BMT CTN Resource Guide

v2.0 8FEB2019

BMT CTN (Blood and Marrow Transplant Clinical Trials Network)

- Established in September 2001 and renewed in 2006, 2011, and 2017 (through 2024)
- Funded through the National Heart Lung and Blood Institute (NHLBI) and the National Cancer Institute (NCI), both part of the National Institutes of Health (NIH)
- One grant for the BMT CTN Data and Coordinating Center (DCC)
- 20 individual Core centers, some of which are consortia of 2 or more centers (see Appendix A), chosen based on their scientific merit and ability to collaborate in carrying out the Network's mission
    - Each Core center has a cooperative agreement with the NHLBI to participate in the BMT CTN
- The Network has approximately 75 affiliate centers that participate on trials through individual subcontracts with the BMT CTN DCC.

BMT CTN Data and Coordinating Center (DCC)

The DCC is a collaborative partnership of the three organizations listed below which provide support to the network.

- CIBMTR (Center for International Blood and Marrow Transplant Research), Milwaukee WI, Minneapolis, MN; PI = **Mary Horowitz, MD, MS** (Project Manager = **Amy Foley, MA**)
    - The CIBMTR provides scientific leadership and overall coordination for the BMT CTN
    - Centers participating in BMT CTN trials must register pre-and post-transplant outcomes of all hematopoietic stem cell transplants done at their institution during their time of participation to the CIBMTR. Registration is done using procedures and forms of the Stem Cell Transplant Outcomes Database (SCTOD) (Note: Federal legislation requires submission of these forms for all US allotransplant recipients). Enrollment on a BMT CTN trial must be indicated on the SCTOD pre-transplant registration form. Additionally, CIBMTR pre- and post- transplant Report Forms must also be submitted for all patients enrolled on this trial.
- NMDP (National Marrow Donor Program), Minneapolis, MN; PI = **Dennis Confer, MD,** Senior Vice President and Senior Medical Director, Research = **Steve Devine, MD**
    - Transplant center contracting: NMDP Budgets and Contracts Associates
    - Patient reimbursement: NMDP Budgets and Contracts Associates
    - Lab Specimens/Repository: Immunobiology Research Specialists
    - Patient advocacy
- Emmes, Rockville, MD; PI = **Adam Mendizabal, PhD** (Project Director = **Iris Gersten**, **MS**)
    - Protocol oversight and monitoring
    - Data capture and management in AdvantageEDC/eClinical
    - Data audit site visits
    - Statistical analysis

BMT CTN Steering Committee (SC)

The SC is responsible for the design, execution, and analysis of all Network studies. The committee members implement all policy decisions.

- Principal Investigators from the 20 Core centers/Consortia centers are members of the Steering Committee. Each center has a PI representative, including those within consortia, with the exception of the Pediatric Blood and Marrow Transplant Consortium (PBMTC), which consists of 48 pediatric centers in the US and Canada and is represented by one PI.
- Representatives of Affiliate Centers selected by the Steering Committee for exemplary performance:
  - University of Texas MD Anderson Cancer Center, University of Wisconsin, University of Kansas. Note: these terms expire on September 30, 2019; however, sites can qualify for another 2 year term starting October 1, 2019 if they meet the accrual threshold.
- NHLBI Project Officer: Nancy DiFronzo, PhD
- NCI Project Officers: Bill Merritt, PhD
- Three DCC Principal Investigators (The PI from the CIBMTR is the only voting member): Mary Horowitz, MD, MS (PI, CIBMTR), Dennis Confer, MD (Co-PI, NMDP/Be The Match), Adam Mendizabal, PhD (Co-PI, Emmes)

The SC selects a Committee Chair who first serves a two-year term as Vice-Chair, then a one year term as Chair-Elect, followed by a two-year term as Chair, and finally a one-year term as Immediate Past Chair.

