REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE *(DD-MM-YYYY)*	2. REPORT TYPE	3. DATES COVERED *(From - To)*
7/14/2020	Interim Technical Report	April - June 2020

4. TITLE AND SUBTITLE
Development of Medical Technology for Contingency Response to Marrow Toxic Agents – Interim Technical Report with SF298 April 1, 2020 – June 30, 2020

5a. CONTRACT NUMBER
N/A

5b. GRANT NUMBER
N00014-20-1-2705

5c. PROGRAM ELEMENT NUMBER
N/A

6. AUTHOR(S)
Spellman, Stephen

5d. PROJECT NUMBER
N/A

5e. TASK NUMBER
Project 1, 2, 3, 4

5f. WORK UNIT NUMBER
N/A

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
National Marrow Donor Program
500 N. 5th St.
Minneapolis, MN 55401-1206

8. PERFORMING ORGANIZATION REPORT NUMBER
N/A

9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)

Office of Naval Research
875 N. Randolph Street, Suite 1425
Arlington VA 22203-1995

10. SPONSOR/MONITOR'S ACRONYM(S)
ONR

11. SPONSORING/MONITORING AGENCY REPORT NUMBER
N/A

12. DISTRIBUTION AVAILABILITY STATEMENT
Approved for public release; distribution is unlimited

13. SUPPLEMENTARY NOTES
N/A

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

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			Steven Devine, MD – Chief Medical Office
U	U	U		13	19b. TELEPONE NUMBER (*Include area code)* 763-406-8239

Grant Award N00014-20-1-2705

DEVELOPMENT OF MEDICAL TECHNOLOGY

FOR CONTINGENCY RESPONSE TO MARROW TOXIC AGENTS

QUARTERLY RESEARCH PERFORMANCE REPORT

SUBMITTED July 14th, 2020

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

N00014-20-1-2705

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 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.

During this quarter RITN continued to develop the preparedness of its network of hospitals through the following activities:

- Much of the typical activity for this quarter was not accomplished due to the impact on hospital systems from the SARS CoV-2 pandemic; RITN tasks were minimized to prevent over straining hospitals during this crisis.
- Collaborated with the RITN Medical Director to update the RITN Acute Radiation Syndrome Treatment Guidelines as well as transform from a MS PowerPoint format to a PDF document for ease of use.
- Continued collaboration with the American Burn Association to develop advanced practice guidelines for the combined care of patients by RITN and burn centers.
- Continued to develop adult and pediatric medical orders in the Epic Electronic Medical Record system.
- Supported Gryphon Scientific CDC funded project to assess United States laboratory capabilities for ionizing radiation related testing.
- Continued to develop the Hospital Radiation Morbidity Toolkit as part of the CDC grant awarded to RITN.

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.

Supported HLA typing of 40,864 newly registered volunteer donors.

Modeling and analysis of registry coverage for the Warfighter

Due to potential radiation emergencies that the Warfighter may encounter, it is important to model and analyze the potential to provide warfighters with cellular therapy. In this work we created synthetic HLA haplotype frequencies based on known racial/ethnic groups of warfighters from 2017 published demographics. Then we prepare for calculation of the likelihood of finding a potential donor in the Be The Match Registry for known warfighter demographic distributions. To examine potential emergency scenarios, we created synthetic multilocus unphased genotypes (MUGs) from the warfighter HLA haplotype frequencies to identify gaps in likelihood of potential donors available for warfighter treatment.

Warfighter Study Population

We use as a foundation the population of 1,977,566 individuals in the military force reported in the 2017 demographic profile of US warfighters. Five reported race groups were explored: White, Native Hawaiian/Pacific Islander, Black or African American, Asian, and American Indian or Alaska, and the number of individuals of each racial/ethnic group is listed in Table 1. Note that there are 73,691 individuals in the military force reported as other/unknown race, so we did not take into account these individuals in the modeling and analysis. We also considered five age groups: 25 years or younger, 26 to 30 years, 31 to 35 years, 36 to 40 years and 41 years or older. The percentages of the warfighter population that are in these age groups are 40.3, 20.6, 15.5, 11.0, and 12.6, respectively. As the age distribution for the individual racial/ethnic groups in the warfighter community are unspecified, we used these percentages to generate population subsets for each age group (Table 2).

