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May 2016 Newsletter

Volume 22, Issue 2

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Perspectives

By Paul Martin, MD

From our foundation as the International Bone Marrow Transplant Registry and evolution to our current identification as the Center for International Blood and Marrow Transplant Research, we have understood our vision and mission to be international in scope. What does this actually mean in practice, and how do we live up to this aspiration?

According to the [CIBMTR 2015 Annual Report](#), 389 transplant centers throughout the world report data to the CIBMTR Research Database. Of these, 219 centers are located in the United States, and 170 (44%) are located in 43 other countries throughout the world, including 19 countries in Europe, 8 in Asia, 3 in the Middle East, 2 in Africa, and 6 in South America, distributed as far north as Turku, Finland, and as far south as Christchurch, New Zealand.



The CIBMTR Advisory Committee likewise has an international scope. We have official representation for Europe (Charles Craddock); Central and South America (Nelson Hammerschlag); and Asia, Africa, and Australia (Mahmoud Aljurf). In addition, the Advisory Committee currently has members at large from England (Jane Apperley), Austria (Hildegard Greinix), Singapore (William Whang), India (Alok Srivastava), Australia (Jeff Szer), and Brazil (Alfonso Vigorito).

During the past several years, representatives of our Coordinating Center have worked with centers throughout the Middle East and Latin America to develop systems that could make it easier for centers to report data to the CIBMTR. In addition, the CIBMTR has a Health Services and International Studies Working Committee that is leading an international comparative analysis of outcomes after HCT for treatment of acute lymphoblastic leukemia.

Since 2010, the CIBMTR has recognized individuals who have made outstanding contributions by promoting research in developing countries, expanding the availability of transplantation or improving outcomes despite unique challenges, or collaborating with worldwide organizations to increase the exchange of data and research collaboration worldwide. Past recipients of the CIBMTR Distinguished Service Award include Ricardo Pasquini (Brazil), Santiago Pavlovsky (Argentina), Ardeshir Ghavamzadeh (Iran), Boris Labar (Croatia), Mammen Chandy (India), and Yoshihisa Kodera (Japan).

This year, it was my pleasure to present the CIBMTR Distinguished Service Award to Professor Dao-Pei Lu from Peking University and Fudan University in Beijing, China. Professor Lu is revered as the founder of HCT in China. In 1964, he performed the first successful transplant for severe aplastic anemia in China, using marrow from a syngeneic twin donor without conditioning, thereby demonstrating the cause as stem cell failure in this case. More recently, he and his colleagues have addressed the lack of sibling donors in China by developing a remarkably effective approach that makes success rates with HLA-haploidentical donors comparable to those with HLA-identical sibling donors. He has also been instrumental in developing cord blood banks in China.

Professor Lu has consistently advocated for China's integration in world-wide transplantation programs whenever possible. The CIBMTR recognized Professor Lu for his scientific and educational contributions and his service and commitment to the CIBMTR and the NMDP/Be The Match. His perseverance, ingenuity, and success in addressing scientific challenges, overcoming political obstacles, and making the most of limited resources serve an inspiring example to all of us, wherever we live and work throughout the world.

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[CIBMTR Trivia](#)

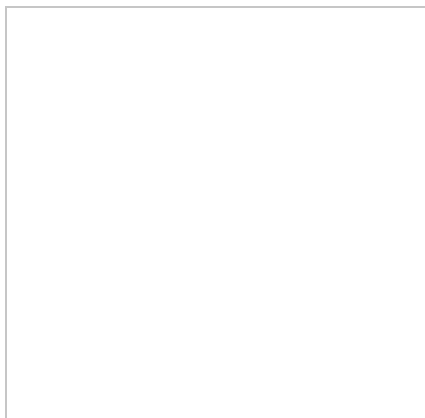
How many people attended the 2016 BMT Tandem Meetings?

1. 2,934
2. 3,021
3. 3,143
4. 3,221

Click [here](#) to enter your answer. If you answer correctly, you will be entered into a drawing to win a CIBMTR prize!

