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Spellman, Stephen

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National Marrow Donor Program
500 N. 5th St.
Minneapolis, MN 55401-1206

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Office of Naval Research
875 N. Randolph Street, Suite 1425
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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

FINAL RESEARCH PERFORMANCE REPORT

SUBMITTED October 15th, 2019

Office of Naval Research

And

The National Marrow Donor Program®

500 5th St N

Minneapolis, MN 55401

I. Heading

PI: Steven Devine, M.D.

National Marrow Donor Program

N00014-18-1-2888

Development of Medical Technology for Contingency Response to Marrow Toxic Agents

II. Scientific and Technical Objectives

The main objective of this grant is to develop, test and mature the ability of the National Marrow Donor Program® (NMDP) to address contingency events wherein civilian or military personnel are exposed to marrow toxic agents, primarily ionizing radiation or chemical weapons containing nitrogen mustard. An accident, a military incident, or terrorist act in which a number of individuals are exposed to marrow toxic agents will result in injuries from mild to lethal. Casualties will be triaged by first responders, and those with major marrow injuries who may ultimately be candidates for hematopoietic cell transplantation (HCT) will need to be identified. HCT donor identification activities will be initiated for all potential HCT candidates. 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 process 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 and clinical research activities promote studies to advance the science and technology of HCT to improve outcomes and quality of life for the patients.

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.

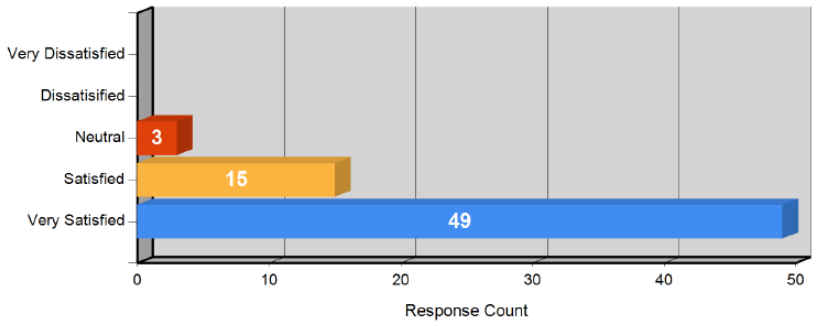
Recovery of casualties with significant myelosuppression following radiation or chemical exposure is optimal when care plans are designed and implemented by transplant physicians.

RITN activities

- Expanded the network of hospitals through the addition of Georgetown Hospital.
- Completed a competency assessment of the network.
- Performed two site visit assessments (University of Chicago, and Roger Williams).
- Provided two Advanced HAZMAT Life Support - Radiological Incidents and Terrorism classes at Mayo Clinics in Rochester, MN with a total of 16 attendees.
- Held the seventh semi-annual 2019 RITN Workshop: *Crisis in context: Minding the gaps in medical preparedness for a Rad/Nuke Incident*; in Crystal City, VA July 30-31. The workshop was well attended with 160 participants including 47 speakers. 95.5% of the attendees, who responded to the satisfaction survey (n=67), reported they were Satisfied or Very Satisfied with the workshop (metrics below).

Chapter: Evaluation
Overall rating of the RITN Workshop.

Total Respondents:	67
Total Skipped:	0



	Choice	Response Percent	Response Total
1	Very Satisfied	73.13 %	49
2	Satisfied	22.39 %	15
3	Neutral	4.48 %	3
4	Dissatisified	0.00 %	0
5	Very Dissatisfied	0.00 %	0

Analytics	
Mean	1.313
Standard Deviation	0.552
Standard Error	0.067
Variance	0.305
Top 2	95.52%
Bottom 2	0.00%

