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14. ABSTRACT

1. Contingency Preparedness: 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.

2. Rapid Identification of Matched Donors: Increase operational efficiencies that accelerate the search process and increase patient access are key to preparedness in a contingency event.

3. Immunogenic Studies: Increase understanding of the immunologic factors important in HSC transplantation.

4. Clinical Research in Transplantation**:** Create a platform that facilitates multicenter collaboration and data management.

15. SUBJECT TERMS
Research in HLA Typing, Hematopoietic Stem Cell Transplantation and Clinical Studies to Improve Outcomes

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DEVELOPMENT OF MEDICAL TECHNOLOGY
FOR CONTINGENCY RESPONSE TO MARROW TOXIC AGENTS
QUARTERLY RESEARCH PERFORMANCE REPORT
SUBMITTED October 13, 2023

Office of Naval Research

And

The National Marrow Donor Program®

500 5th St N

Minneapolis, MN 55401

I. Heading

PI: Jeffrey Auletta, M.D.
National Marrow Donor Program
N00014-23-1-2057
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 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 immunobiology bioinformatics and clinical research activities promote studies to advance the science and technology of HCT transplantation and directly translate research results to improve outcomes 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. 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 with marrow toxic injuries, such as Acute Radiation Syndrome (ARS), from exposure to ionizing radiation or chemicals. The NMDP manages a network of hospitals that work in concert to facilitate unrelated HCT. The Radiation Injury Treatment Network (RITN), comprised of a subset of NMDP's network centers as well as non-NMDP network centers, is a national network of medical centers with expertise in the management of bone marrow failure and works with partners from other medical specialties to assist with managing ARS and its health-related consequences in response to marrow toxic mass casualty incidents.

B. Development of Science and Technology for Rapid Identification of Matched Donors
Rapid progression to successful transplantation following a marrow toxic exposure or disease diagnosis affects survival. Decreasing the time to identify the optimal donor is critical. Methods are under development to rapidly identify and provide the optimal 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 focus on strategies to maximize success of HCT while minimizing the toxicity related to alloreactivity between the donor graft and the recipient.

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

- 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.
    - Due to cancelation of REAC/TS sponsorships, four additional RITN hospitals will host two 4-hour sessions on radiological incidents and terrorism. This is in addition to the one RITN hospital in the FY2023 budget (West Virginia University Hospital, Morgantown, WV) which was hosted and completed April 11, 2023.
        - Additional hospitals:
            - Corewell Health (Grand Rapids, MI) - hosted and completed June 4 and June 5, 2023
            - University of Wisconsin (Madison, WI) - hosted and completed July 26, 2023
            - Orlando Health, (Orlando, FL) - hosted and completed August 7, 2023

- Temple University (Philadelphia, PA) - hosted and completed September 7, 2023
  - Activity under this section has been completed.

Radiation disaster preparedness training

- No updates at this time.

Hospital radiation disaster preparedness

- Annual disaster readiness tabletop exercises (drills) were scheduled for current RITN hospitals to participate for their annual task completion. Seven sessions were offered and completed between June and August 2023: June 23, July 18, July 27, August 8, two on August 9, and August 16, 2023.
- Two additional disaster readiness exercises (drills) were scheduled, conducted, and completed: Maryland Healthcare Coalitions (April 20, 2023) and Guam (February 28, 2023).
- Activity under this section has been completed.

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 Administration for Strategic Preparedness and Response plans for response to a radiological/nuclear disaster with-in the continental U.S.

- Targeted hospitals in the following cities:
  - Atlanta, GA
  - Nashville, TN
  - Los Angeles, CA
  - San Antonio, TX
  - Dublin, CA
  - Memphis, TN
  - Phoenix, AZ
  - New Orleans, LA
  - Albuquerque, NM
- Specific hospitals approached:
  - Children's Healthcare of Atlanta (CHOA) (Atlanta, GA) - in process of signing agreement
  - Skyline Medical (Nashville, TN)
  - Children's Hospital Los Angeles (CHLA) (Los Angeles, CA)
  - Stanford-Pleasanton (Pleasanton, CA) - in process of signing agreement
  - Corewell East Beaumont Children's Hospital (Royal Oak, MI)
  - Cooper Health (Camden, NJ)
  - LCMC (New Orleans, LA)
- Hospitals signed in FY2023
  - Stanford-Pleasanton (Pleasanton, CA)
  - Children's Healthcare of Atlanta (Atlanta, GA)
- Cooper Health System (Camden, NJ)
- Activity under this section has been completed for FY2023.