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[Graft-vs-Host Disease Working Committee](#)





[Steve Spellman](#),
MBS,
Scientific Director

GVHD is the most critical complication of allogeneic HCT, and its occurrence prevents favorable outcomes in a large proportion of affected patients. GVHD is an entirely iatrogenic complication of allogeneic transplantation, and its prevention and treatment are of paramount importance to the transplantation community as a whole. In the last few years, increased attention has been paid to the prevention and treatment of GVHD as alternative and mismatched donors have been increasingly used in transplantation and as novel immunosuppressive agents have been developed for the treatment of the autoimmune and rheumatologic conditions. The GVHD WC examines both acute and chronic GVHD outcomes across all diseases treated by allogeneic transplantation.

Committee Leadership

Co-Chairs:

- [Amin Alousj](#), MD, MD Anderson Cancer Center
- [Daniel Couriel](#), MD, MS, Utah Blood and Marrow Transplant Program
- [Joseph Pidala](#), MD, PhD, H. Lee Moffitt Cancer Center and Research Institute

Scientific Directors:

- [Mukta Arora](#), MD, MS
- [Steve Spellman](#), MBS

Statistical Director:

- [Tao Wang](#), PhD

Statistician:

- [Michael Hemmer](#), MS

CAC Representatives:

- [Hilary Hall](#)
- [Jim Omel](#), MD

Under the current leadership, the GVHD WC focused on:

1. Prognostic implications of upper GI acute GVHD;
2. Comparisons of GVHD incidence and outcomes of different GVHD prophylaxis regimens and stem cell sources, including UCBT;
3. Overviews in the trends of GVHD as transplantation practices evolve;
4. Evaluations of GVHD free–relapse free survival (GRFS) after URD PBSC and bone marrow HCT.

In recent years, the GVHD WC published nine articles (four in 2014-2015, five in 2011-2013) and presented six abstracts at the ASH Annual Meeting. The committee has 11 ongoing studies with plans of completing at least 3 studies in each academic year, making it one of the most efficient and productive committees around. The GVHD WC benefits from broad enrollment in the CIBMTR Research Database. The number of allogeneic transplants from 2001-2014 total more than 37,000 for

leukemic diseases (acute myeloid leukemia, acute lymphoblastic leukemia, myelodysplastic syndrome, chronic myeloid leukemia, and other leukemia) and more than 15,000 for non-leukemia malignancies. To ensure that the CIBMTR Research Database will continue to capture relevant GVHD data, the Working Committee leadership participated in the revision of the data collection forms for implementation in 2016. The changes will allow capture of new GVHD prophylaxis strategies; relevant dates of acute GVHD onset and maximum grade on the TED forms, rather than on just the CRF-level forms; and NIH organ scoring criteria for chronic GVHD.

The GVHD WC is always seeking interesting and novel ideas for study as well as encouraging the involvement of junior investigators and those wanting to break into the field of blood and marrow transplantation and outcomes research.

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[Pediatric Cancer Working Committee](#)



[Gregory Hale,](#)
MD,
Chair



[Angie Smith,](#)
MD, MS
Chair



[Parinda Mehta,](#)
MD,
Chair

Autologous and allogeneic HCT are important treatment options in the multidisciplinary care for children and adolescents with cancer. As definitions of cancer risk groups change and as new therapeutic agents are incorporated into treatment plans, the need to understand the role and timing of HCT in pediatric cancers is essential. Trends in pediatric transplantation, prognostic information for pediatric leukemia survivors, the role of transplantation in patients with hypodiploid ALL and T cell ALL, and the role of autologous HCT in Wilms' tumor are just some of the topics which have been or are currently being evaluated.

The Pediatric Cancer Working Committee (PCWC) focuses on cellular therapy for children and adolescents with cancer, conducts studies addressing a wide range of issues in both allogeneic and autologous transplantation, and works collaboratively with other Working Committees and Pediatric Cancer Consortia.

Committee Leadership

Co-Chairs:

- [Gregory Hale](#), MD, All Children's Hospital
- [Parinda Mehta](#), MD, Cincinnati Children's Hospital Medical Center
- [Angela Smith](#), MD, MS, University of Minnesota Medical Center, Fairview

Scientific Director:

- [Elizabeth Thiel](#), MD, MS

Statistical Director:

- [Kwang Woo Ahn](#), PhD

Statistician:

- [Heather Millard](#), MPH

The PCWC focuses on and prioritizes the following transplant topics:

- Role and timing of HCT as primary pediatric cancer therapy and how to improve outcomes, especially by identifying risk-appropriate populations;
- Alternative donor transplantation and graft source selection in pediatric cancers;
- Identification of variables in predicting outcomes of HCT in pediatric cancers;
- Broadening the participation of pediatric transplant physicians at all levels in the scientific endeavors of the WC.

