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14. ABSTRACT <p><u>1. Contingency Preparedness:</u> Collect information from transplant centers, build awareness of the Transplant Center Contingency Planning Committee and educate the transplant community about the critical importance of establishing a nationwide contingency response plan.</p> <p><u>2. Rapid Identification of Matched Donors:</u> Increase operational efficiencies that accelerate the search process and increase patient access are key to preparedness in a contingency event.</p> <p><u>3. Immunogenic Studies:</u> Increase understanding of the immunologic factors important in HSC transplantation.</p> <p><u>4. Clinical Research in Transplantation:</u> Create a platform that facilitates multicenter collaboration and data management.</p>					
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Grant Award N00014-21-1-2954

DEVELOPMENT OF MEDICAL TECHNOLOGY
FOR CONTINGENCY RESPONSE TO MARROW TOXIC AGENTS
QUARTERLY RESEARCH PERFORMANCE REPORT
SUBMITTED October 13, 2022

Office of Naval Research

And

The National Marrow Donor Program®

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I. Heading

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National Marrow Donor Program

N00014-21-1-2954

Development of Medical Technology for Contingency Response to Marrow Toxic Agents

II. Scientific and Technical Objectives

The main goal of all activities funded through this grant is to develop, test and mature the ability of the NMDP Coordinating Center and NMDP contracted network sites network sites to address contingency events wherein civilian or military personnel are exposed to marrow toxic agents, primarily ionizing radiation or chemical weapons containing nitrogen mustard. As a result of prior efforts in this regard a solid foundation has been established. The proposed new activities will continue to enhance and expand our capabilities in each of the four focus areas. Contingency preparedness activities will continue to integrate NMDP's role with federal, state and local agencies.

An accident, a military incident, or a terrorist act in which a number of individuals are exposed to marrow toxic agents will result in injuries from mild to lethal. But the extent of individual injuries and the likelihood of recovery in many cases will not be apparent until days or weeks after the event. Casualties will be triaged by first responders, and those with major marrow injuries who will need aggressive medical support and may be ultimately candidates for hematopoietic cell transplantation (HCT) will need to be identified. While these patients are being supported, HCT donor identification activities will be initiated because it will not be initially clear which ones may ultimately require HCT. NMDP-approved transplant centers will provide a uniform and consistent clinical foundation for receiving, evaluating and caring for casualties. NMDP Coordinating Center will orchestrate the selection and testing necessary to rapidly identify the best available donor or cord blood unit for each patient utilizing its state-of-the-art communication infrastructure, sample repository, laboratory network, and human leukocyte antigen (HLA) expertise. NMDP's on-going immunobiologic, bioinformatics and clinical research activities promote studies to advance the science and technology of HCT transplantation to improve outcome and quality of life for the patients.

Importantly, most individuals with near-lethal marrow toxic injuries will recover their own marrow function provided they receive intensive supportive care from the medical professionals that are part of the contingency response community.¹ These professionals can save the lives of persons with severe marrow suppression using the knowledge and skills practiced every day to treat patients undergoing HCT coordinated through the NMDP.

III. Approach

A. Contingency Preparedness

HCT teams are uniquely positioned to care for the casualties of marrow toxic injuries. The NMDP manages a network of centers that work in concert to facilitate unrelated HCT. The Radiation Injury Treatment Network (RITN), comprised of a subset of NMDP's network centers, is dedicated to radiological disaster preparedness activities and develops procedures for response to marrow toxic mass casualty incidents.

B. Development of Science and Technology for Rapid Identification of Matched Donors

Disease stage at the time of transplantation is a significant predictor of survival, decreasing the time to identify the best matched donor is critical. Methods are under development to rapidly provide the best matched donor for HCT.

C. Immunogenetic Studies in Transplantation

Improving strategies to avoid and manage complications due to graft alloreactivity is essential to improve the outcomes of HCT. Research efforts are focused on strategies to maximize disease control while minimizing the toxicity related to alloreactivity in HCT.

D. Clinical Research in Transplantation

Clinical research creates a platform that facilitates multi-center collaboration and data management to address issues important for managing radiation exposure casualties. Advancing the already robust research capabilities of the NMDP network will facilitate a coordinated and effective contingency response.