- Increased awareness of the RITN through presentations at 4 national conferences reaching over 700 attendees.
    - ASPR Innovation Day presentation for RITN and the Be The Match BioBank,
    - BARDA invited speaker series
    - Society of Disaster Medicine and Public Health Annual Conference
    - Binational Radiation Emergency Advisory Council in El Paso, TX.
- Held a variety of exercises from tabletop exercises to functional exercises.
    - The RITN annual tabletop exercise offered two focus areas this year involving a total of 1,046 medical professionals.
        - Path 1 was a Planning and Messaging focused exercise which included 27 hospitals that participated in one of three web-based exercises and five hospitals which held the exercise on their own.
        - Path 2 was a Medical Treatment focused exercise which included 36 hospitals that participated in one of three web-based exercises and 11 hospitals which held the exercise on their own. The total number of medical professionals who were involved with these exercises was 1,046.
    - RITN conducted four regional tabletop exercises with the metropolitan communities of Buffalo, Chicago, Denver and Omaha strengthening preparedness through the coordination between RITN hospitals and their National Disaster Medical System partners in the region.
    - Developed and conducted two functional exercises, one at Texas Children's Hospital (Houston) and the other at West Penn Hospital (Pittsburgh).

NMDP's critical functions must remain operational during contingency situations that directly affect the Coordinating Center.

Operational Continuity Planning

As part of the organizations pursuit to improve operational resiliency the business impact analysis was updated and collaboration with the Information Technology Disaster Recovery team was intensified resulting in multiple IT software system tabletop exercises and the addition of ten recovery plans for software systems into a web-based interface. The organization Media Crisis Team participated in a tabletop exercise to assess their response to an active assailant scenario; this is the first of three department level exercises that will culminate with a combined exercise to assess the organization's readiness.

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

Increasing the resolution and quality of the HLA testing of volunteers on the Registry will speed donor selection.

Donor Recruitment HLA Typing

Year to date, completed HLA typing of 180,279 newly recruited U.S. donors (30% minority).

Registry data on HLA allele and haplotype frequencies and on the nuances of HLA typing can be used to design computer algorithms to predict the best matched donor or cord blood unit.

Machine Learning Strategies for Optimizing Donor Selection

During the past quarter, analysis continued on a patient cohort which was prepared for this project (N=3,751) with the clinical outcomes from an 8/8 allele match unrelated donor transplant and the corresponding list of equally well-matched donors and a series of attributes involved in donor selection.

We trained a machine learning model (Bayesian Additive Regression Trees) on the outcomes of 180 day survival and acute graft versus host disease and applied it to the donors in the potential match list for a 3-year cohort of patients.

The main finding is that for 50% of searches there was some potential for an improved risk alternative donor choice. For 25% of the transplants there was a better option with > 50% chance of providing better outcome. For 12.5% of transplants where was a better donor option with >75% chance of providing better outcome. These results indicate that if this model were operationalized and used to prospectively inform donor selection decisions this would have a measurable impact in terms of transplants with regard to these clinical endpoints.

These results are being replicated with refreshed data to address minor issues with the donor age variable. Based on these encouraging results we are planning a follow-up project to train a model based on the 1-year endpoints that constitute the operational definition of event-free-survival (death, moderate to severe chronic graft vs host disease, relapse and graft rejection).

HLA Imputation

During the past quarter improvements have been made to the method to impute HLA, building on the system described at https://www.ncbi.nlm.nih.gov/pubmed/30689784.

The approach for imputing multi-race individuals has been validated on a clinical cohort of patients and donors in order to tune the parameters to optimize the performance of the algorithm in terms of its accuracy in predicting the high-resolution HLA type of the donor.

Validation of this new graph-based imputation method have uncovered a number of bugs that have been addressed and several performance optimizations to allow the imputation process to be scaled across a

number of CPUs on a single host. The most recent experiment ran on a 72 CPU server and reduced run time from 15 hours down to 20 minutes for a cohort of 57,000 separate requests. The clinical performance of this new algorithm is still being evaluated and is expected to provide improved prediction compared with the current algorithm, particularly for patients from underserved populations, with mixed ethnic background or with lower representation in the US population frequency data.