- Chair: Richard Jones, MD, Johns Hopkins University (began two-year term on January 1, 2018)
- Chair-Elect: Helen Heslop, MD, DSc (Hon), Baylor College of Medicine
- Vice-Chair: Edward Stadtmauer, MD, University of Pennsylvania

BMT CTN New Staff Member – Email requests to send during first week[1]

Notify Emmes of Role (PI, Sub-I, Pharmacist, Lab Director or Coordinator [Clinic, Data, Regulatory and/or Lab Coordinator]) & specific studies	bmtctnac@emmes.com bmtctndm@emmes.com
Access to BMT CTN SharePoint website (all personnel above)	bmtctnsp@emmes.com
Access to password-protected section of public BMT CTN website[2] (all coordinators)	bmtedc@emmes.com
Complete Advantage EDC[SM]/eClinical Data System Training (Data Coordinators)[3]	
Complete GlobalTrace[SM] Specimen Tracking Training (coordinator responsible for preparing manifests for shipments)[4]	
Complete and submit Required Documents for each protocol (see page 6)	bmtctnXXXX@emmes.com

[1] Provide first and last name, email address, center name, role, and protocol #s in all emails

[2] The password-protected section includes accrual reports. Those with access to EDC may use their EDC username and password to access the public website; those without EDC rights (e.g., regulatory coordinators) should include in their request that they are not responsible for data entry but need access.

[3] **AdvantageEDC/eClinical Request for Training:** Once your request is received and processed (usually within 2 business days), you will be provided a username and password to access the AdvantageEDC Training System (yellow background for EDC, orange background for eClinical), as well as a practicum to document your training. Once you have completed and returned the training, you will be provided a username and password to access the production system (grey background for EDC, navy blue background for EDC, navy blue background for eClinical), which is the real world system.

[4] **GlobalTrace Training:** After you have read the GlobalTrace Training Module Instructions, you may begin viewing the training module. Use your browser's "Back" button to return to the menu once complete. After viewing the module, complete the GlobalTrace Training Quiz (using the link from the instructions document) and the Request for GlobalTrace Access form and send via email to the BMT EDC Coordinator.

BMT CTN Coordinator Resources

Principal Investigator	Adam Mendizabal, PhD amendizabal@emmes.com
Project Director	Iris Gersten, MS igersten@emmes.com
AdvantageEDC/eClinical or GlobalTrace Access/Training	bmtedc@emmes.com Roe Wright
BMT CTN Websites	Public: http://www.bmtctn.net/ SharePoint: https://www.bmtctnsp.net/
BMT CTN Protocols	Posted on Public and SharePoint websites
BMT CTN Research Sample Information Guides (details on collecting, processing, and shipping samples)	Posted on SharePoint website by protocol subweb in Transplant Center Materials folder
BMT CTN Research Specimens Labels	bmtctnac@emmes.com
BMT CTN Research Specimens and Repository Questions	Stephanie Waldvogel swaldvogel@nmdp.org Ashley Spahn aspahn@nmdp.org Allie Erickson aericks2@nmdp.org
BMT CTN Site Contracting	Pam Budnick pbudnick@nmdp.org
BMT CTN Administrative Manual of Procedures (MOP)	Posted on Public website under 'Resources' and on SharePoint website under 'Manual of Procedures'
BMT CTN Annual Progress Report	Posted on Public website under 'About Us' and on SharePoint website under 'BMT CTN Misc Documents'
Adverse Event Reporting Questions	Jennifer Romeril Audra Thompson Kari Bingham bmtctn_ae@emmes.com
CRAs (Protocol Monitors)	Iris Gersten igersten@emmes.com
GlobalTrace Questions	Brianne Allison ballison@emmes.com
General or Urgent Questions*	bmtctndm@emmes.com
CIBMTR Forms Questions	Kavita Bhavsar kavitab@mcw.edu
BMT CTN Protocol-Specific Questions	Emmes Protocol Coordinator (see Appendices B-1, B-2, and B-3)
Administrative Coordinators	bmtctnac@emmes.com Ellen Parker, MBA Jacqui Ottey Thomas Tamura

*Please only send urgent questions to the DM email alias if the person you are trying to reach is out of the office and you need a response before they get back or if it's outside of normal business hours and you need a response before the next business hours. If the question does not pertain to a specific patient and/or does not have a strict timeline, the Emmes coordinator will respond to it when they return to the office.

Frequently Asked Questions

Note: Specific information for Protocol 1506 Allo HCT for AML is not included in this guide. Refer to 1506 materials for further guidance.

***Current BMT CTN Studies**:*

1. *What BMT CTN studies are open?* See Appendix B-1.
    - In addition, check the public website (www.bmtctn.net) under Protocol header ('Protocols' link).
2. *Where can I find the latest version of a protocol or its consent documents?*
    - The latest version of the protocol and informed consent documents are located on the SharePoint website (https://www.bmtctnsp.net). From the main page, click on 'Link to #[Protocol #] Subweb' on the right-hand side, then go to 'Transplant Center Materials' on the left-hand side.