IV. Updates

A. Contingency Preparedness

Maintain the Radiation Injury Treatment Network (RITN) to prepare for the care of patients resulting from a hematopoietic toxic event

- **Radiation disaster and countermeasure research education:**
 - RITN Biennial (FY2022) Workshop “Past Informing the Present, Past Improving the Plan for a Rad/Nuc Incident” is (1) Targeted towards physicians and other healthcare providers, support staff, hospital and hospital system administrators, emergency managers, research scientists, and appropriate federal agency staff that would be involved in radiation response and treatment of patients with radiation-induced bone marrow injury; and (2) Will (a) highlight recent developments in Covid pandemic response and applicable lessons we have learned, (b) review and disseminate novel radiation countermeasures and dosimetry, (c) discuss optimizing triage and on the ground federal resources, (d) present strategies to ensure the availability and appropriate use of medical and psycho-social supportive care and resilience, and (e) explore applying telemedicine as a force multiplier for care and education.
 - The Workshop was held August 4-5, 2022, at The Westin Alexandria Old Town.
 - Attendance
 - Participants – 128
 - Speakers

- Invited – 17
 - Selected Abstract Submissions – 20
- Feedback
 - Very well organized and executed conference. Thank you.
 - Great conference- learned a lot.
 - The speakers were top notch at this conference. Thank you for putting together a great agenda!
 - This was an excellent conference. Very well organized, very informative. Thank you very much.
 - I am looking forward to the next workshop.
- Planning Committee members represent RITN hospitals: Dana Farber Cancer Institute, Duke University, and the Mayo Clinic Rochester; as well as federal partners: The Administration for Strategic Preparedness and Response (formerly the Assistant Secretary for Preparedness and Response - ASPR) and the Biomedical Advanced Research and Development Authority (BARDA).
- Advanced HAZMAT Life Support (AHLS) for Radiological Incidents & Terrorism 4-hour course (1) Has a target audience of physicians, physician multipliers, nursing staff, administrators and coordinators from departments such as bone marrow transplant, hematology, oncology, radiation safety, nuclear medicine, and the emergency department, as well as emergency management, and first responders; and (2) Will include interactive lectures and tabletop exercises that trains healthcare professionals to evaluate and care for irradiated and radiologically contaminated patients.
 - One, half-day course the afternoon of Wednesday, August 3 (day before biennial RITN Workshop) at the Westin Alexandria Old Town was canceled due to lack of enrollment.
 - Two, half-day courses were successfully completed July 20, 2022. The Region 9 Healthcare Coalition (Chicago) hosted in Elgin, IL.
- **Radiation disaster preparedness training:**
 - No updates at this time.
- **Hospital radiation disaster preparedness:**
 - Annual disaster readiness tabletop exercises (drills) have been scheduled for current RITN centers to participate for their annual task completion. Six sessions were completed between June and August 2022.
 - Additional disaster readiness exercises (drills) resumed pre-COVID scheduling. Successfully completed include:
 - Full-scale exercise (Franciscan St. Francis, Indianapolis, IN)
 - Functional exercises (Illinois Regions 8 & 9)
 - Regional Tabletop exercise (Region X, Chicago North suburbs) medical response workshop
 - Assist request from Nebraska Medicine to streamline the interactions they have with national specialty organizations such as RITN as well as potentially supporting them in their regional exercise (drill) has been canceled due to external circumstances.

- **Hospital network growth:**
 - To ensure the appropriate growth in a direction that supports the vision and needs of the Department of Defense-Office of Naval Research as well as the Department of Health and Human Services Assistant Secretary for Preparedness and Response plans for response to a radiological/nuclear disaster with-in the continental U.S.
 - Activity under this section is complete and will continue under a subsequent award.

- **Federal partnership development:**
 - Support the Gryphon Scientific’s Center for Disease Control (CDC) funded project as a subcontractor to assess United States laboratory capabilities for ionizing radiation related testing.
 - The project was completed September 22, 2022, with all of the project deliverables submitted to the CDC.
 - Currently the final report is only available to work group members as it has not yet been cleared for public release.

- **Other projects:**
 - RITN Automated Tracking System project seeks to develop an integrated means to collect, review, report and store data related to the activity and annual task deliverables of the hospitals that are part of its’ network. This system should automate where feasible all steps that are currently manually accomplished. Users of this system range from staff at RITN headquarters to staff at each individual RITN center across the United States.
 - Currently in Beta testing phase of project.
 - Updated scheduled completion – November 2022.

**B. Development of Science and Technology for
Rapid Identification of Matched Donors**

Expand the genetic diversity of the registry through continued addition of adult donors and cord blood units, utilizing high volume HLA typing methodologies

During the past quarter, a total of 62,414 newly registered volunteer donors were HLA typed and added to the Be The Match Registry.

