

Frequently Asked Questions about the Blood and Marrow Transplant Clinical Trials Network (BMT CTN)

What is the BMT CTN?

The BMT CTN is an association of scientific and clinical organizations that work together to conduct large, multiinstitution, clinical trials involving hematopoietic stem cell transplantation (HCT). HCT is used mainly to treat malignancies of the blood and lymphatic systems (including lymphoma, leukemia, and myeloma), non-malignant marrow disorders (including severe aplastic anemia), and genetic disorders (including sickle cell disease).

Who is the BMT CTN?

Twenty **"Core" Clinical Centers** (some of which are consortia of two or more centers) participate in the BMT CTN. Core Centers are responsible for recruiting, examining, and treating study participants. They are also responsible for collecting all clinical, laboratory, demographic, and other data required by the study. Each Core Center is led by a Principal Investigator who is personally responsible for monitoring all aspects of BMT CTN clinical trials. Additional centers may participate in BMT CTN trials as "Affiliate" Centers through subcontracts with the Data and Coordinating Center (DCC), described below. The BMT CTN Core Centers are:

- Baylor College of Medicine consortium Baylor College/Houston Methodist Baylor College/Texas Children's Hospital Children's National Medical Center
- City of Hope National Medical Center
- Dana-Farber Cancer Institute consortium Brigham & Women's Hospital Massachusetts General Hospital
- Duke University Medical Center consortium Duke University Medical Center University of Virginia
- Fred Hutchinson Cancer Research Center
- H Lee Moffitt Cancer Center H Lee Moffitt Cancer Center Moffitt at Memorial Healthcare System
- Johns Hopkins University
- Medical College of Wisconsin
- Memorial Sloan-Kettering Cancer Center
- Mount Sinai Medical Center consortium Mount Sinai Medical Center Mayo Clinic Minnesota Vanderbilt University
- Northside Hospital Atlanta consortium Northside Hospital Atlanta Levine Cancer Institute/Carolinas HealthCare University of Miami

- Ohio State University consortium Ohio State University Roswell Park Cancer Institute University of California San Francisco University of North Carolina VCU/Medical College of Virginia
- Oregon Health Sciences University consortium
 Oregon Health Sciences University
 Case Western Reserve University
 Cleveland Clinic
 Loyola University
- Pediatric Transplantation and Cellular Therapy Consortium (PTCTC)
- Stanford University Medical Center
- University of Florida consortium University of Florida Emory University
- University of Michigan University of Michigan Indiana University Karmanos Cancer Institute
- University of Minnesota
- University of Pennsylvania
- Washington University

How can other transplant centers participate in a BMT CTN trial?

The BMT CTN is committed to widespread participation in its trials. However, due to limited resources, not all participation requests can be accommodated. An institution that would like to participate as an Affiliate Center can find more information on the BMT CTN website (<u>http://www.bmtctn.net</u>).



How is BMT CTN managed?

The scientific direction of the BMT CTN is overseen by the **BMT CTN Steering Committee**, which includes transplant clinicians and others with expertise in the field. This committee sets the scientific direction of the Network and supervises the design of its clinical trials.

Administration of the BMT CTN is shared among three partner organizations that form the **Data and Coordinating Center (DCC)**. The DCC is made up of representatives from:

- The Center for International Blood and Marrow Transplant Research (www.cibmtr.org)
- The National Marrow Donor Program/Be The Match (<u>www.bethematch.org</u>)
- The Emmes Company (www.emmes.com), a contract research organization

The DCC's functions are to:

- Coordinate and provide continuity for the Network's HCT trials
- Monitor clinical trials, including medical procedures, lab work, and research sample repositories
- Advocate for patients involved in the trials
- Manage and evaluate trial data, including statistical methods and analyses
- Facilitate effective communication and cooperation among the participating transplant centers and with the National Institutes of Health (NIH)
- Offer trial participation to patients in all regions of the U.S.

What kinds of clinical trials does the BMT CTN conduct?

The BMT CTN conducts large, multi-center clinical trials at transplant centers across the United States. These trials are designed to improve the outcomes of HCT for patients facing life-threatening disorders.

To date, more than 16,600 patients have participated in 61 clinical trials, and these numbers continue to grow. BMT CTN studies are evaluating differences in patient outcomes for the following variables:

- Comparison of HCT to standard therapies for myelodysplastic syndromes and sickle cell disease;
- Optimal timing of HCT;
- Pre-transplant conditioning regimens;
- Graft source [autologous, human leukocyte antigen (HLA)-identical and haploidentical related donors, unrelated donors, and umbilical cord blood];
- Anticancer cellular vaccine therapy;
- Cellular therapy, including natural killer (NK) cell and chimeric antigen receptor (CAR) T-cell therapies;
- Prevention and treatment of acute and chronic graft-versus-host disease (GVHD);
- Maintenance therapy;
- Post-transplant infection and organ toxicity;
- Disease control;
- Biomarkers for transplant complications;
- Outcomes of transplant in patient populations of all ages, including children and older adults;
- Quality of life after HCT

The BMT CTN has published more than 150 manuscripts in peer-reviewed scientific journals and presented over 140 abstracts at professional hematology and transplantation meetings.

How is the BMT CTN supported?

The BMT CTN was established in 2001 and is funded through grants from two Institutes of the NIH: the National Heart, Lung, and Blood Institute (NHLBI) and the National Cancer Institute (NCI). Additional support for specific trials is provided by other public and private organizations.

How can I find out more about the BMT CTN?

For more information, visit the BMT CTN web site (<u>www.bmtctn.net</u>) or contact us at <u>bmtctn@emmes.com</u>. Also connect with us via twitter: @BMTCTN