Table 1. Race/ethnicity of the military force

Racial/Ethnic Group	Population
White	1,487,237
Native Hawaiian/Pacific Islander	19,990
Black or African American	356,870
Asian	91,943
American Indian or Alaska	21,526
Total	1,977,566

Table 2. Age group and population distribution of the military force

Racial/Ethnic Group	Y25L	Y26-30	Y31-35	Y36-40	Y41G
White	599356	306371	230522	163596	187392
Native Hawaiian/Pacific Islander	8056	4118	3098	2199	2519
Black or African American	143818	73515	55315	39256	44966
Asian	37053	18940	14251	10114	11585
American Indian or Alaska	8675	4434	3337	2368	2712

Be The Match Registry

According to final inventory and adult donor models in 2017, National Marrow Donor Program® (NMDP) /Be The Match maintains a registry of 18,267,161 adult donor registrants as of December 31, 2016. We considered HLA haplotype frequencies of 8 U.S. racial and ethnic groups to generate synthetic haplotype frequencies for the warfighter population.

HLA Match Definitions

We consider an HLA-matching model with high-resolution matching at HLA-A, HLA-B, HLA-C, and HLA-DRB1. We have 8/8 HLA matching when we have matches at all of these loci and we consider a single-allele mismatch at any of these loci in case of 7/8 HLA matching.

HLA Haplotype Frequency Generation

We generated HLA haplotype frequencies for different race groups of warfighters from the haplotype frequencies of Be The Match registry racial/ethnic groups. If a race group of the warfighter directly matches with a race group of Be The Match registry, we considered same HLA frequency file for that race group. Otherwise if a race group of the warfighter is combination of some Be The Match registry

racial/ethnic groups, we identified the unique haplotypes from the race groups and then generated frequency of a particular haplotype using Eq. 1, where *count* is the count value of haplotype *i* in the race group *k*.

$$\text{Frequency of haplotype } i = \frac{\sum_{k=1}^{n} count_k}{Total\ count\ in\ the\ race\ groups} \quad (1)$$

Generation of Multilocus Unphased Genotypes

To examine potential emergency scenarios and to identify gaps in likelihood of potential donors available for the warfighter treatment, we generated synthetic multilocus unphased genotypes (MUGs) for each race group by sampling the haplotype pairs *P* times, where *P* is the size of the warfighter population of the respective race group. Note that we considered the frequency values of haplotypes as the probability values during random sampling. After generating MUGs, we count each MUG and rank them based on their count values. In other words, the top ranked MUG has the largest count value and the total count values of all MUGs in a race group is equal to the population size of that group.

Statistical Analysis

Going forward, we plan to model the match likelihoods for 8/8 or 7/8 HLA-matched available adult donors. To model the emergency scenarios, we will consider the top 500 and top 1000 MUGs of each warfighter race groups and run queries to search the donor registry database for estimated match counts.

Next, we will calculate the likelihood of identifying HLA-matched adult donors for 8/8 and 7/8 matches and identify gaps in the likelihood of potential donors available for warfighter treatment for each racial group identified in the US warfighter demographics repot. With this calculation, we will reduce the size of available donors based on previously calculated Donor Availability rates for a more accurate representation of potential donor availability. Currently, we do not have actual HLA data and age-specific population distributions for the warfighter. However, we can refresh this calculation upon obtaining any new HLA frequencies and actual population distributions for warfighters. We also plan to revamp our methods to redefine and re-estimate match rates, including consideration for greater mismatches and improved population detail to revisit assumptions.

Development of science and technology for rapid communication of HLA data

A Data Standards Hackathon (DaSH) was held in April (23-25) that will continue this work with more involvement from the commercial vendors. This hackathon was held "virtually" due to the pandemic and included a component to support data collection for a number of projects trying to link HLA and COVID-19 infection.