Modeling and analysis of registry coverage for the Warfighter

Over the last quarter, additional methods and data sources for validation of registry models was investigated. Our models seek to better understand the contribution of racially and ethnically diverse donors for matching in diverse groups. Current resources for validation of these results through simulations of donor registry searches with patient-donor HLA match criteria require more frequent and comprehensive data updates and greater flexibility in matching rules along with the ability to consider outcome probabilities

in the presence of missing data. Further solutions in this space continue to be explored and evaluated. Population genetics-based registry models projected donor coverage for warfighters as potential patients approaches but does not reach 100% when considering HLA match levels down to 5 of 8 matching alleles. This modeling aids in preparation for coverage of potential donor sources to Warfighters of diverse race and ethnic backgrounds in case of radiation emergencies.

Development of science and technology for rapid communication of HLA data

This quarter, a Hackathon was held on the development of tools and resources to optimize standard nomenclature and data handling. These collaborative hands-on working sessions brought researchers and developers from around the world together to discuss and implement standards and services for sending and utilizing HLA and other immunogenetic data. HLA and other immunogenetic data communicated from laboratories in HML (Histoimmunogenetics Markup Language) format, from research and inventory reference files, or from transplant center facing user interfaces was collected and analyzed. This data is then parsed and compared against existing reference data or assigned/translated to further feature annotation in order to provide rapid handling and communication of HLA data across datasets for downstream use. Further validation and computational efficiencies were introduced and validated for HLA data in higher volumes in addition to added features for automating workflows. These tools and resources pave the way for rapid communication of HLA data to promote both research studies that rely on HLA information and the operational matching of patients and donors.

Use of population genetics and machine learning to automate the donor selection process

Machine learning models for censored time-to-event and multiple competing risk statistical and machine learning models were explored for prediction of event-free survival after allogeneic stem cell transplant. Event-free survival is defined as survival where the patient does not experience any significant adverse events including graft rejection, moderate or severe chronic graft versus host disease, or relapse. Our objectives are to develop methods for optimizing donor selection to improve overall survival (OS) and event-free survival (EFS) and quantify the potential benefit in patient outcomes from doing such donor optimization.

To optimize donor selection, we first needed to build a flexible prediction model that could be used to predict patient specific outcomes over a range of potential donors, while also quantifying the uncertainty in such predictions. Since there were limited methods available to serve this purpose, we developed a novel Bayesian machine learning model called Nonparametric Failure Time Bayesian Additive Regression Trees (NFT BART), which can flexibly handle complex time to event survival outcomes and provide prediction uncertainty measures. A revised manuscript describing this novel biostatistical approach was submitted. Prediction models for OS and EFS as a function of patient, disease, transplant, and donor characteristics, using this NFT BART were applied to a cohort of all 8/8 matched unrelated donor transplants between 2016 and 2019. These models allow for patient-specific predictions for any potential donor. After examining the variable importance of each donor characteristic, we identified that donor age and donor gender are the only variables with a measurable impact to date on OS or EFS outcomes. Ongoing work examines the achievable benefit from optimizing additional donor selection variables over donor age and gender.

This quarter, from an established OS dataset of 6238 unique patients with AML from the CIBMTR outcomes database, we trained an alternative decision tree model with information on patients, donors,

disease, transplantation, therapy, and recipient-donor matching. From this model, a cumulative prediction score was calculated for an AML patient by traversing the tree according to their features. Positive and negative cumulative prediction scores represent ‘expired’ and ‘alive’ patient outcomes, respectively. For example, the cumulative score for a patient with AML and age <45 years with >1 induction cycle to achieve first complete remission from this model was found to be -0.694 (alive). The higher the absolute cumulative score of a patient for a certain binary outcome, the higher their probability of being classified in that category. In this regard, the ADTree-based model can potentially provide individualized prediction results for a patient with AML even if a subset of the required feature values is unknown. Development of prediction models incorporating these factors may help to complement clinical decision-making. Further validation is needed for these models and future work considers how multiple models can be incorporated for a cohesive outlook on optimization of actionable variables in the patient journey toward best transplant outcomes.

C. Immunogenetic Studies in Transplantation

Evaluate HLA disparity and impact on HCT by adding selected pairs to the Donor/Recipient Pair project utilizing sample selection criteria that optimize the new data generated by the typing project

The NMDP/CIBMTR maintains a research repository of peripheral blood samples from transplant donors (pre-donation) and recipients (pre-transplant). These samples are routinely genotyped through the ongoing Donor/Recipient Pair project to ensure sample identity and enhance the immunogenetic data available for histocompatibility research. This sample inventory and upgraded data are critical for expanding and optimizing research scenarios for evaluation of the role of HLA and other immunogenetic factors in HCT.