Haplotype Frequency Curation
A small number of enhancements and bugfixes where made during the past quarter on a database for curating haplotype frequencies. User authentication models are being evaluated with the goal of providing a public system for accessing licensed HLA haplotype frequency data in clinical web-based and mobile applications

Reducing the time and effort required to identify closely matched donors for patients in urgent need of HSC transplants will improve access to transplantation and patient survival in the context of a contingency response and routine patient care.

- Facilitated the procurement of 4 products for the NIH Transplant Program (3 PBSC and 1 CBU)

C. Immunogenetic Studies in Transplantation

HLA mismatches may differ in their impact on transplant outcome, therefore, it is important to identify and quantify the influence of specific HLA mismatches. In contingency situations, it will not be possible to delay transplant until a perfectly matched donor can be found.

Donor Recipient Pair Project and Whole Genome Genotyping

- Initiated data evaluation and curation of whole genome genotyping (WGG) from 2000 samples genotyped using the Illumina Infinium Global Screening Array-24 v2.0 chip.
- Donor/Recipient Pair Project testing of 475 pairs transplanted for acute lymphocytic leukemia, acute myelogenous leukemia and myelodysplastic syndromes was initiated at the centralized contract laboratory. Testing will be complete early next quarter.

Full HLA Gene Matching Analysis

- The Donor-Recipient Pair Project has employed ultra-high resolution (UHR) HLA typing techniques for several years. Recent studies by the Anthony Nolan Research Institute and MCW/BCofWI have described potential benefits of matching at UHR resolution. A validation

study using the CIBMTR database is needed to offer further guidance to the field on donor selection and support decisions regarding resolution for Registry typing.

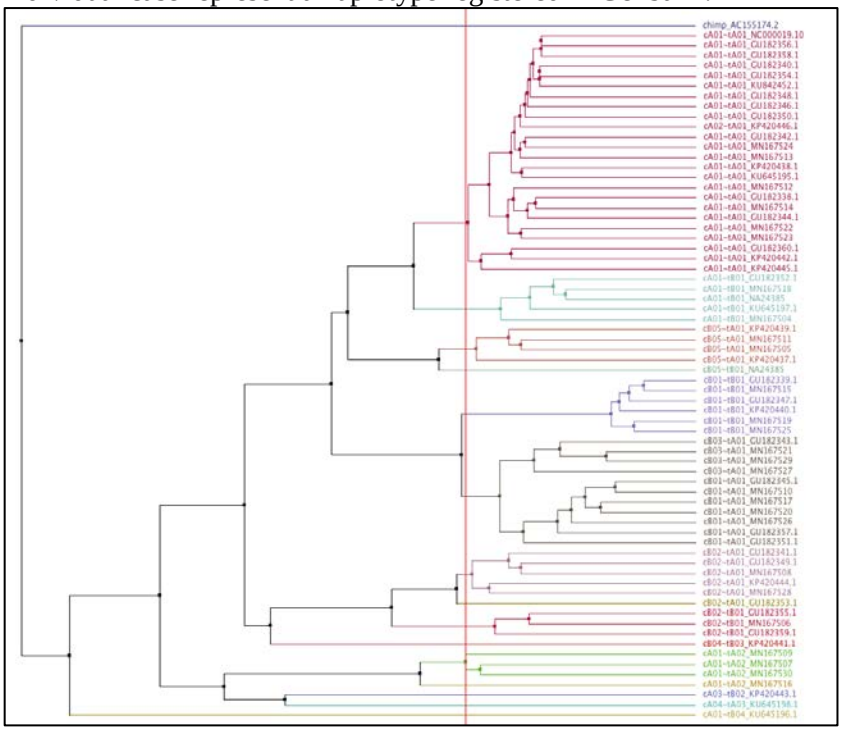
- Assessment of UHR matching was completed on a cohort of ~5,600 donor/recipient pairs. Match assignments were shared with the study team and independent validation of the coding is underway and will be completed early next quarter.
- Clinical correlation of UHR matching will be completed next quarter with the goal to submit a late breaking abstract to the 2020 American Society of Transplant and Cellular Therapy meeting.