This hackathon was a 48-hour event. There were 52 participants: nine from NMDP, 29 from academia, registries or health organizations, and 14 from HLA typing companies. Of the 52 attendees, exactly half the attendees were attending their first DaSH. There were people in eight time zones, with a 16-hour spread. We used slack, GitHub and video conferencing to collaborate. Areas that were worked on included

- Clarification of HML validation rules, discussions across countries with strong input from a range of users. In particular, several commercial vendors were able to get focused

Q &A with the developers of the HML format and address issues in the files generated by their software. This has the potential to improve electronic reporting of HLA.
- Tools and validators were built for HML and HAML (HLA antibody test results) files.
- Validation of new NMDP high resolution haplotype frequencies occurred by comparing to other published datasets.
- Progress on the Gene Feature Enumeration project including extended the references for the KIR system.

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

A manuscript entitled "Excess homozygosity in HLA alleles and haplotypes at mating and population levels" was submitted to Frontiers in Immunology. This study evaluates the population genetics of HLA in the US population where we find excess homozygosity in all non-African populations and all loci. This excess can be the result of preferential mating, population substructure, and perhaps transmission imbalance in chromosome 6. In Asian populations, even stronger homophily is observed in HLA that present epitopes involved in NK cell education through KIR and the C2 and Bw4 KIR binding motifs in combination with the leader peptide of HLA-B. This finding is relevant for understanding HLA at population levels and modeling registry growth and matching since many current population genetics methods assume Hardy-Weinberg Equilibrium in the distribution of HLA genotypes. Population substructure and natural selection driven by regulation of the immune system, observable in generational transmission bias of HLA, result in substantial deviation from an equilibrium state which needs to be accounted for when analyzing HLA in US populations.

New HLA haplotype frequencies were generated from the NMDP registry database. These frequencies are the first to extend to the HLA-DPB1, -DPA1 and -DQA1 loci and are the largest cohorts analyzed to date (23.5M total, 10.4M). This data will be prepared for publication during the next quarter.

A manuscript entitled "Optimal donor selection for hematopoietic cell transplantation using Bayesian machine learning" has been prepared for submission to the Journal of Clinical Oncology describing the results of machine learning experiments to assign risk of clinical endpoints (180 day survival and acute Graft vs Host Disease) on a per donor and per patient basis. The main finding of the study is that upon re-evaluation of searches that resulted in an 8/8 allele matched adult unrelated donor transplant from the period 2015-2016 an achievable improvement was possible with 10% of patients where a risk reduction of ~5% was possible with a younger available donor. This work is being extended in the current grant period to extended to a larger and more recent cohort (2016-2018) and focusing on the 4 clinical endpoints at the 1-year milestone that constitute "Event Free Survival" (death, relapse, rejection and moderate-to-severe chronic Graft vs Host Disease).

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.

Donor Recipient Pair Project

- The study team selected >8,000 pairs for enrollment in the project and will use grant funds to support approximately half of the typing costs. To date, >6,700 pairs have shipped to the project laboratory for testing with the remainder scheduled for distribution next month. Pairs are being prioritized based on needs of the CIBMTR observational research program. Results are expected by the end of next quarter.