***Data Reporting**:*

3. *Why does data need to be collected for every patient including those that end up being ineligible, refuse study treatment, etc?*
    - Most BMT CTN studies are designed as "intention to treat," which requires that all data is required from every patient randomized on the trial - including those patients that did not complete any study-specific study procedures or deemed ineligible. An intention to treat (ITT) analysis is an analysis based on the initial treatment intent, not on the treatment eventually administered. ITT analysis is intended to avoid various misleading artifacts that can arise in intervention research. For example, people who have a more refractory or serious problem tend to drop out at a higher rate. Even a completely ineffective treatment may appear to be providing benefits if one merely compares the condition before and after the treatment for only those who finish the treatment (ignoring those who were enrolled originally, but have since been excluded or dropped out). For the purpose of ITT analysis, everyone who is assigned a study treatment is considered part of the trial, whether they finish it or not.

Withdrawal of Consent:

4. *What happens when a patient withdraws consent?*
    - When a patient withdraws consent, a site staff member must discern specifically which aspects the patient is withdrawing consent from. For example, a patient may state he/she wants to stop taking the study drug or stop providing the research samples but may still be willing to continue providing data for the study.
        - For BMT CTN studies 1101 and 1102, the site coordinator must notify the Protocol Coordinator at Emmes.
        - For BMT CTN studies 07LT, 1301, 1302, 1401, 1501, 1502, 1503, 1507, and the upcoming 1700 series of studies, the data coordinator must complete the "Withdrawal of Consent Form" in AdvantageEDC/eClinical which collects information on patient consent withdrawal. It is required that this form be completed within 7 business days of knowledge of the patient's withdrawal of consent. The types of consent withdrawal collected on this form include:

- Patient withdraws consent to all study procedures but will still provide follow-up data
- Patient withdraws consent to receive study drug or treatment but will receive other study treatment and provide follow-up data
- Patient withdraws consent to provide optional samples for future research or ancillary studies
- Patient withdraws consent to provide data for the study which includes withdrawal from all study treatment.
- Documentation of consent withdrawal must be uploaded to the form (with appropriate redaction of PHI). For questions about whether an event meets criteria for reporting on this form, please contact the Protocol Coordinator.

***CIBMTR reporting**:*

5. *Why do we have to report data to both the CIBMTR and the BMT CTN for study participants?*
   - All transplant centers in the US, including BMT CTN centers, are required by law to report pre-and post-transplantation clinical data on allogeneic HCT recipients to the Stem Cell Transplant Outcomes Database, which is a component of the C.W. Bill Young Cell Transplantation Program and is managed by the CIBMTR. The Network stipulates that Core and Affiliate Centers must also report similar data for autologous transplant recipients.

   - Some pre-and post-HCT information collected by the CIBMTR is deliberately not captured by the BMT CTN Data capture system (Emmes AdvantageEDC or eClinical), but rather is transferred from the CIBMTR Research Database to the Emmes database for incorporation into study files. Some data such as death, graft failure, GVHD, and relapse need to be captured in real time in AdvantageEDC/eClinical to assist with safety monitoring of the trial. All long-term follow-up for Network studies (beyond the primary and secondary endpoints) is captured through CIBMTR report forms to avoid a duplicative long-term follow-up program.

***Center Performance**:*

6. *How is our center's performance monitored?*

- The DCC regularly monitors the performance of BMT CTN Core and Affiliate Centers and their contributions to the Network. Activation dates, monthly accrual, form delinquency, and missing values are tracked for each protocol by site and are posted on the password-protected section of the public website. The Data and Safety Monitoring Board routinely reviews these data. Data audits are performed at each center at least every three years and as often as biannually for centers with high enrollment, excessive delays in data submission, a high number of protocol deviations, and/or a history of high data discrepancy rates. These visits provide an opportunity for information exchange between the centers and the DCC as well as an opportunity to provide continuing education on protocol adherence and case report forms completion to help maximize data and overall study quality. Reports are reviewed by the NHLBI and DCC and referred to the Executive Committee if results are below expectations or if other issues of concern are identified.