Even when patient and donor are HLA matched, GVHD occurs, therefore, other loci may play a role.

KIR Region Genomics

- During the past quarter a manuscript was drafted describing a method for efficient sequencing and assembly of human KIR haplotypes. The results suggest an 18-probe pool is sufficient to capture the KIR region. This analysis evaluates the performance of the Pacific Biosciences "Sequel" platform relative to the RSII and shows modest increases in read length and orders-of-magnitude increases in quality and coverage for minimal increase in cost. This probe capture and sequencing approach is the first of its kind to fully sequence and phase all human KIR haplotypes, and it is efficient enough for population-scale studies and clinical use. This study also implements a new method for analyzing structural variation across the KIR region by comparing the full set of 69 KIR region genomic structures characterize in humans (and 1 chimpanzee).

- The figure below shows a phylogenetic analysis of these KIR region genomic regions the different colors represent a particular pattern of gene content and arrangement and each individual case represent a haplotype registered in Genbank.



D. Clinical Research in Transplantation

Clinical research in transplantation improves transplant outcomes and supports preparedness for a contingency response.

Observational Research

- Completed analyses on 16 studies and submitted abstracts describing the results to the 2020 American Society of Transplant and Cellular Therapy meeting.
- Identified 8 high impact observational studies to complete in FY20.
- Published 20 peer-reviewed manuscripts in the last quarter.
- 25 abstracts (12 oral and 13 poster) were accepted for presentation at the 2019 American Society of Hematology Annual Meeting (list below).

2019 American Society of Hematology Meeting Presentation Schedule

Title	***Status***	***Presenter***
Saturday, December 7, 2019		
Fludarabine and Melphalan Compared with Reduced Doses of Busulfan and Fludarabine Improves Transplant Outcomes in Older MDS Patients	**Oral**	Betul Oran
Primary Plasma Cell Leukemia Outcomes Remain Dismal Despite Novel Agents and Hematopoietic Cell Transplantation	**Oral**	Sagar Patel
Superior Survival with Post-Remission Pediatric-Inspired Chemotherapy Compared to Myeloablative Allogeneic Hematopoietic Cell Transplantation in Adolescents and Young Adults with Ph-Negative Acute Lymphoblastic Leukemia in First Complete Remission: Comparison of CALGB 10403 to Patients Reported to the CIBMTR	**Oral**	Matthew Wieduwilt
Comparison of Reduced-Intensity Conditioning (RIC) Regimens for Allogeneic Hematopoietic Cell Transplantation (alloHCT) in Non-Hodgkin Lymphomas (NHL)-a Center for International Blood & Marrow Transplant Research (CIBMTR) Analysis	**Oral**	Nilanjan Ghosh
Allogeneic Hematopoietic Stem Cell Transplantation for Therapy-Related Myelodysplastic Syndromes and Acute Myeloid Leukemia	**Poster**	Leland Metheny
Lower Hematopoietic Progenitor Cell Counts and Yields at Subsequent Donations Is Influenced By a Shorter Inter-Donation Interval between the First and Subsequent Mobilizations	**Poster**	Sandhya Panch