Full HLA Gene Matching Analysis

- Completed the final analysis for the study IB19-01: Impact of ultra-high resolution (UHR) HLA matching on the outcome of unrelated donor hematopoietic cell transplantation. A draft manuscript is in process and will be submitted by the end of next quarter. Summary of findings:
    a. UHR matching was not associated with the primary outcome of overall survival in the T cell deplete, T cell replete or full cohort.
    b. 12/12 UHR matching was associated with lower aGVHD2-4 compared to <=11/12 UHR matched.
    c. TCE non-permissive mismatch was associated with worse aGVHD2-4 than matched: HR=1.26 (1.10,1.45), P=0.0007.
    d. The combination of TCE and CMV 'TCE_CMV' was associated with OS, TRM, DFS and relapse in various models (full cohort, TCD and T replete). Although highly statistically significant they are not consistent with hypothesized biologic mechanisms.
    e. The HLA-DPB1 TCE effect was weaker than previously observed in CIBMTR studies (Pidala et al Blood 2014) HR 1.2 vs. 1.08 for permissive vs. non-permissive mismatching. A post-hoc power calculation suggests that a sample size of N=21,267 would be required to detect a difference at the 0.05 significance level with 80% power. Study team reviewing differences between the Pidala and current cohort to identify factors that could have influenced the impact of DPB1-TCE matching.

Develop and mature typing protocols for the highly polymorphic KIR.

- Typing of 48 samples is underway to further validate the protocol developed under this aim. The method has been multiplexed to reduce the per-sample cost further. This set of 48 samples is well characterized for KIR allow the quality of this round of typing to be evaluated and leading to further scale up of this approach to cohort scale for investigating the role of KIR genomics in transplant outcomes at unprecedented levels of resolution.
- A manuscript "Efficient Sequencing, Assembly, and Annotation of Human KIR Haplotypes" has been prepared with the collaborators and is being submitted to a special issue of Frontiers in Immunology on the topic: "HLA and KIR Diversity and Polymorphisms: Emerging Concepts"

Determine the frequency and risks associated with donor clonal hematopoiesis of indeterminate potential in HCT.

- Completed development of a CIBMTR Graft Versus Host Disease Working Committee protocol for evaluation of donor clonal hematopoiesis of indeterminate potential (CHIP) on HCT outcomes. The study is titled "GV19-01 "Exploring the link between donor-engrafted clonal hematopoiesis and adverse outcomes in allogeneic hematopoietic cell transplant recipients: Pilot study".
- CHIP testing of N=300 donor samples for evaluation in the pilot project was completed in March and sequence analysis revealed insufficient sequence depth to accurately assess CHIP. Re-sequencing was initiated and completed in late June. CHIP assessment is in process with clinical correlation analysis planned for August. Study results will be summarized in an abstract for submission to the 2021 Transplant and Cellular Therapy meeting. Testing is funded through an in-kind donation from an industry partner. Navy funds will be used to support the pilot analysis and additional CHIP testing on a larger cohort.

D. Clinical Research in Transplantation

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

Observational Research

- Published 24 manuscripts in peer-reviewed journals.
- No presentations this quarter due to COVID-19 related cancellations of scientific meetings.

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:

- The Japanese multi-language support, allowing FormsNet system and forms to display in a language other than English, was updated in May 2020 to reflect one Cellular Therapy form revision.
- Implemented priority work on updating FormsNet to support data capture for COVID-19.
- Completed six FormsNet Forms Definition Manager (FDM) grid conversions from the Telerik to Kendo ahead of Telerik's impending retirement in September 2020, thereby improving FormsNet security.
- Updated the FDM Mapping Tool to pull select field mapping info from caDSR and display in a new user interface to improve the speed and quality of form mapping for AGNIS.
- Updated FormsNet 3 Donor Module to successfully interface with required changes to the option group/review section of the Protocol Deviation Form (Form 3000).
- Completed development and integration testing in advance of a June 24th deployment of the Infections Disease Marker (IDM) Automation which will reduce the time it takes to clear a donor by automating the reporting of IDM results and improve any error handling should these messages fail to send as expected.
- Deployed updates to the audit tool to allow for the querying of forms in query/pending status to prepare for and maximize an audit's completeness, up-to-date accuracy, and transplant center satisfaction.
- Completed the work to support the Multi-Center reporting/viewing functionality. This functionality, which provides centers the ability to see all forms completed for a patient

regardless of which center reported the data, was released in May. This change has become necessary as patients can receive multiple infusion types (e.g., HCT, CT), at different centers.