- In addition, Core centers are evaluated via Annual Center Performance Reports (most recently in January 2019). Overall Center Performance Scores are based on five categories:

  - (1) Scientific and Administrative (10 points)
  - (2) Accrual (60 points)

- (3) Activation and Enrollment (10 points)
- (4) Data Quality (10 points)
- (5) Laboratory Compliance (10 points)

- Final scoring is a composite of category-specific metrics associated with each of these measures of commitment and involvement. Centers that receive a "needs improvement" score in any area must submit an action plan for resolving problems within six weeks of receiving the report. Additionally, Center Performance "snapshots" of actual vs. projected accrual and laboratory compliance reports are distributed to Core Centers quarterly.

***Enrollment**:*

7. *I am trying to enroll a patient in AdvantageEDC, but the study is not showing up as an option.*
    - Call the Emmes Protocol Coordinator if the enrollment is urgent. If the Emmes Protocol Coordinator for that study is not available and the enrollment is urgent, send an email to bmtctndm@emmes.com and someone else will assist you. Additionally, check that you have emailed your most recent IRB approval letter to the Protocol Coordinator at Emmes. If you haven't and your previous IRB approval has expired, the system closed your enrollment due to the IRB expiration. You should email your most recent IRB approval letter to the Emmes Protocol Coordinator. If you find that you have emailed the most recent IRB approval letter, but you still aren't able to access the correct study for enrollment, you should send an email to the Emmes Protocol Coordinator for assistance.
8. *I'm trying to enroll a patient but the enrollment form will not let me because it says a field has an out-of-range value. However, this field is not listed as an eligibility criterion in Chapter 2. What should I do?*
    - Email the Emmes Protocol Coordinator right away. Do not enter an incorrect value on the enrollment form.
9. *Can patients on BMT CTN studies also enroll on other BMT CTN, pharmaceutical, or institutional trials?*
    - See Numbered Memorandum CTN-149 under the "Numbered Memos" folder on the SharePoint Website: The BMT CTN encourages co-enrollment of research subjects in complementary studies provided that co-enrollment does not confound the analysis of individual BMT CTN study endpoints. The following considerations are provided to guide centers in decisions about co-enrollment:
        - Differential enrollment must be avoided. That is, a secondary study where the intervention depends upon the randomization assignment of the primary study is not allowed. For example, a GVHD prophylaxis study that is open only to myeloablative transplant recipients is incompatible with a trial of randomized comparison of full versus reduced intensity transplant.
        - Each center must submit a Co-enrollment Request Form and study synopsis to the DCC/Emmes Protocol Coordinator for each study where co-enrollment with a BMT CTN study is contemplated. Decisions will normally be provided within one to three business days and, unless otherwise indicated, would apply to all subsequent candidates for that particular BMT CTN study. If a center wishes to enroll patients from multiple different BMT CTN studies onto an institutional or pharmaceutical trial, they will need to get approval for each BMT CTN study.
        - The center should check the BMT CTN SharePoint website subwebs' Co-enrollment folders for a list of all co-enrollment requests previously submitted by other sites, along with

whether they were approved or denied, prior to submitting a Co-enrollment Request Form and study synopsis. They are posted in the "Co-enrollment" Folder under each protocol subweb.

- In some cases, patients can be co-enrolled on multiple BMT CTN protocols (see below). For additional instructions see Numbered Memorandum CTN-149, "Considerations for Enrollment of Patients on Multiple Protocols".

Initial enrollment	Co-enrollment ALLOWED[1]
BMT CTN 1502 CHAMP	None
BMT CTN 1503 STRIDE2	None
BMT CTN 1507 Haplo Sickle Cell	None

[1] The order of enrollment allowed is determined by protocol requirements

Research Samples:

10. *How do I request more sample labels for speciments?*
    - Send an email to bmtctnac@emmes.com with your address to request more labels, and you will typically receive them in 5 business days. If you need labels sooner, please indicate that in your request.
11. *How do I order a shipping kit for specimens?*
    - The shipping kit order form is located at the end of your Research Sample Information Guide for this study. This guide was sent to you as part of your activation kit and is also located on the SharePoint website under Link to #[Protocol #] Subweb' on the right hand side, then under 'Transplant Center Materials' on the left hand side.
12. *The patient is coming in this afternoon and we have to draw the optional samples, but by the time we're done, we'll have missed our shipping deadline. Can we store them overnight and ship them tomorrow?*
    - Refer to your protocol's Lab Sample Information Guide for relevant information. If you can't find the answer in there, email the Protocol Coordinator.