Since 2014, the PCWC has published five manuscripts, including one in Blood, two in Pediatric Blood and Cancer, and two in Biology of Blood and Marrow Transplantation. These abstracts were also presented at various national and international meetings prior to publication. The PCWC has four ongoing studies addressing important topics, such as the role of autologous HCT for Wilms' tumor, trends in pediatric transplant, personalized prognostic information for pediatric leukemia survivors, and outcomes of second transplant for relapsed malignancy.

One of the unique features of PCWC is our recent focus on the involvement of fellows and junior faculty on new studies. We have been able to engage two enthusiastic fellows on one of our current studies, and the whole experience has been mutually rewarding. We plan to continue this tradition and will be proactively contacting and inviting fellows and junior faculty members to participate in each of the upcoming studies. We believe this early involvement will encourage long-term participation of young investigators in PCWC activities in the future.

The PCWC is interested in studies designed to answer questions that are highly relevant for advancing pediatric patient care, particularly in areas where data from prospective trials are not available, such as rare diseases. Registry data are essential for providing hypothesis-generating data that inform future prospective HCT trials.

The success of the committee depends on new ideas and testable hypotheses as well as participation by individuals with different perspectives and scientific backgrounds. The PCWC encourages all investigators with an interest in pediatric cancer to propose studies, which may be submitted year-round on the [CIBMTR website](#). Please contact one of the chairs or a member of the scientific staff to learn more or to discuss your research ideas and proposals ahead of time. We encourage everyone to be an active participant in the protocol and manuscript writing, which will ensure authorship on manuscripts coming from the PCWC.

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[Response to Perspectives: A Third Option](#)

By D'Eta Waldoch Snyder

I was very surprised and humbled by Dr. Paul Martin's Perspectives column in the [February 2016 edition of the CIBMTR newsletter](#) when it featured me (!?!) and a great deal of numbers and statistical information about my work with the IBMTR / CIBMTR and BMT Tandem Meetings. Thank you, Dr. Martin. I'm not sure I have ever recapped the years with that kind of accuracy. As a kid who wouldn't take a chemistry class and hated math, I still have no idea how I landed in the middle of world-renowned medical professionals, scientists, and statisticians at the ripe old age of 21! However, there is one number that I have held on to as my career waxed and waned and that is the number 3, in terms of considering ones' options.

I have had a sign in my office for nearly 38 years that says:

*Staying or quitting
Staying or quitting
Staying or quitting
What's the third option?
There's always a third option.*



I can't say I've ever been serious about quitting my job because I'm just too stubborn to give up, and I've respected the talent of the many awesome folks surrounding me. I have many of you to thank for that. Tenacity has served me well as I was fortunate to witness many options turn into realities during my trek starting in 1978 from Medical Secretary to Database Manager to BMT Tandem Meetings Manager – three very different yet interrelated careers. I watched the IBMTR move from a closet in the Winter Research Lab at Mount Sinai Medical Center in Milwaukee to the Medical College of Wisconsin. I remember talks at BMT meetings about the earliest experiments in a series of mice and dogs, which now focus on successful outcomes with happy, human survivors. I was dazzled as the IBMTR became the CIBMTR, expanding into a well-oiled collaboration between our Milwaukee Campus and our Minneapolis Campus. I witnessed the birth of ASBMT, BMT CTN, EBMT, WBMT, and more alphabet soup than dear old Dr. Mort Bortin could ever have imagined when he founded the IBMTR in the early 1970's. I am most grateful that I have been able to contribute to the growth of the BMT Tandem Meetings from 200 attendees to nearly 3,500 in a little more than 25 years. There were so many twists, turns and options along this winding road.

I find myself pondering fond memories of people and meetings all over the world as I sit here, one day away from retirement from the Medical College of Wisconsin. Is it finally time to quit?