Federal partnership development

- Association of Healthcare Preparedness Professionals (AHEPP)
  - AHEPP's mission is to provide healthcare and other preparedness professionals with opportunities for networking, resource sharing, continuing education, and scholarly exchange (ahepp.org).

- Activities under this section are complete.

- National Association of County and City Health Officials (NACCHO) Preparedness Summit
  - In recovering from a long pandemic response, there is a need to redefine not only the endemic phase of COVID-19, but reassess responses to natural disasters, emerging infectious diseases, terrorist threats, climate issues, and maintenance of all-hazards plans. "Recover. Renew: Reprioritizing All-Hazards Preparedness" is the theme for the summit and will give attendees the opportunity to reevaluate issues (old and new) in preparedness, share resources, build skills, and to network with others in the industry.
- RITN is a member of the Radiation Workshop Planning Committee which conducted a 1-day radiation-specific planning workshop Sunday, April 23, 2023, with over 100 attendees.
- Activity under this section has been completed.

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

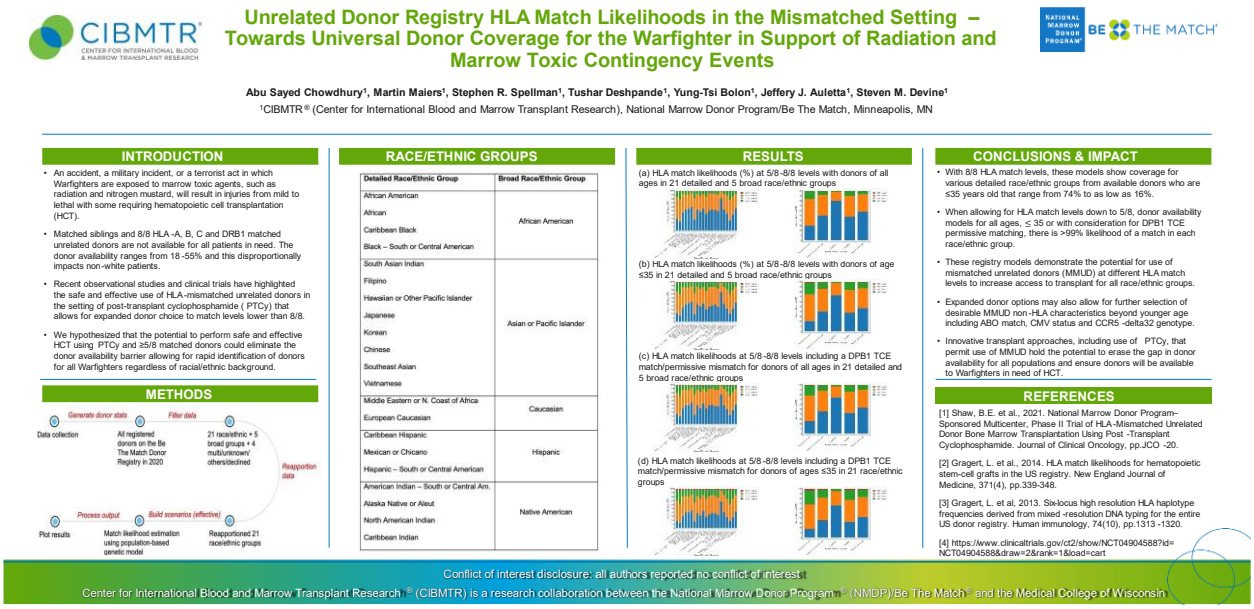
Expand the genetic diversity of the registry through continued addition of adult donors and cord blood units, utilizing high volume HLA typing methodologies

During the past quarter, a total of 48,167 newly registered volunteer donors were HLA typed and added to the Be The Match Registry.