***Regulatory**:*

13. *How many patients are currently enrolled on the study? How many patients have been enrolled from each center participating?*
    - This information can be found on https://bmtctn.net. From the main page, click on the link that says 'Reports' in the upper right-hand corner and then click on the first link that says 'Data Reports' on the next page. You will need to use your AdvantageEDC username and password to login at this point. On the next page, you will see a table listing all of our BMT CTN studies along the left-hand side. Find the protocol number in question and click the link in the column under 'Accrual by Site' to see the number of patients enrolled at each site as well as the total number of patients enrolled on the study.
14. *Where can I find the most recent DSMB report?*
    - This information can be found on the SharePoint website (https://www.bmtctnsp.net). From the main page, click on 'Link to #[Protocol] Subweb' on the right-hand side, then go to the 'Numbered Memos' folder on the left hand side and look for the last memo for DSMB Recommendations.
15. *What regulatory documents are required for studies?*

Summary of Required Documents for New Transplant Center Staff by Protocol										
Protocol	Roster	1572 or Investigator Agreement (IA)	Financial Disclosure	CV	Medical License	Delegation of Authority Log	Human Subjects Training Certificate	EDC Training/ Practicum	GT Training/ Test	Staff-specific Protocol-specific Trainings/Documents
1101	PI, CC, DC, RC, LC	none	none	PI	PI	N/A	PI	DC	DC or LC	3 CBU blood thaw results; CBU blood thaw SOP
1102	PI, CC, DC, RC, LC	N/A	PI, Sub-I	PI, Sub-I	PI, Sub-I	N/A	all staff on roster	DC	DC or LC	Site Declaration of Institutional Standards (for hypomethylating therapy, RIC, and GVHD prophylaxis)
1301	PI, CC, DC, RC, LC	PI, Sub-I	PI, Sub-I	PI, Sub-I	PI, Sub-I	all staff performing study-related tasks and procedures	all staff on DoA	DC	DC or LC	CD34 SOP - LD Declaration of Deviations form - LD
1302	PI, CC, DC, RC, LC	PI, Sub-I	PI, Sub-I	PI, Sub-I	PI, Sub-I	all staff performing study-related tasks and procedures	PI, Sub-I	DC	DC or LC	N/A
1401	PI, CC, DC, RC, LC, LD	PI, Sub-I, LD	PI, Sub-I, LD	PI, Sub-I, LD	PI, Sub-I, LD (if applicable)	all staff performing study-related tasks and procedures	all staff on DoA	DC	DC and LC	1401 Vaccine Manufacturing SOPs (PI)
1501	PI, CC, DC, RC, LC	PI, Sub-I	PI, Sub-I	PI, Sub-I on IA	N/A	all staff performing study-related tasks and procedures	all staff on DoA	DC	DC or LC	Myopathy Training Certification (CC)
1502	PI, CC, DC, RC, LC	PI, Sub-I	PI, Sub-I	PI, Sub-I	PI, Sub-I	all staff performing study-related tasks and procedures	all staff on DoA	DC	DC or LC	Metrics for Bone Marrow Harvest (PI)
1503	PI, CC, DC, LC, RC	PI, Sub-I	none	PI, Sub-I	none	all staff performing study-related tasks and procedures	all staff on DoA	DC	DC or LC	N/A
1507	PI, CC, DC, RC	PI, Sub-I	PI, Sub-I	PI, Sub-I	Not Required (site maintains)	all staff performing study-related tasks and procedures	all staff on DoA	DC	N/A	N/A

KEY

PI = Principal Investigator
Sub-I = Sub Investigator
DC = Data Coordinator
CC = Clinic Coordinator
RC = Regulatory Coordinator
LC = Lab Coordinator
LD = Lab Director

***Numbered Memorandums**:*

16. *What are Numbered Memoranda?*
    - Numbered Memorandums are distributed to staff at participating transplant centers to communicate important information regarding both the BMT CTN (general) and specific BMT CTN protocols (study-specific). The distribution list includes PIs, regulatory, data, clinic, and laboratory coordinators listed on protocol rosters provided by each center. It is each center's responsibility to read and understand all Numbered Memos. The General numbered memos are posted in the 'General Numbered Memos' folder under 'Documents' on the left-hand side of the main page of the SharePoint website. Protocol-specific memos are posted under each protocol subweb in the "Numbered Memos" Folder on the SharePoint website. A subset of recent important memos is listed below:
        - CTN-164: Impact of Revised Common Rule (21DEC2018)
        - CTN-163: AdvantageEDC System Updates (30NOV2018)
        - *1507-001 and 1503-008*: These memos outline how sites can participate in protocol BMT CTN 1503 (STRIDE2) and 1507 (Haplo Sickle Cell) as both trials compete for the same patient population ages 15.00 – 40.99 years.