- Developed and released the following data collection forms in May 2020. Forms that are "updated for COVID-19" had additional options or questions added to quickly capture COVID-19 data but the forms themselves did not go through a new revision:

Form	Form Name	Category
2402r5	Disease Classification	Revised recipient form
2014r4	MDS Pre-Infusion Data	Revised recipient form
2114r4	MDS Post-Infusion Data	Revised recipient form
2057r1	MPN Pre-Infusion Data	Revised recipient form
2157r1	MPN Post-Infusion Data	Revised recipient form
2400r7	Pre-Transplant Essential Data	Revised recipient form
2500r4	Recipient Eligibility Form	Revised recipient form
2532r2	BMT CTN 1702 Enrollment Form	Revised study form
2533r2	BMT CTN 1702 Donor Testing	Revised study form
2534r2	BMT CTN 1702 Monthly Update	Revised study form
2536r2	BMT CTN 1702 Off Study	Revised study form
2149r1	Respiratory Viruses	New recipient form
2450r5	Post-Transplant Essential Data	Updated for COVID-19
4000r6	Pre-Cellular Therapy Essential Data	Updated for COVID-19
2900r4	Recipient Death Data	Updated for COVID-19

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:

- Successfully connected OSU Production environment using the CIBMTR Reporting App and began exchanging:
  - Patient demographics
  - CRID assignment
  - GVHD observations
- 7 form revisions have been released in Production for AGNIS users.
- 4 form revisions have been released for external AGNIS users to test.
- Successfully updated 6 forms with COVID-19 options.
- The AGNIS team has worked closely with AGNIS users to gather requirements for an auto-population enhancement. This is currently in the development phase.

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
- Incorporated additional metric capture capability into the CIBMTR's Data Quality Dashboard
- Added additional checks to CIBMTR's Critical Systems Dashboard to track the status of CIBMTR systems and reports
- Implemented new processes to support CIBMTR's International CPI Processes
- Added additional reporting capabilities to our business intelligence suite to support operational needs
- Developed a data file sharing process with external partner, Emmes
- Developed pathway to capture and store survey data from CIBMTR's ePRO system
- Enhanced Cord Blood Data Quality Report to include additional Cellular Therapy data
- Began processes to complete the 2020 Center Volumes Data Reporting project
- 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:

Data Operations Dashboard

- Introduced a new dashboard to facilitate secure, self-service file downloading.
- DataOps dashboard currently contains files for Consecutive Transplant Audit (CTA Reports) and Transplant Center Specific Analysis reports.

Consecutive Transplant Audit (CTA reports)

- Formerly a service offered through secure email; is now offered on a self-service portal
- Reports are updated weekly

Transplant Center Specific Analysis (TCSA reports)

- Formerly a service offered through secure email; is now offered on a self-service portal
- Contains both the draft report collaborations and the final reports
- Reports are updated in the spring and winter

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

- Completed loading and validation of CAR T-cell and attendant infectious disease data.
- Completed building domain model infrastructure for enabling data extracts from the unified database.
- Delivered first research-ready CAR T-cell data extracts out of the unified database.
- Continued mapping of infectious disease data, transplant essential data, and new respiratory virus data to the physical data model.
- Completed loading of new and updated data tied to Spring 2020 FormsNet revisions.
- Created design for and began building of infrastructure required to incorporate HLA donor and recipient data into the unified database.

Support for the Clinical Transplant-Related Long-term Outcomes of Alternative Donor Allogeneic Transplantation (CTRL-ALT-D) trial

BMT CTN 1702: Clinical Transplant-Related Long-term Outcomes of Alternative Donor Allogeneic Transplantation (CTRL-ALT-D) trial had accrued over 406 subjects through June 2020. Accrual was temporarily paused late last quarter in response to the 2019 COVID-19 public health emergency and re-activated accrual in the middle of this quarter.

Rapid mobilization and collection of stem cells for HCT will decrease time to transplant and simplify the logistics of product harvest.

Developed a draft protocol for evaluation of a novel mobilization strategy. The project will transition to an alternative funding source for the remaining effort.