Modeling and analysis of registry coverage for the Warfighter

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. 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. Previously, registry models were restricted in the number of mismatched HLA alleles that could be calculated.

Over the last quarter, we incorporated registry modeling results using new validated code engineered to improve the capabilities and efficiency of registry analysis, including the ability to calculate a wider range of HLA matches and mismatches, into a manuscript that was submitted to and published in the Journal of Transplant and Cellular Therapy. This modeling aids in preparation for coverage of potential donor sources to Warfighters of diverse race and ethnic backgrounds in case of radiation emergencies. We also initiated design for a tool to provide summary projections of donor existence in populations with a variety of diversity ratios. In addition, an abstract summarizing the Warfighter modeling was presented in poster format (below) at the 2023 Military Health System Research Symposium in August.



Development of science and technology for rapid communication of HLA data

Data Standards Hackathon 13

In order to advance the goal of rapid communication of HLA data, NMDP has hosted a series of data standards hackathons to bring together implementers to advance data standards in this field.

NMDP organized a two-and-a-half-day hackathon September 13-15, 2023, concentrating on HLA Gene Feature Enumeration, in Rochester, MN. It was attended by 21 people, including 6 international people. Representatives from the World Marrow Donor Association (WMDA), DKMS and the Anthony Nolan Research Institute were present. We received sponsorship from Histogenetics (a global leader in high-resolution HLA Sequence-based Typing), Omixon (a molecular diagnostics company dedicated to transitioning the HLA community to Next Generation Sequencing technologies) and GenDx (molecular transplant diagnostics), showing their continued interest in the area. Of the 21, 4 were first time attendees, and 2 were from commercial companies (GeneDx and LabCorp). Other topics at the hackathon were pangenomics of the MHC and building interfaces with the new Global Alliance for Genomics and Health (GA4GH) variant representation syntax for HLA.

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

A new methodology using machine learning was developed entitled “Navigating the Trade-offs of HCT and the use of machine learning-driven decision support tools.” Here, time-to-event modeling was used along with multi objective optimization to compare the tradeoffs for impact to patient survival in selection of specific donor characteristics against others. A manuscript demonstrating applications of these methods in selection of donors was drafted in the last quarter. In addition, results were generated with the combination of classical statistics and machine learning and explainable AI methods to decode the influence of donor age, HLA matching, and relatedness on HCT success in leukemia patients.

Preliminary substitution ratios were calculated along with confidence intervals to develop potential quantitative support for donor selection decision-making.

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 Donor/Recipient Pair project continues to enroll the most recent related and unrelated transplant pairs for high resolution HLA typing to ensure that changes in practice can be evaluated using quality-controlled data. Strategic selection of pairs for testing and optimization of practices associated with data storage and management ensure that investigators have timely access to robust, high-quality data to analyze the impact of matching as either the focus of or as a variable in CIBMTR-approved research studies.

During the past quarter, we initiated a pilot with Base5 Genomics for typing across the MHC (Major Histocompatibility Complex) and LRC (Leukocyte Receptor Complex)

The goals of the pilot were:

- Confirm that the method can produce data at this unprecedented resolution
- Test the bioinformatics analysis workflow on representative NMDP samples

Data from the pilot was successfully returned on 10 samples from 8 individuals, comparing the performance from different starting material (2 whole blood aliquots & 8 whole blood aliquots preserved with 10% Dimethylsulfoxide (DMSO)). The goal in terms of sequencing targets were 76 genes in the MHC including 18 classical HLA genes and 42 non-classical HLA genes and 12 other MHC genes of interest. In the LRC region the goal was to sequence 18 KIR genes, 24 LILR genes and 4 LAIR genes.

All gene sequences were provided along with phase information, which all previous methods have not been able to provide, and which is essential for understanding the deeper genomics and evolution of these systems. In terms of sample types, both worked with a slight preference for 10% DMSO.