***Single IRB for the BMT CTN (NMDP IRB)**:*

17. *What do I need to know about the NEW Single IRB for BMT CTN Research?* See Memo CTN-147 for complete details.
    - The National Marrow Donor Program (NMDP) Institutional Review Board (IRB) has been chosen as the single IRB (sIRB) for the BMT CTN. Centers participating in BMT CTN research are required to use the NMDP IRB as their IRB of record for BMT CTN studies released after July 1, 2017 (i.e., beginning with the BMT CTN 1701 study). This requirement applies to BMT CTN Core, Consortium, and Affiliate Centers. The use of a sIRB for BMT CTN research is in response to both the National Institutes of Health (NIH) single IRB mandate and the revised Common Rule. To be compliant with NIH policy and the revised Common Rule, the 2017 BMT CTN grant renewal included a plan to use the NMDP IRB as the sIRB for BMT CTN research.
        - Note that some centers opted to use the NMDP IRB as their IRB of record for protocols BMT CTN 1501 and 1503.
        - Centers are asked to start enrolling in the sIRB immediately so they are already enrolled when the first study they want to participate in requires use of the sIRB.
        - If you have general questions about the sIRB, please email them to NMDPSIRB@nmdp.org

Institutional IRBs:

18. *The study has closed to accrual and all patients have completed study follow-up, can we close the study with our IRB?*
    - No – If you have enrolled patients on a study, it may not be closed with your IRB until Emmes notifies you that it can be closed. This is generally after all queries are completed for endpoint review and publication data.
19. *The study has closed to accrual and we didn't enroll any patients, can we close the study with our IRB?*
    - Yes, you may close the study with your IRB. Make sure to send the IRB closure notice to the Emmes Protocol Coordinator once you receive it.

20. *Where can I get information for submissions?*

- The following materials that are typically required for submission to an institutional IRB for continuing review of protocols (that are not under the purview of the NMDP IRB of record) are readily available on the BMT CTN Public or SharePoint websites:

Item	Location
Total Accrual – Actual and Projected	BMT CTN Public Website
Monthly Accrual by BMT CTN Center	
Demographics	
Protocol and Consent (pdf copy)	
DSMB review	BMT CTN SharePoint Website
Adverse Events	
Protocol and Consent (word copy)	
Protocol Amendment & Summary of Changes	
Other important protocol information	

BMT CTN SharePoint Website (https://www.bmtctnsp.net)

21. *How do I get access to the SharePoint website?:*

- To request 'individual' access, please send an email to bmtctnsp@emmes.com with your first name, last name, e-mail address, center name, and protocols that you work on.
- The login credentials will be different from the ones you use to login to AdvantageEDC.
- Location of documents in SharePoint:

BMT CTN Manual of Procedures (MOP)	Home Page: DOCUMENTS
Budget & Contract Information	
General Numbered Memos	
Steering Committee Meeting Materials	
Upcoming Calls/Meetings	Home Page: Announcements
Protocol and Consent Form Template (MS Word)	Protocol-specific Subweb Link > Transplant Center Materials
Protocol Amendment Summaries/Change Docs	
Laboratory Sample Guides	
Current Protocol	Protocol-specific Subweb Link > Current Protocol Version
Protocol-Specific Numbered Memorandums	Protocol-specific Subweb Link > Numbered Memos
Co-Enrollment Information	Protocol-specific Subweb Link > Co-enrollment
DSMB Reports	Protocol-specific Subweb Link > Numbered Memos > DSMB Recommendations
Adverse Events/Significant Protocol Deviations	Included in DSMB Reports (see above)
Information for IRB Continuing Reviews	Home Page: Links > Link to Accrual/Demographics Reports (Enter AdvantageEDC username & password when prompted)