This year, samples from an additional 1438 unrelated and 428 related Donor/Recipient Pairs were prepared and sent for DNA extraction and HLA typing upgrades. This figure leaves just under eight thousand remaining pairs eligible for future typing upgrades at this time, though additional Donor/Recipient Pairs continue to accumulate as samples from ongoing transplants are collected. In addition, a more comprehensive inventory of the Donor/Recipient Pair collection was initiated to provide a current state outlook of the genomic and upgraded genetic typing data generated on these subjects and samples from our biorepository inventory. Key demographic features were linked for reference and to facilitate future study design and cohort building from the Donor/Recipient Pair inventory.

Transplantation practices are constantly evolving, and the DRPP will continue enroll the most recent related and unrelated transplant pairs to ensure that changes in practice can be evaluated using quality-controlled high resolution immunogenetic data. Strategic selection of pairs for genomic and other molecular testing and optimization of practices associated with data storage and management also continue to be conducted to ensure that investigators have timely access to robust, high-quality data to analyze the impact of Donor/Recipient immunogenetic data as either the focus of or as a variable in NMDP/CIBMTR-approved research studies.

Development of a national framework to standardize measurable residual disease evaluation in the clinical care of patients receiving allogeneic transplant for acute myeloid leukemia

While allogeneic HCT is a curative therapy for many patients with acute myeloid leukemia (AML), the risk of relapse even after achieving a cytomorphological complete remission (CR) is the most common form of treatment failure and death. Transplant-related morbidity and mortality is a major obstacle for the effective use of alloHCT, resulting in the potential under- or over-utilization of conditioning regimen intensity to prevent AML relapse. The presence of residual leukemic burden, known as measurable residual disease (MRD), prior to transplant is associated with worse outcomes after transplantation. AML MRD testing is not standardized, and no clear path to translate findings from research laboratories to clinical transplant settings currently exists.

Planning continued on a project designed to address this issue by developing a coordinated national framework to 1) allow collection of leftover initial AML diagnosis material from patients who have received alloHCT in US centers, 2) prospectively collect samples from AML patients after alloHCT to determine optimal timing and method for post-alloHCT MRD monitoring and 3) implement findings from phases 1 and 2, together with a central reference laboratory, to allow local centers to perform standardized MRD testing pre or post alloHCT. This would allow both selection of conditioning intensity, but also inform post-transplant maintenance and allow patient selection for novel clinical trials.

During the past quarter the protocol team continued to meet regularly to finalize plans to launch the IRB approved and [ClinicalTrials.gov](https://clinicaltrials.gov) registered study protocol entitled, “MEASURE: Molecular Evaluation of AML patients after Stem cell transplant to Understand Relapse Events”. To date, 15 centers have committed to participate in the study and combined plan to enroll >250 patients per year. Eight of 15 sites have received local IRB approval for the protocol. All sites have initiated submission of regulatory documents required for participation. Site initiation visits were completed for 3 sites with 2 more scheduled for early next quarter. One site has fully opened the study and has enrolled 3 patients. The study will continue under a subsequent grant.

Determine the impact of peripheral blood stem cell graft composition on the outcome of hematopoietic cell transplantation

While allogeneic HCT offers potentially curative therapy to patients with a variety of benign and malignant diseases, both acute and chronic GVHD continue to plague the field and often limit the longevity and quality of life for patients. The composition of PBSC grafts has been evaluated in multiple studies to attempt to discern associations between various cellular subsets and outcomes. The BMT CTN 0201 randomized trial of bone marrow versus PBSC found that PBSC grafts were associated with a higher risk of cGVHD and worse quality of life following unrelated donor HCT compared to BM. A correlative study of graft immunophenotype failed to identify any associations between PBSC graft composition and outcomes. However, the PBSC cohort included only 147 evaluable products limiting the power to evaluate various cellular subsets. The association between PBSC graft immunophenotype and outcomes remains unclear.

