML in the state of Virginia. This study aims to determine if geographic location of residence and other socioeconomic factors are associated with receipt of HCT. Results of this study will inform development of interventions to help mitigate barriers to HCT, focusing on areas of Virginia that may benefit most.

- Another collaboration with external investigators resulted in a national survey of transplant physicians to learn more about their perceptions of the impact of older age (≥60 years) on HCT candidacy and their utilization of tools to gauge candidacy. Results of this study will inform efforts to address age-related barriers to HCT.

For more information about the Health Services Research Program, visit the Health Services Research webpage or email HSRrequests@nmdp.org.

Bioninformatics Research: New DPB1 and TCE Prediction Tools

By Yung-Tsu Eo, PhD
While a perfectly matched transplant cell source is not always possible, we want to help identify donors that will provide the best possible outcome for the patient. To this end, Ray Sajulga, Jr., on the Bioinformatics Research team with Pradeep Bashyal, is launching a new DBP1 Prediction Service with an accompanying interface called the TCE Prediction Tool in conjunction with Martin Maiers, Kim Wadsworth, and the rest of the Donor Optimization for Transplant Success (DOTS) team at NMDP/Be The Match.

Matching and mismatching between the patient and donor within HLA genes is known to affect patient transplant outcome. While HLA-DBP1 matching is not the first criteria, many studies over the last decade and a half have determined connections between Patient-Donor HLA-DBP1 mismatches corresponding to T cell epitope reactivity that affect transplant outcomes. HLA-DBP1 typing, however, may not initially be available for this assessment, especially for potential donors that did not join a registry in recent years.

That is where Sajulga’s DBP1 Prediction Service and TCE Prediction Tool come to the rescue. Behind the scenes, the DBP1 Prediction Service connects to reference HLA population frequencies and self-identified race and ethnicity as well as to previously-developed imputation and T-cell epitope matching services. The TCE Prediction Tool provides a window for the user to access these services.

Users provide patient HLA typing and obtain a donor list (NMDP’s MatchSource® has an export feature) with HLA typing and population codes as input into the DBP1 prediction application. Then the DBP1 Prediction Service and TCE Prediction interface provides an output that includes estimates for HLA-DBP1 permissible/matching and non-permissible/mismatch likelihoods. Above is a screenshot of the interface. While predictions require confirmation, upfront assessment of likelihoods for best donor matches can save time and resources for patients urgently requiring transplant. As part of the DOTS strategic initiative, these tools deliver prediction and potential donor risk assessment capabilities to transplant centers and physicians to save and improve patient lives.
By Carls Litovich, MPH

CIBMTR staff members worked in partnership with our EBMT colleagues to harmonize data collection on cellular therapies to ensure a strong collaborative relationship. We recently reviewed the content of the CIBMTR cellular therapy forms suite and their corresponding MED-C forms from EBMT. The harmonization effort focused on reviewing each question asked in both registries’ forms to better align them. Forms are compared in both directions: CIBMTR to EBMT and EBMT to CIBMTR. Questions asked by one registry and not the other are reviewed and may be incorporated in subsequent revisions. Once questions are aligned, the variables related to these questions are then mapped to facilitate future data merges for collaborative studies or projects.

After initial harmonization work began in 2018, the group began routinely meeting in January 2020 to review recent form modifications. The group reviewed all CT forms. The next step is to harmonize the disease specific forms frequently used for patients receiving CAR T cells.

Both EBMT and the CIBMTR have contracts with Kite and Novartis to follow patients who receive their respective CD19 CAR T cells as part of the manufacturers’ post market regulatory obligations. As these are global products, this ongoing collaboration allows the organizations to continue serving as a resource to the community, capturing data on CAR T cell therapies both now and in the future. Due to differences in regulatory frameworks, this approach (using US- and Europe-based registries to capture long term outcomes on recipients of CAR T cells) is considered most efficient. Participating centers can use a single infrastructure to report all products, maximizing ease of reporting and participation.

This collaboration also prepares both organizations for the future by providing a mechanism to discuss emerging therapies for other indications, including creating parallel mechanisms to appropriately capture outcomes of gene therapies.

This initiative with our European colleagues is part of a combined broader effort to work together. We are grateful to be part of this process and excited for the future.

The EBMT group includes Christian Chabannon, Marianne Mol, Debra Gordon, Lucas Stolarczyk, Marco Bressers, Steffie Van Der Werf, Annelot Van Amerongen, and Sofie Terwel. From the CIBMTR, Marcelo Pasquini, Sharon Graminske, Bob Thompson, Tiffany Hunt, Jaime Santi, and Carlos Litovich participated in these conversations.

Return to Top

Sharing Research In Plain Language

By Jennifer Motl

These five new plain-language summaries may help your patients:

For people with aplastic anemia, fresh cells rather than frozen are better for blood and marrow transplant

Read more

Medicine for COVID-19 does not raise risk of other infections

Tocilizumab is already used in people with cancer after CAR T-cell therapy

Read more

In year after blood or marrow transplant, 6-8% regret it

Regret was more likely if cancer returned or if the patient felt less support from family and friends prior to transplant

Read more
Teens and young adults need check-ups for side effects, even years after leukemia treatment

Blood or marrow transplant cures leukemia but may have late side effects

Read more

Quick testing for a blood or marrow donor helps people with leukemia

People who had fast-tracked tests (cytogenetics and HLA-typing) were more likely to get a BMT.

Read more

Each quarter, the Consumer Advocacy Committee chooses a few studies of particular interest to patients. CIBMTR staff members create the plain-language summaries, which are reviewed by scientific directors.

Watch for new summaries on the Study Summaries for Patients webpage as well as Twitter, Facebook, and LinkedIn.

Return to Top

Additional Research Datasets Available for Secondary Analysis

By Liz Siepmann

Research Datasets for Secondary Analysis

The CIBMTR makes its publication analysis datasets freely available to the public for secondary analysis while safeguarding the privacy of participants and protecting confidential and proprietary data.

View the Terms and Conditions.

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<td>Survival rates of autologous hematopoietic cell transplantation with EBV-positive or EBV-negative cord-registered hematopoietic donor in CIBMTR study</td>
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<td>2015</td>
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In accordance with the NIH Data Sharing Policy and NCI Cancer Moonshot Public Access and Data Sharing Policy, the CIBMTR is making publication analysis datasets publicly available on the CIBMTR Research Datasets for Secondary Analysis webpage.

These publication analysis datasets are freely available to the public for secondary analysis. While providing these data, the CIBMTR is committed to safeguarding the privacy of participants and protecting confidential and proprietary data.

NEW datasets are now available online.

Return to Top

Our Supporters
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Abbreviations

Need an acronym defined? Review our list of common abbreviations.

The views expressed in this newsletter do not reflect the official policy or position of the National Institute of Health, the Department of the Navy, the Department of Defense, Health Resources and Services Administration (HRSA), or any other agency of the U.S. Government.

**CIBMTR® is a research collaboration between the National Marrow Donor Program (NMDP) Be the Match and the Medical College of Wisconsin.**

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