I begin to smile, knowing I have found my third option as I hand in my keys to the CIBMTR office. Although I am indeed also handing over the reins to Tia Houseman as BMT Tandem Meetings Manager, I am delighted to confirm that I have agreed to stay involved with the Meetings on a consulting basis and that option means I'm still not quitting! I look forward to supporting Tia and the BMT Tandem Meetings staff for a while longer as we watch future options unfold and to seeing all of you at the 2017 BMT Tandem Meetings in Orlando!

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[2016 BMT Tandem Meetings](#)

By Tia Houseman

The 2016 BMT Tandem Meetings, held at the Hawaii Convention Center in Honolulu, Hawaii, February 18-22, broke another record with 3,221 attendees from more than 40 countries! This is 89 more attendees than in 2015 and 826 more than the 2011 BMT Tandem Meetings in Hawaii. Countries with the highest representation, aside from the United States, were Canada, Japan, Australia, Germany, China, Greece, and Turkey. Forty-one percent of attendees were first time attendees. We also had 83 exhibitors.



Program Co-Chairs Pavan Reddy, MD, for ASBMT, and Corey Cutler, MD, MPH, for CIBMTR, along with the Scientific Organizing Committee put together an excellent program for this year's meeting with 5 plenary sessions, 5 product theaters, 6 satellite symposia, 9 concurrent sessions, 96 oral abstracts, 6 best abstract awards, 2 poster sessions, 15 Working Committee meetings, and 8 Meet-the-Professor sessions. A record-breaking 762 abstracts were submitted this year, and the new system of only selling Meet-the-Professor tickets on-site

was successful; nearly all sold out. In addition to an outstanding scientific program, parallel sessions were held for Clinical Research Professionals / Data Managers, BMT CTN Coordinators, Administrative Directors, BMT CTN Investigators, Pharmacists, Transplant Nurses, Medical Directors, and Nurse Practitioners.

During the CIBMTR business meeting, Mary Horowitz presented D'Etta Waldoch Snyder with a small token of appreciation for her many years of service to the CIBMTR and the BMT Tandem Meetings. We are truly grateful for everything that D'Etta has done to make the BMT Tandem Meetings what they are today. D'Etta is retiring from her position at the Medical College of Wisconsin but will remain



involved in future BMT Tandem Meetings in some capacity. Expect to see her at the 2017 Meetings at the Gaylord Palms in Orlando, FL, February 22-26.



The CIBMTR Distinguished Service Award was presented to Dao-Pei Lu, MD. Dr. Lu received this award for his service and commitment to the CIBMTR, pioneering the field of BMT in China, including organizing the China BMT Registry, founding the China Marrow Donor Program, and establishing the first cord blood bank in China.

The Mortimer M. Bortin Lecture entitled "Personal Reflections on a Life in Transplant: Is It a Man's World?" was presented by Jane F. Apperley, MD. The Mortimer M. Bortin Lecture commemorates the Founding Scientific Director of the International Bone Marrow Transplant Registry, now the CIBMTR. Dr. Bortin's foresight and dedication were critical to the development of the CIBMTR as a global resource for HCT research.

ASBMT presented the Public Service Award to Pablo Rubinstein, MD, and the Lifetime Achievement Award to Robert Korngold, PhD. They also presented three Biology of Blood and Marrow Transplantation Editorial Awards and seven ASBMT New Investigator Awards. FACT celebrated their 20th Anniversary at the BMT Tandem Meetings.



Attendees at the Tandem Reception enjoyed fire dancers, music, and a variety of food at the Royal Hawaiian Hotel, Ocean Lawn and in the Monarch Room.

Once again, in addition to the printed program guide, attendees were able to download the BMT Tandem Meetings App (BMTTANDEM). The App allowed registered attendees access to the meeting program schedule and general information, session evaluations, speaker information, exhibit booth locations mapped out on the exhibit hall floor plan, messaging to other attendees, and the ability to create a personal schedule. This was the second year during which attendees could also use their smart phones as audience response devices, making use of efficient electronic meeting technology. More than 60% of attendees used the mobile app most often as their resource for viewing the meeting schedule as opposed to 30% who used the printed program guide. For the first time this year, a BMT Tandem Home Site was used, which made information such as hotel information, transportation, the agenda, grant information, dates, etc. more readily available for attendees.