The primary aim of this study is to evaluate PBSC graft stem cell and associated immune cell composition and to determine at 12-months of follow-up how either the comprehensive graft cellular composition profile or specific graft composition elements influences the primary outcomes of time to neutrophil engraftment and overall survival. Secondary outcomes of interest include, but not limited to, incidence of acute and chronic GVHD, primary disease relapse, TRM, and DFS. The study will evaluate approximately 2,100 PBSC products over a 3-year accrual period with 1,100 collected in the U.S. through the NMDP and an additional 1,000 collected in Germany for U.S. based patients through the DKMS. The U.S. testing will be

supported through this grant and DKMS will support testing of German collected products. Data will be merged with CIBMTR collected clinical outcomes for analysis and correlation with clinical outcomes.

Analyses include:

- Stem cell subset composition (not just number) influences time to engraftment and immune reconstitution
- Both conventional and novel unconventional T cell subsets within the graft influence GVHD, relapse, infection and immune reconstitution after transplant
- Natural killer cells have a role in transplant biology and number and phenotype in the donor graft influence GVHD, relapse, infection and immune reconstitution after transplant.
- The myeloid/antigen presenting cell compartment of the graft influences infection risk and immune reconstitution, thus play a role in long term patient outcome

The secondary aims of this study are:

- Explore potential associations of favorable PBSC graft composition features that may be predicted by analysis of peripheral blood samples at time of unrelated donor work-up such that these biomarkers could be incorporated into donor selection algorithms.
- Evaluate graft composition association with >12-month outcomes for overall survival, primary disease relapse, DFS and the incidence of late transplant effects including, but not limited to, chronic GVHD, diseases of the cardiovascular, pulmonary, and endocrine systems, dysfunction of the thyroid gland, bone diseases and the development of secondary primary malignancies.
- Establish a cohort of pre-transplant recipient and pre-donation adult unrelated donor biologic samples (whole blood, plasma, viable PBMC and viable donor PBSC graft mononuclear cells) collected prospectively from donors and patients enrolled on this study. This important biospecimen resource will be critical for the support of additional protocol team defined allogeneic HCT related correlative studies that will extend the knowledge gained from the primary study.

During the past quarter accrual continued for U.S. based donors. A total of 212 product samples were received and tested through September 30, 2022 with 67 tested in the last quarter. Testing costs are covered under this grant while staff support is funded under a subsequent grant. The DKMS laboratory continued efforts to establish the standardized immunophenotyping panel for testing of Germany based donors. The study team met several times to finalize plans for concordance testing between the U.S. and DKMS laboratories. Concordance testing using known controls supplied by the NMDP testing laboratory will be performed in the next quarter. Accrual of German donors has begun on a limited basis and will be expanded following successful completion of the concordance evaluation to ensure that data is being consistency captured in both the U.S. and German laboratories. Testing of German donors will be fully funded by DKMS.

Even when patient and donor are HLA matched, post-transplant complications occur, therefore, other loci may play a role

With pre-transplant whole genome sequencing results from a cohort of 494 patients with MDS and their respective donors, we sought to identify the contribution of genomic factors beyond HLA to the prediction of overall survival outcomes following allogeneic HCT. Previously we identified a number of genomic factors that correlated well with transplant overall survival outcomes in this cohort and used random survival forest modeling to build prediction models first with the foundation of the known revised international prognostic scoring system data (base model) on these patients. After adding other known clinical patient data (clinical model = base model + MDS type, hypomethylating agent treatment, chemo

data) and then adding previously selected genomic candidates, we were able to obtain a striking increase of almost 0.2 in the concordance index for prediction of overall survival in patients with MDS.

Further analyses were conducted on a more a comprehensive set of genomic variants with a concentration on calling structural variants with a new machine learning framework applied to classify somatic variants validated by cytogenetic data. We previously observed when additional genomic variants were combined with clinical data that machine-learned prediction models produced an even higher concordance (~0.8) for prediction of overall survival in patients with MDS. With this new framework, we seek to apply high confidence structural variant detection to the dataset to leverage this information for use in future models. Our preliminary results show promise for the detection of true somatic structural variants. The evaluation of the contribution of structural variant genomic features in patients versus donors will contribute to downstream association analyses with transplant outcomes for patients with MDS. Additional related efforts on the analysis of mitochondrial genome contributions and the effect of deleterious variants are also under way. These efforts support the analysis and discovery of additional factors that play a role in patient transplant outcomes.

D. Clinical Research in Transplantation

Conduct clinical outcomes research using the CIBMTR research database and repository.

Observational Research

- Published 14 manuscripts in peer-reviewed journals during the last quarter (see publications below).
- A total of 30 abstracts were accepted for presentation at the 2022 American Society of Hematology (ASH) Annual Meeting scheduled to be held Dec. 10-13 in New Orleans, LA. Presentation titles and type are detailed in the table below. Abstracts will be available on the ASH meeting website in November.