The pilot produced all the expected results. Due to the new level of resolution, from only 8 individuals the pilot generated 574 HLA alleles (150 of which are putative novel allele), 146 KIR alleles (of which 71 are putative novel alleles) and phasing across the relevant blocks of the LRC and MHC (e.g., alpha, beta, gamma, delta, epsilon). Due to the overwhelming success of this results observed to date, we are considering making this platform the new standard for retrospective typing of donor/recipient pairs which will be a great leap forward compared to the resolution used over the past decade.

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.

A multicenter prospective observational study was launched in 2022 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 manage the IRB approved and ClinicalTrials.gov registered study protocol entitled, "MEASURE: **M**olecular **E**valuation of **A**ML patients after **S**tem cell transplant to **U**nderstand **R**elapse **E**vents". To date, 18 centers have committed to participate in the study and combined plan to enroll >250 patients per year. Fourteen of 18 sites have received local IRB approval for the protocol. All sites have initiated submission of regulatory documents required for participation. Twelve sites have fully opened the study and have enrolled a total of 92 patients through September 2023.

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 the ONR (prior grant years and the current) 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.

During the past quarter accrual continued for U.S. based donors. A total of 502 product samples were received and tested through March 31, 2023, with 56 tested in the last quarter. Preliminary analyses focused on graft composition correlation with donor characteristics and the impact of cryopreservation are underway. Initial results were submitted as the following abstracts to the 2023 ASH annual meeting:

- MAIT Cell Frequencies within PBSC Grafts Are Associated with Donor CMV Serostatus and Age: An Initial Analysis from the DKMS and NMDP Graft Composition Study
- Cryopreservation Changes the Immune Effector Cell Composition of Peripheral Blood Stem Cell Grafts: An Analysis from the DKMS and NMDP Graft Composition Study

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Determine the impact of non-HLA genes and gene expression on allogeneic cell transplantation

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This quarter, a new manuscript entitled, "CYTO-SV-ML: a machine learning framework for discovery and classification of cytogenetic structural variants using whole genome sequencing data" was prepared from methods developed and data analyzed from this grant for submission.

Cytogenetic abnormalities and large genome structural rearrangements detected during tumor progression promote the development of genome instability in cancer patients. Despite technological innovations, it is still biologically and computationally challenging to fully recapitulate structural variation profiles and distinguish somatic cytogenetic abnormalities from artifact or germline structural variations in massive datasets from cancer genomics.

This study introduces a novel machine learning approach for the classification of cytogenetic structural variants (CYTO-SV) using whole genome sequencing data derived from multiple cohorts of patients with myelodysplastic syndromes (MDS). We built an automated workflow CYTO-SV-ML that incorporates a set of classic structural variation pipelines and public databases. With sophisticated optimization of machine learning models, CYTO-SV-ML pipeline demonstrated high sensitivity (translocation / non-translocation CYTO-SV: 0.92 / 0.85) and specificity (translocation / non-translocation CYTO-SV: 0.96 / 0.82) for controlled CYTO-SV classification. Compared to published platforms, this approach displayed competitive performance in detection of clinical cytogenetic abnormalities in patients with MDS. We believe that CYTO-SV-ML is a valuable tool for broad genomics applications with impact for the future of precision medicine.

D. Clinical Research in Transplantation

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

Observational Research

- Published 17 manuscripts in peer-reviewed journals during the last quarter (see publications below).
- A total of 36 abstracts were submitted to the 2023 American Society of Hematology (ASH) annual meeting to be held in San Diego, CA, December 9-12, 2023. Presentation acceptance notices are still being collected and additional detail will be included in the next quarterly report. Abstracts will be published in a supplement to the journal Blood in November 2023.

Research data collection and systems enhancements

During the past quarter, CIBMTR has continued support for electronic data submission initiatives, production FormsNet[SM] Recipient, FormsNet[SM] 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.