Busulfan, Melphalan, and Bortezomib Compared to Single Agent High- Dose Melphalan As a Conditioning Regimen for Autologous Hematopoietic Stem Cell Transplantation in Multiple Myeloma: Long Term Follow up of a Novel Conditioning Regimen	**Poster**	Patrick Hagen
Genome-Wide Association Study Identifies an Immune-Related Etiology for Severe Aplastic Anemia	**Poster**	Sharon Savage
De Novo and Therapy-Related Acute Myeloid Leukemia and Myelodysplastic Syndrome: Similarities and Differences in SNP-Array Detected Chromosomal Aberrations in Pre-Transplant Blood Samples	**Poster**	Youjin Wang
Sunday, December 8, 2019		
Allogeneic Transplantation for Myelodysplastic Syndrome in Adults over 50 Years Old Using Reduced Intensity/Non-Myeloablative Conditioning: Haploidentical Relative Versus Matched Unrelated Donor	**Poster**	Michael Grunwald
Impact of Renal Dysfunction Measured By Estimated Glomerular Filtration Rate (eGFR) on Outcomes after Allogeneic Hematopoietic Cell Transplantation (HCT)	**Poster**	Ajoy Dias
Comparison of Reduced-Intensity Conditioning (RIC) Regimens for Allogeneic Hematopoietic Cell Transplantation (alloHCT) for Classical Hodgkin Lymphoma (cHL): A Center for International Blood & Marrow Transplant Research (CIBMTR) Analysis	**Poster**	Sairah Ahmed
Tisagenlecleucel Chimeric Antigen Receptor (CAR) T-Cell Therapy for Relapsed/Refractory Children and Young Adults with Acute Lymphoblastic Leukemia (ALL): Real World Experience from the Center for International Blood and Marrow Transplant Research (CIBMTR) and Cellular Therapy (CT) Registry	**Poster**	Stephan Grupp
Monday, December 9, 2019		
Early Broad-Spectrum Antibiotics and Risk of Acute Graft-Versus-Host Disease in Children: an analysis from the Center for International Blood and Marrow Transplantation Research (CIBMTR) and the Pediatric Health Information System (PHIS)	**Oral**	Caitlin Elgarten
Excellent Overall Survival and Low Incidence of Late Effects in Patients Undergoing Allogeneic Hematopoietic Cell Transplant for Sickle Cell Disease: A Report from the Center for International Blood and Marrow Transplant Research (CIBMTR)	**Oral**	Elizabeth Stenger
Post-Transplant Work Status of Young Adult Survivors of Allogeneic Hematopoietic Cell Transplant: A Report from the Center for International Blood and Marrow Transplant Research (CIBMTR)	**Oral**	Neel A. Bhatt
Post-Marketing Use Outcomes of an Anti-CD19 Chimeric Antigen Receptor (CAR) T Cell Therapy, Axicabtagene Ciloleucel (Axi-Cel), for the Treatment of Large B Cell Lymphoma (LBCL) in the United States (US)	**Oral**	Marcelo Pasquini
Breaking the Glass Ceiling of Age in Transplant in Multiple Myeloma	**Oral**	Pashna N. Munshi

Novel Prognostic Scoring System for Autologous Hematopoietic Cell Transplantation (AHCT) in Multiple Myeloma (MM)	**Oral**	Binod Dhakal
Tisagenlecleucel Chimeric Antigen Receptor (CAR) T-Cell Therapy for Adults with Diffuse Large B-Cell Lymphoma (DLBCL): Real World Experience from the Center for International Blood & Marrow Transplant Research (CIBMTR) Cellular Therapy (CT) Registry	**Oral**	Samantha Jaglowski
Does Addition of Rituximab® to BEAM Conditioning Improve Outcomes of Patients with Diffuse Large B-Cell Lymphoma (DLBCL) Undergoing Autologous Hematopoietic Cell Transplantation (auto-HCT)?	**Oral**	Deepa Jagadeesh
Impact of Depth of Pretransplant Clinical Response on Outcomes of Acute Myeloid Leukemia Patients in First Complete Remission (AML-CR1) Who Undergo Allogeneic Hematopoietic Cell Transplantation (AlloHCT)	**Poster**	Mary-Elizabeth Percival
Cognitive Impairment Is Associated with Inferior Survival and Increased Non-Relapse Mortality in Older Allogeneic Hematopoietic Cell Transplant (alloHCT) Recipients: A Multicenter Retrospective Study	**Poster**	Rebecca Olin
Myeloablative Conditioning Is Preferred for Allogeneic Transplantation of Acute Myeloid Leukemia and Myelodysplastic Syndromes with Low/Intermediate but Not High Disease Risk Index	**Poster**	Nelli Bejanyan
Genome Wide Interaction Analysis Identifies Expression Quantitative Trait Loci Associated with Reduced Survival after Reduced Intensity Conditioning HLA-Matched Unrelated Donor Allogeneic Hematopoietic Cell Transplant	**Poster**	Ezgi Karaesmen

Research data collection and systems enhancements

During the grant year, CIBMTR has continued support for electronic data submission initiatives, production FormsNet Recipient, FormsNet Donor, and AGNIS customers, as well as Data Warehouse users.