Table 1: CIBMTR presentations at 2022 ASH Annual Meeting

Title	Status
Does Race/Ethnicity Impact Umbilical Cord Blood Transplant Outcomes in a Contemporary Era?	Oral
Association between patient-reported outcomes and the social transcriptome profile as a predictor of clinical outcomes following hematopoietic stem cell transplant	Oral
Graft Failure in MDS and Acute Leukemia Patients After Allogeneic Stem Cell Transplantation Receiving Post Transplant Cyclophosphamide	Oral
Younger Matched Unrelated Donors Confer a Decreased Relapse Risk As Compared to Older Sibling Donors for Adult B-Cell ALL Patients Undergoing Allogeneic Hematopoietic Cell Transplantation	Oral

Comparison of Allogeneic Hematopoietic Cell Transplantation Outcomes from Younger Matched Unrelated Donor Versus Older Sibling Donor for Acute Myeloid Leukemia	Oral
Germline-somatic interactions drive JAK2-mediated clonal expansion in myelofibrosis.	Oral
A Real-World Evidence Comparison of One-Year Overall Survival and Relapse-Free Survival Between Patients Treated with Abatacept in Combination with a Calcineurin Inhibitor and Methotrexate versus Antithymocyte Globulin or Post-Transplant Cyclophosphamide Following Allogeneic Hematopoietic Cell Transplantation	Oral
Real-World Outcomes for Patients with Relapsed or Refractory (R/R)Aggressive B-Cell Non-Hodgkin's Lymphoma (aBNHL) Treated withCommercial Tisagenlecleucel: Subgroup Analyses from the Center for International Blood and Marrow Transplant Research (CIBMTR) Registry	Oral
Clinical outcomes following allogeneic transplant with omidubicel or other donor sources in patients with hematologic malignancies: comparison of clinical trial results to external controls drawn from the CIBMTR database	Oral
Development of A risk score to predict the incidence of acute graft versus host disease after allogeneic HEMATOPOIETIC cell transplantation (HCT)	Oral
Observational cohort study of people living with HIV treated with CD19-directed CAR T cell therapy for B-cell lymphoid malignancies	Oral
Improved Outcomes of UM171-Expanded Cord Blood Transplantation Compared with Other Graft Sources: A Real-World Database Study	Oral
Ongoing Risk of Unrelated Donors Testing Positive for COVID-19 Following Medical Clearance and Impact on Operations: A Report from the National Marrow Donor Program	Oral
Associations of Minor HistocompatibilityAntigens with Clinical Outcomes FollowingAllogeneic Hematopoietic Cell Transplantation	Oral
International Collaborative Study to Compare the Prognosis for Acute Leukemia Patients Transplanted with Intensified Myeloablative Regimens	Poster
Impact of center specific analysis on hematopoietic cell transplant center volumes	Poster
Comorbidities, Toxicities and Efficacy Outcomes after Chimeric Antigen Receptor T-cell Therapy in B cell Lymphoma	Poster
Impact of Age on Outcomes after CD19 Directed CAR T Cell Therapy for Large B Cell Lymphomas: Real World Experience from the Center for International Blood & Marrow Transplant Research (CIBMTR)	Poster
Racial, ethnicity and socioeconomic disparity in outcome of patients with chronic graft-versus-host disease	Poster
Utilization of Autologous HCT in Multiple Myeloma: A novel linkage of CIBMTR, cancer registry and hospitalization data in California	Poster
Subsequent Solid Neoplasms Following Hematopoietic Cell Transplantation (HCT) for Hematologic Malignancies: Comparing Center For International Blood And Marrow Transplant Research (CIBMTR) and California Cancer Registry (CCR) Data	Poster
Comparison of vital status and cause-specific mortality after Hematopoietic Cell Transplantation between the Center for International Blood and Marrow Transplant Research and the California Cancer Registry: a record-linkage analysis from 1991 to 2018	Poster
Access: A Multi-Center, Phase II Trial of HLA-Mismatched Unrelated Donor Hematopoietic Cell Transplantation with Post-Transplantation Cyclophosphamide for Patients with Hematologic Malignancies	Poster