FormsNet3[SM] (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 functionality for supporting the Data Transformation Initiative
- Enhancements to allow the system to correctly update survival data when death is incorrectly reported.
- Updates to transplant algorithm to be event-level based instead of patient-level based.
- Enhancements to internal tool for managing a recipient's reporting track
- Updated Consent Tool to change the Not Approached reason from open textbox to option list based on frequently reported reasons, with a planned October 2023 release.
- FormsNet3 Forms Definition Manager (FDM): Completed several proactive security vulnerability updates revealed by new scans
- Enhanced internal FDM editors for validation and events & actions rules
- Study updates were made to the FN3 Donor Form 3000
    - Audit Migration to FN3:
    - Testing in progress for Audit Patient and Event Randomization (released month by month) that reduce manual work, increase data quality, reporting capabilities, and configurability for the future

- Developed and tested the following forms that were released in July 2023:

Form	Form Name	Category
4000R10	Pre-Cellular Therapy Essential Data	Revised Cellular Therapy Form
4001R1	Pre-Cellular Therapy Baseline Data	New Cellular Therapy Form
4100R9	Post-Cellular Therapy Essential Data	Revised Cellular Therapy Form
4101R1	Post-Cellular Therapy Follow-up	New Cellular Therapy 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.
  - One AGNIS form was released to production:
    - 2450r7 Post-Transplant Essential Data
  - Four Three forms were released to external test and are awaiting external partner testing before they will move to production:
    - 2199 Donor Lymphocyte Infusion
    - 4003 Cellular Therapy Product
    - 2006 Hematopoietic Stem Cell Transplant Infusion
    - 4006 Cellular Therapy Infusion

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 29 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. 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.

- Recent electronic data collection accomplishments
  - Expansion of data collected by the CIBMTR Reporting Application to include medications

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.

- Completed Phase1 of the annual Center Volumes Data Reporting project.
- Continued enhancing study information and visualizations to support our Clinical Research Outcomes team.
- Enhanced Sample Inventory data repotting dashboards with data from other CIBMTR systems
- Provided Cord Blood Banks new supplemental report capabilities in the Quarterly Cord Blood Quality Report
- Updated Survivorship Plans for external partners use through the DBtC portal based on data consumer feedback
- Provided Survivorship Plans for external pilot centers
- Provided variable-specific audit instructions for Japanese Data Center Hematopoietic Cell Transplantation.

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.

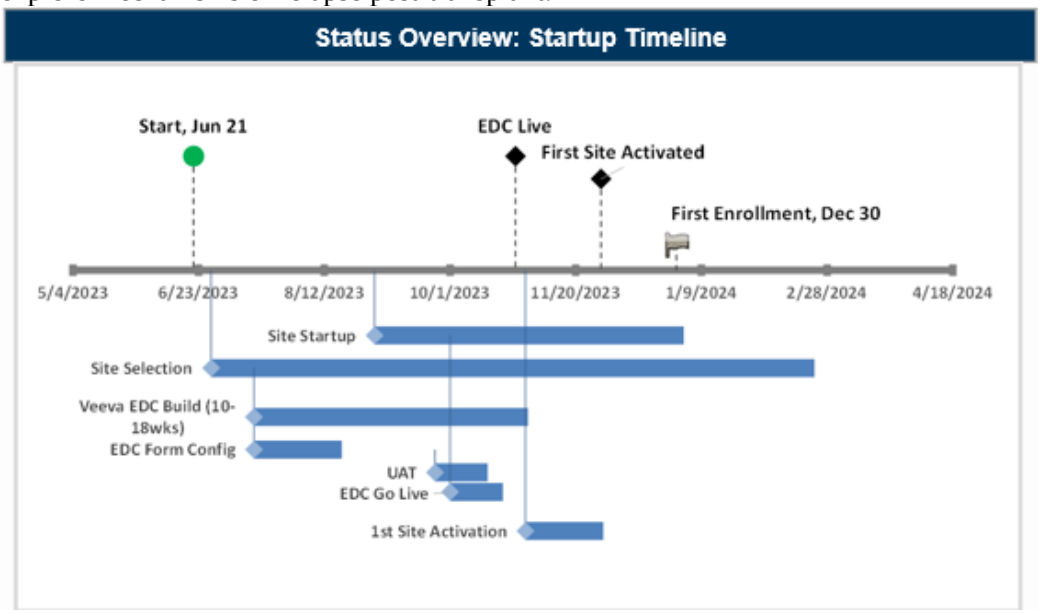
- Continued transitioning HCT data from the Research Database to the Unified Domain Model (UDM) including delivery of 15 data extracts directly from UDM and continued development of a relapse-specific data domain.
- Continued delivery of monthly and quarterly CAR T-cell data sets to our Japan (JDCHCT) and pharmaceutical partners.
- Continued refinement and delivery of Periodic Safety Update Reports (PSUR) for CAR T-cell therapies.
- Provided quarterly Stem Cell Therapeutic Outcomes Data required for the HRSA SCTOD quarterly report.