Watch for details pertaining to the 2017 BMT Tandem Meetings over the upcoming months. Links for meeting requests will be available in May. Contact Sherry Fisher at slfisher@mcw.edu for information regarding support opportunities for next year's meeting.

Scientific Organizing Chairs, David Marks, MD, for the CIBMTR, and Marcel van den Brink, MD, PhD, for ASBMT, look forward to seeing you at the Gaylord Palms in Orlando, Florida, February 22-26, 2017.

To view additional photos from the 2016 BMT Tandem Meetings, visit the [CIBMTR Facebook page](#).

Meet the CIT Program Management Team

The CIT (CIBMTR Information Technologies) Program Management team consists of two Program Managers, four Project Managers, one Project Coordinator, and four Business System Analysts. The Minneapolis team is led by Senior Program Manager, Katherine Gee, and the Milwaukee Team is led by Program / IS Manager, Tom Moerke.

Milwaukee Campus



Left to Right: Tom Moerke, Andrew Davidson

Minneapolis Campus



*Front Row (left to right): Shawn Freeman, Katherine Gee, Ericka Wheeler
Back Row: Dean Kloker, Sharon Ewer, Dan Campbell, Karen O'Connor, Bridget Wakaruk, Ashley Pull*

The primary focus of the Program Management team is to manage the overall CIT Portfolio of Programs (groups of related projects) to achieve CIBMTR strategic objectives and benefits. Project Managers are responsible for planning, coordinating, and monitoring projects to accomplish their objectives while balancing time, scope, resources, and quality. Business Systems Analysts (BSAs) work as liaisons among CIBMTR partners to understand CIBMTR structure and operations and to facilitate implementation of solutions that enable the organization to achieve its goals. BSAs accomplish this by working with business partners to understand user requirements and needs and to facilitate their implementation into technology solutions.

At any given moment in time, the CIT Program Management team works on many simultaneous projects that collectively support data capture, data quality, and data

sharing. For example, we recently announced the availability of data analytics tools for transplant centers at the BMT Tandem Meetings this year. Forms Revision is also a major, reoccurring initiative designed to update forms to be consistent with current medical practice and make the most relevant data available for research. This year, 13 recipient forms are being revised along with one new form, and the capability to collect and report on cellular therapies is being developed. Forms Revision requires extensive planning and careful coordination within the CIBMTR and among its network partners.

The primary goal of our team is to provide technology solutions that enable distribution of the highest quality data possible to all CIBMTR stakeholders for research and other activities aimed at improving patient outcomes. Our group accomplishes this goal through careful planning and execution of projects in partnership with stakeholders and aligned with organizational strategy.

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[Springing Into 2017 - News from the Health Services Research Program](#)

By Linda Burns, MD; Ellen Denzen, MS; Stephanie Farnia, MPP; and Beth Murphy, EdD

The Health Services Research Program has been busy! We have new projects and several updates on ongoing initiatives to share with you this quarter.

New Projects

Engaging Patients in Developing a Patient-Centered HCT Research Agenda

We were recently awarded a two-year Eugene Washington Engagement Award by PCORI. Linda Burns, MD, Medical Director of the Health Services Research Program, will lead the project focused on engaging patients and other key stakeholders in developing a patient-centered HCT outcomes research agenda. The inaugural symposium was held on February 20, 2016, during the BMT Tandem Meetings. More than 100 participants attended, including patients and their caregivers, clinicians, researchers, program directors, administrators, policy makers, and payers. Plenary speakers included San Keller, PhD, Principal Investigator of the NIH Patient-Reported Outcome Measurement Information System (PROMIS) Network Center, and David Vanness, PhD, Associate Professor of Population Health Sciences at the University of Wisconsin. Keynote panelists were Gloria Gee (HCT recipient) and her husband / caregiver, Jeffrey Bender, and Susan Philips (HCT recipient) and her sister / caregiver, Laurie Derse. Each spoke about their experiences pre-, during, and post-HCT from their personal perspectives, and they provided insights into how transplant teams can best prepare patients and their families for the totality of the transplant course, including survivorship. Next steps include populating Working Groups around patient-centered topics and planning the next symposium to be held in December.