Quality of Life in Patients Undergoing Double Umbilical Cord Blood vs. Haploidentical Marrow Transplantation: a QOL Analysis Report of BMT CTN 1101	Poster
Comparable Incidence Rates of Hematologic and Non-Hematologic Malignancies, Thrombotic Events, and Autoimmune Disorders in Unrelated Adult Donors Undergoing Bone Marrow Collection Versus Peripheral Blood Stem Cell Mobilization with Recombinant Human Granulocyte Colony-Stimulating Factor (rHuG-CSF): Results of the Donor Long-Term Follow-up Study By the National Marrow Donor Program (NMDP)	Poster
An Exploration of Unrelated Donor Existence for Patients Who Received Haploidentical Hematopoietic Cell Transplants	Poster
Analysis of US Registry Data on Patient Characteristics, Treatment Patterns and Outcomes of Patients Receiving Extracorporeal Photopheresis with or without Ruxolitinib	Poster
Veno-Occlusive Disease Risk and Other Outcomes in Patients with B-Cell Precursor Acute Lymphoblastic Leukemia Who Received Inotuzumab Ozogamicin and Proceeded to Hematopoietic Stem Cell Transplantation: A Registry-Based, Observational Study	Poster
Shared Graft Versus Leukemia Minor Histocompatibility Antigens in DISCOVeRY-BMT	Poster
Genome-Wide Non-HLA Mismatches Improve Risk Stratification for Overall Survival and Cause Specific Mortality after Unrelated Donor Allogeneic HCT	Poster

Research data collection and systems enhancements

During the past quarter, CIBMTR has continued support for electronic data submission initiatives, production FormsNet Recipient, FormsNet Donor, and AGNIS customers, as well as Data Warehouse users. Progress has been made on the following critical projects to upgrade our technology supporting the program:

Simplify Data Acquisition

To acquire timely, high quality, data with less administrative burden to current and new partners/patients.

FormsNet (FN3)

Continued the quarterly releases of recipient form revisions to be current with existing treatment practices, as well as implemented revisions of forms to support the cellular therapies registry. Completed and in-process enhancements within Data Capture applications include:

- Added collection fields within FN3 and updated tools for supporting Data Transformation Initiative, with a planned October release
- Enhancements to query functionality, including ability to mass upload CRID and consent queries, with a planned October release
- Enhancements to internal tool User Interface (UI) features to support reprocessing multiple forms at a single time, with a planned October release
- Study Tool enhancements to site selection and excel export of subjects, with a planned October release
- FormsNet3 Forms Definition Manager (FDM): Completed several proactive security vulnerability updates revealed by new scans
- FDM/AGNIS Mapping Tool:

- Further configuration of tool to connect to new Cancer Data Standards Registry and Repository (caDSR) API
- FN3 Donor drug administration question updates:
 - Forms 710-714, 715, and 730-731 (additional drug option added)
 - Forms 710 -714 and 730-731: Question about whether filgrastim was self-administered in a non-clinical setting was separated into two separate questions
- Update FormsNet Donor module to send an automated email to Transplant Centers when Form 773 (MNC-A) is complete
- Audit Tool: Changed settings so Form 2005 is no longer auditable
- Audit Migration to FN3:
 - Completed Question Tree Management functionality in FN3 to reduce manual work, increase data quality, reporting capabilities, and configurability for the future

- Developed and released the following data collection forms in September 2022.

Form	Form Name	Category
2400R10	Pre-Transplant Essential Data	Revised recipient form
2402R7	Disease Classification	Revised recipient form
2006R6	Hematopoietic Cellular Transplant (HCT) Infusion	Revised recipient form
4000R9	Cellular Therapy Essential Data Pre-Infusion	Revised recipient form
2450R7	Post-Transplant Essential Data	Revised recipient form
2100R8	Post-Infusion Follow-Up	Revised recipient form
2199R1	Donor Lymphocyte Infusion	New recipient form
710r8/712r8/713r8/714r8	Filgrastim Mobilized PBSC Day One / Day Two / Day Three / Day Four Donor Assessment	Revised Donor Form
Form 715r5	Neupogen (filgrastim) Administration Confirmation	Revised Donor Form
Form 730/731	Filgrastim Mobilized PBSC Day Five and Day Six Donor Assessment / Apheresis Procedure	Revised Donor Form

Electronic data submission/AGNIS

CIBMTR continued support for electronic data submission initiatives and production AGNIS customers. Effort focused on support for CIBMTR form revision updates to existing forms.