***BMT CTN Public Website Resources* (http://www.bmtctn.net)**

22. How do I get access to the BMT CTN Public website?:

- If you already have access to AdvantageEDC, you should use the same username and password to login to the password-protection sections of the BMT CTN public website.
- If you do not need access to AdvantageEDC because you are not a data coordinator, you can send an email to bmtedc@emmes.com and let them know that you need login credentials for the website only, not EDC.
- Location of documents on the public website:

Accrual by Site – Actual and Projected	Home Page > Reports Tab > Data Reports Link (Enter *AdvantageEDC username & password* when prompted) Monthly Accrual and Data Quality are listed in Table 2.
Demographics (summary by protocol/blinded)	
Missing Forms Summary (by protocol and site)	
Laboratory Compliance Report (Overall)	
Site Activation Status	
Monthly Accrual by BMT CTN Centers	
Data Quality by BMT CTN Centers	
Affiliate Center Application	Home Page > Protocols Tab
BMT CTN Manual of Procedures (MOP)	Home Page > Resources Tab
Current Version of Protocols (PDF)	Home Page > Protocols Tab

Appendix A: List of BMT CTN Core/Consortia Centers (effective January 2019)

CORE CENTER/CONSORTIUM	PARTICIPATING CENTERS
Baylor College of Medicine (Consortium)	Baylor College of Medicine/Houston Methodist Hospital
	Baylor College of Medicine/Texas Children's Hospital
	Children's National Medical Center
City of Hope National Medical Center	City of Hope National Medical Center
Dana-Farber/Partners in Cancer Care (Consortium)	Brigham & Women's Hospital
	Massachusetts General Hospital
Duke University Medical Center	Duke University Medical Center
Fred Hutchinson Cancer Research Center	Fred Hutchinson Cancer Research Center
H. Lee Moffitt Cancer Center	H. Lee Moffitt Cancer Center
Johns Hopkins University Oncology Center	Johns Hopkins University
Medical College of Wisconsin	Medical College of Wisconsin
Memorial Sloan-Kettering Cancer Center	Memorial Sloan-Kettering
Mount Sinai Hospital (Consortium)	Mount Sinai Hospital
	Mayo Clinic - Minnesota
	Vanderbilt University
Northside Hospital Atlanta (Consortium)	Northside Hospital Atlanta
	University of Miami
	Levine Cancer Institute
Ohio State University Comprehensive Cancer Center (Consortium)	Ohio State University
	Roswell Park Cancer Institute
	University of California, San Francisco
	University of North Carolina
	Virginia Commonwealth University
Oregon Health and Science University (Consortium)	Oregon Health and Science University
	Case Western Reserve University
	Cleveland Clinic
	Loyola University
Stanford Hospital and Clinics	Stanford Hospital and Clinics
University of Florida College of Medicine (Consortium)	University of Florida
	Emory University
University of Michigan Medical Center Consortium (Consortium)	University of Michigan
	Indiana University
	Karmanos Cancer Center
University of Minnesota	University of Minnesota
University of Pennsylvania Hospital	University of Pennsylvania
Washington University	Washington University/Barnes Jewish Hospital
PBMTC (Consortium)	Assorted pediatric centers

Appendix B-1: Accruing BMT CTN Studies (effective January 15, 2019)

Protocol	Description	BMT CTN DCC/Emmes Contact(s)
BMT CTN 1201	Ibrutinib Before and After Stem Cell Transplant in Treating Patients with Relapsed or Refractory Diffuse Large B-cell Lymphoma	Destin Carlisle *(Externally managed by The Alliance for Clinical Trials in Oncology)* dcarlisle@uchicago.edu
BMT CTN 1502	Optimizing Haploidentical Aplastic Anemia Transplantation (CHAMP)	Alyssa Ramirez aramirez@emmes.com
BMT CTN 1503	A Study to Compare Bone Marrow Transplantation to Standard Care in Adolescents and Young Adults with Severe Sickle Cell Disease (STRIDE2)	Jamie Garrison, MS bmtctn1503@emmes.com
BMT CTN 1507	Reduced Intensity Conditioning for Haploidentical Bone Marrow Transplantation in Patients with Symptomatic Sickle Cell Disease	Brianne Allison bmtctn1507@emmes.com
BMT CTN 1601	A Randomized Phase III Trial of Consolidation with Autologous Hematopoietic Cell Transplantation Followed by Maintenance Rituximab vs. Maintenance Rituximab Alone for Patients with Mantle Cell Lymphoma In Minimal Residual Disease-Negative First Complete Remission	Colin Burnett *(Externally managed by ECOG-ACRIN)* cburnett@ecog-acrin.org