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.

- 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.
- Annual update initiatives for the applications *One-Year Survival Calculator* and *Center Performance Analytics (CPA)* have begun.
- Pilot centers have been identified for the Virtual Survivorship application and are being trained on how to use the application.
- Updates to the *Center Volumes Dashboard Reporting (CVDR)* application have been completed; the application has been released to production. The annual CVDR event will take place from October into November. A new application *PartnerShare - StudyLink BMTCTN* has begun user acceptance testing with a pilot a pilot organization. This application has been released to production and will soon be available for other organizations interested in receiving their BMTCTN data as self-service.

Conduct clinical trials on the use of HLA mismatched graft sources to expand access to all patients in need of allogeneic cell transplantation

During the last quarter, work continued on the development of a new prospective clinical trial protocol designed to build upon the successful MMUD post-transplant cyclophosphamide platform. The study protocol entitled, "OPTIMIZE: A Phase II Study of Reduced Dose Post Transplantation Cyclophosphamide as GvHD Prophylaxis in Adult Patients with Hematologic Malignancies Receiving HLA-Mismatched Unrelated Donor Peripheral Blood Stem Cell Transplantation" was approved by the NMDP IRB in September 2023. Enrollment on the trial is anticipated to start in the next quarter (timeline below). Funds from this grant will support protocol defined correlative studies to evaluate immune reconstitution and explore mechanisms of relapse post-transplant.



Publications

1. Cusatis R, Balza J, Uttke Z, et al. Patient-reported cognitive function among hematopoietic stem cell transplant and cellular therapy patients: A scoping review. Quality of Life Research. doi:10.1007/s11136-022-03258-0. Epub 2022 Oct 6. Impact Factor: 4.14

2. Olson TS, Frost BF, Duke JL, et al. Pathogenicity and impact of HLA class I alleles in aplastic anemia patients of different ethnicities. Journal of Clinical Investigation Insight. 2022 Nov 22; 7(22):e163040. doi:10.1172/jci.insight.163040. Epub 2022 Oct 11. PMC9746824. Impact Factor: 9.48

3. Boyiadzis M, Zhang MJ, Chen K, et al. Impact of pre-transplant induction and consolidation cycles on AML allogeneic transplant outcomes: A CIBMTR analysis in 3113 AML patients. Leukemia. doi:10.1038/s41375-022-01738-3. Epub 2022 Oct 12. Impact Factor: 12.88

4. Pagliuca S, Gurnari C, Hercus C, et al. Molecular landscape of immune pressure and escape in aplastic anemia. Leukemia. doi:10.1038/s41375-022-01723-w. Epub 2022 Oct 17. Impact Factor: 12.88

5. Cusatis R, Martens MJ, Nakamura R, et al. Health-related quality of life in reduced intensity hematopoietic cell transplantation based on donor availability in patients aged 50-75 with advanced myelodysplastic syndrome: BMT CTN 1102 American Journal of Hematology. doi:10.1002/ajh.26768. Epub 2022 Oct 17. Impact Factor: 10.05

6. Vasu S, Holtan S, Shimamura A, et al. Bringing patient and caregivers voices to the clinical trial chorus: A report from the BMT CTN patient and caregiver advocacy task force. Transplantation and Cellular Therapy. doi:10.1016/j.jtct.2022.10.016. Epub 2022 Oct 22. Impact Factor: 5.60

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