- Recent AGNIS and other electronic data submission accomplishments:
- The AGNIS team continues to release forms for centers to use in data submission to the CIBMTR as well as address questions or issues raised by centers and their vendors.
- Three AGNIS forms were released to external test and awaiting external partner testing before moving to production:
 - 2900r5 Patient Death Data
 - 2450r6 Post-Transplant Essential Data
 - 2400r9 Pre-Transplant Essential Data

Automated data exchange using electronic data collection systems that interface directly with source health and laboratory records

CIBMTR has continued to update its reporting application to exchange additional discrete electronic data records. Using the data extracted directly from data collection systems at partner centers, CIBMTR further expanded capabilities to populate additional laboratory data points on 26 forms at both pre-infusion and

post-infusion time points. These expanded capabilities provide partner transplant centers with improved time savings and eliminate the potential of manual data entry errors. Additionally, the underlying structures for data exchange and storage were updated based on current standards – these updates are the foundation upon which we will be able to expand the types of data that can be exchanged electronically.

Simplify Data Analysis

Collect & analyze more data more frequently without increasing the burden on centers.

Integrated Data Warehouse (IDW)

CIBMTR continued to increase the capabilities of the IDW, which is the Operational Data Warehouse utilized for delivery of key data to stakeholders. Accomplishments include:

- Incorporated ongoing forms revisions into the warehouse
- Continued enhancing processes to support CIBMTR's Domestic and International CPI Processes.
- Continued enhancing study information and visualizations to support our Prospective Research team.
- Began planning to enhance our Sample Inventory data processes with Labvantage
- Completed first round of 2022 Center Volumes Data Reporting project.
- Provided ePRO data for use in Data Back to Centers (DBtC) dashboard.
- Provided Survivorship Plans for external partners use through the DBtC portal

Unified Domain Model (UDM)

Continuing the process of building this single source of truth of data that will contain high quality, validated data readily available to researchers for immunobiology, outcomes, and other types of analyses.

- Continued transitioning HCT data from the Research Database to the Unified Domain Model (UDM) including delivery of 16 data extracts directly from UDM and continued development of a relapse-specific data domain.
- Continued delivery of monthly and quarterly CAR T-cell data sets to our Japan (JDCHCT) and pharmaceutical partners.
- Continued refinement and delivery of Periodic Safety Update Reports (PSUR) for two CAR T-cell therapies.
- Provided quarterly Stem Cell Therapeutic Outcomes Data required for the HRSA SCTOD quarterly report.
- We have recently completed the work allowing UDM to fully ingest the HLA and match grade data pertaining to all allogeneic and autologous transplants tracked by the CIBMTR. This data is provided internally through an HLA Save extract (discussed below) and can be combined with any other data extracts.
- Added new DLI table structure to database to enable loading of this new FormsNet form data into UDM.

Enhance Data Sharing and Visualization

Deliver data visualization and analytic tools that will enable stakeholders to more efficiently interact with data to identify relevant trends and patterns.

- Enhanced the Data Back to Centers (DBtC) dashboard and Data Back to Centers Download (DBtC-Download) to leverage the extracts produced from UDM and the HCT Centralization project

- Created additional reports in new Business Intelligence tool, Looker, to support CIBMTR Prospective Research team needs. Enhanced Business Intelligence reports to support ePRO Data Quality efforts.
- Business Intelligence Data Sharing- Continued expansion of business intelligence tool capabilities. Adding to the existing suite of external Business Intelligence data sharing applications including the introduction of more data, dimensions and measures, stakeholder groups, and continuing data quality initiatives.
- This quarter, CIBMTR has released a version of the HLA Save extract. This extract has been developed on CIBMTR's new UDM data platform. This delivery has dramatically transformed the production of this important data set. The HLA Save extract contains the best match grade information (HLA typing and computed match grade scores) for every transplant known to the CIBMTR. This includes all NMDP facilitated transplants, non-NMDP facilitated un-related transplants, related transplant and autologous transplants. The extract for this quarter contains ~174,000 cases from 1999 to 2022, and the technical changes that have occurred have reduced the preparation time from 3-4 weeks down to less than one day. In the past, the process involved 7-8 people performing tasks, and the new process needs only a single person to do the technical work, and a single person to check the automated QA results. Our new platform will allow for new service integrations, new match grade computations, and much better integration with patient outcomes.

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* The American Society of Blood and Marrow Transplant was renamed as The American Society of Transplant and Cellular Therapy in 2020. The change led to an update to the name of the society journal from *Biology of Blood and Marrow Transplant* (Impact Factor: 3.9) to the *Journal of Transplant and Cellular Therapy* resulting in a reset of the impact factor.