FormsNet

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:

- A concerted effort to enhance performance and monitoring for the FormsNet application, as our user base continues to grow and evolve. In this reporting period, FormsNet 3 code efficiencies were identified, developed, and deployed, significantly increasing FormsNet 3 performance despite a significant increase in the utilization of the FormsNet database by a variety of newer tools and queries. We will continue to utilize feedback from the user perspective surveys to inform future performance enhancements.
- Investigations towards more modular (domain-based) data capture, to decrease form size and increase re-use of modules.

- Created and updated tools to enhance efficiencies. Continued work on multi-center reporting to accommodate cellular therapies. Developed proposal for this work including concurrent reporting and patient data portability.
- Added multi-language support to allow FormsNet system and forms to display in a language other than English. Cellular therapy forms translated into Japanese. This functionality will be released into FormsNet in October, 2019.
- Continued work on form revisions for data collection forms for the Winter 2020 release. Developed and prepared the following data collection forms for release in October 2019:
    - CIBMTR Research Id Assignment Form (2804)
- FormsNet 2 was retired in September 2019, after remaining applications were migrated to the FormsNet 3 platform. FormsNet2 server decommissioning will be complete by December 2019.

Electronic data submission/AGNIS

CIBMTR continued support for electronic data submission initiatives and production AGNIS customers. Effort focused on development of new AGNIS instances of CIBMTR disease specific forms, and support for CIBMTR form revision updates to existing forms. The team is in process of completing communication, educational and technical project implementations to lower AGNIS submission burden and increase the client-base including but not limited to:

- Increasing the reuse of existing AGNIS modules when supporting form revisions and other Forms Builder reports enhancements
- Investigations and pilots into the acquisition of discrete / structured data elements outside of the forms context; such as acquisition of structured laboratory data from source systems.
- Additional AGNIS reports and enhancements to the AGNIS test environments to help support external users when they are testing new AGNIS forms.

Recent AGNIS and other electronic data submission accomplishments:

- CIBMTR Reporting App v0.2 was submitted to and published by the Epic AppOrchard. The App was enhanced to permit the exchange of acute GVHD observation data.
- Four Cellular Therapy forms were released into production. Two vendors have successfully tested and are working to deploy these forms.

Integrated Data Warehouse (IDW) and Unified Data Model (UDM)
CIBMTR continued to increase the capabilities of the IDW and UDM. Accomplishments include:

- Integrated Data Warehouse (IDW) – Operational Data Warehouse utilized for delivery of key data to stakeholders.
- Incorporated ongoing forms revisions into the warehouse
- Transitioned the remaining reports from Management Reporting Web (MRW) to Integrated Data Warehouse. This enables decommissioning of the MRW application.
- Business Intelligence Data Sharing- Continue 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. Recent accomplishments include:

Enhanced electronic Data Back to Centers (eDBtC) Data Download to include:

- Cellular Therapy data for transplant centers
  - DBtC bulk download (pre-TED and post-TED). This is a self-service download of 2,000 TED level variables for all transplants going back 40 years
- eDBtC – Simplified downloads for registries.

- Finance Dashboard – created a new dashboard for financial reporting downloads
- Work on the annual refresh of the Center Volumes Data Report is nearing completion. It will be published on https://bloodcell.transplant.hrsa.gov.

- Unified Domain Model- in 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
  - Loaded cellular therapy data into the data warehouse, and continued validation of the extract.
  - Continued mapping of transplant essential data to the physical data model.
  - Continued building infrastructure for enabling data extracts from the unified database.