Appendix B-2: Studies in Follow-Up

Protocol	Description	BMT CTN DCC/Emmes Contact(s)
BMT CTN 1101	A Multi-Center, Phase III, Randomized Trial of Reduced Intensity Conditioning and Transplantation of Double Unrelated Umbilical Cord Blood versus HLA-Haploidentical Related Bone Marrow for Patients with Hematologic Malignancies	Jamie Garrison, MS bmtctn1101@emmes.com
BMT CTN 1102	A Multi-Center Biologic Assignment Trial Comparing Reduced Intensity Allogeneic Hematopoietic Cell Transplant to Hypomethylating Therapy or Best Supportive Care in Patients Aged 50-75 with Intermediate-2 and High Risk Myelodysplastic Syndrome	Alyssa Ramirez aramirez@emmes.com
BMT CTN 1202	Prospective Multi-Center Cohort for the Evaluation of Biomarkers Predicting Risk of Complications and Mortality Following Allogeneic HCT	Dylan Mawby dmawby@emmes.com

BMT CTN 1301	A Randomized, Multicenter, Phase III trial of Calcineurin Inhibitor-free Interventions for Prevention of GVHD (PROGRESS II)	Kristy Applegate, MBA bmtctn1301@emmes.com
BMT CTN 1302	Multicenter Phase II, Double-blind Placebo Controlled Trial of Maintenance Ixazomib after Allogeneic HSCT for High Risk Multiple Myeloma	Courtney Nelson cnelson@emmes.com
BMT CTN 1304	A Randomized Phase III Study Comparing Conventional Dose Treatment Using a Combination of Lenalidomide, Bortezomib and Dexamethasone (RVD) to High-Dose Treatment with Peripheral Stem Cell Transplant in the Initial Management of Myeloma in Patients up to 65 Years of Age	Amy Foley afoley@nmdp.org
BMT CTN 1401	Phase II Multicenter Trial of Single Autologous Hematopoietic Cell Transplant Followed by Lenalidomide Maintenance for Multiple Myeloma with or without Vaccination with Dendritic Cell (DC)/Myeloma Fusions	Kelly O'Brien, PhD Courtney Nelson bmtctn1401@emmes.com
BMT CTN 1501	A Randomized, Phase II, Multicenter, Open Label Study Evaluating Sirolimus and Prednisone in Patients with Refined Minnesota Standard Risk, Ann Arbor 1/2 Confirmed Acute Graft-Versus-Host Disease	Terry Pritchard, MS Kristy Applegate, MBA Dylan Mawby Sue Isman bmtctn1501@emmes.com

Appendix B-3: Studies to be released in 2019

Protocol	Description	BMT CTN DCC/Emmes Contact(s)
BMT CTN 1702	Clinical Transplant-Related Long-term Outcomes of Alternative Donor Allogeneic Transplantation	Jenny Vogel *(Externally managed by NMDP)* jvogel@nmdp.org
BMT CTN 1703	A Randomized, Multicenter, Phase III Trial of Tacrolimus/Methotrexate versus Post-Transplant Cyclophosphamide/Tacrolimus/ Mycophenolate Mofetil in Reduced Intensity Conditioning Allogeneic Peripheral Blood Stem Cell Transplantation	Kristy Applegate kapplegate@emmes.com
BMT CTN 1704	Composite Health Assessment Model for Older Adults: Applying Pre-transplant Comorbidity, Geriatric Assessment, and Biomarkers to Predict Non-Relapse Mortality after Allogeneic Transplantation	Bailey Protz *(Externally managed by NMDP)* bprotz@nmdp.org
BMT CTN 1705	A Randomized, Double-Blind, Placebo-Controlled Multicenter Phase III Trial of Alpha 1 – Antitrypsin (AAT) Combined with Corticosteroids vs. Corticosteroids Alone for the Treatment of	Alyssa Ramirez Terry Pritchard, MS bmtctn1705@emmes.com

	High Risk Acute Graft-versus-Host Disease (GVHD) Following Allogeneic Hematopoietic Stem Cell Transplant	
BMT CTN 1802	An Open-Label, Single-Arm, Multicenter Study of Combination Anti-CD3/CD7 Immunotoxin (T-Guard) for Steroid-Refractory Acute Graft-versus-Host Disease	Grace Bennett gbennett@emmes.com