Palliative Care

The Health Services Research Program is working closely with the ASBMT Palliative Care Task Force to develop and conduct a survey of clinicians regarding palliative care options for their patients; subsequently, a survey of patients will be performed to better understand their perspectives on palliative care. Stay tuned for more information in the next newsletter.

Updates on a few of our ongoing initiatives:

ASBMT HCT Value and Health Economics Special Interest Group

The Health Services Research Program, in conjunction with NMDP/Be The Match Payer Policy, obtained approval from ASBMT to form an HCT Value and Health Economics Special Interest Group (SIG). The inaugural meeting was held on February 19, 2016, during the BMT Tandem Meetings and moderated by Richard Maziarz MD, Chair of the Steering Committee. More than 40 members attended and heard informative presentations from researchers across the United States conducting research on topics ranging from comparative effectiveness to continuous quality control. Ruth Brentari, Kaiser Permanente, reviewed the 2016 priorities of the NMDP/Be the Match Advisory Group on Financial Barriers to Transplant (AGFBT). Pat Martin provided an update from the "Aligning Quality and Value in Stem Cell Transplantation" Payer Forum held in Minneapolis on July 15-16, 2015. The SIG meeting concluded with a brief discussion on next steps. Envisioned opportunities include sharing efforts and identifying common interests, facilitating international connections, spawning research efforts, publishing position and "Op Ed" position papers, and developing a half-day symposium at the 2017 BMT

Tandem Meetings. If you'd like to join the SIG, contact Olivia King at oking@nmdp.org.

Transplant Center Financial Barriers to HCT: Health Insurance Coverage and Reimbursement

As part of our ongoing collaboration with NMDP/Be The Match Payer Policy, the Health Services Research Program conducted a survey of transplant centers to gain insight into financial barriers to HCT and identify how we can best assist centers to overcome barriers. Results showed that centers, and their patients, continue to face significant financial barriers. Government payers continue to provide low reimbursement, and an increasingly limited number of transplant centers are considered "in-network," which decreases options for patient access to transplant. Insights were shared in a webinar presented on February 1, 2016, by Kristen Edsall, RN, MSN, Manager Payer Relations (kedsall@nmdp.org), and Linda Burns, MD.

HCT Multidisciplinary Care Teams: Burnout, Moral Distress, and Career Satisfaction

We were excited to provide the transplant community with results of a survey performed as part of the NMDP/Be The Match System Capacity Initiative to address challenges in recruitment and retention. Joyce Neumann, PhD, University of Texas MD Anderson Cancer Center and Principal Investigator, presented the oral abstract during the 2016 BMT Tandem Meetings. Unfortunately, but perhaps not very surprising, burnout and moral distress are prevalent across all HCT disciplines, with pharmacists having the highest prevalence. The majority of survey respondents reported a low level of depersonalization but high personal accomplishment and gratification in caring for patients, and most recommended a career in HCT despite moderate to high emotional exhaustion. A manuscript with complete details is in preparation.

Our research portfolio also includes:

- Costs and utilization of allogeneic HCT compared to chemotherapy alone as initial therapy for older patients with AML
- Education needs assessment with adults who received an HCT at age 65 or older (in partnership with the City of Hope, Dana Farber Cancer Institute, and the University of Minnesota)
- Healthcare costs and utilization for acute myeloid leukemia patients treated with chemotherapy and allogeneic HCT (abstract presented at the 2016 BMT Tandem Meetings)
- Individualized care plans for HCT survivors (PCORI funded; partnership with RCI BMT)
- Payer partnered approach to community-based referral for HCT (NCCN/Pfizer grant)
- Easy-to-read informed consent forms for HCT multicenter trials (NHLBI ancillary grant to BMT CTN; BMT CTN 1205)

Recent Health Services Research Program Peer-Reviewed Publications:

- MacWilliams MA et al. **An Innovative educational program for International Hematopoietic cell transplant pediatric patients.** Journal of Cancer Education. 2016 Feb 3. Epub ahead of print.
- Preussler JM et al. **Patient Housing Barriers to Hematopoietic cell transplantation: results from a mixed-methods study of transplant center social workers.** Supportive Care in Cancer. 2016 Mar 1;24(3): 1167-1174.

For any questions about the Health Services Research Program, please contact Elen Denzen, Senior Manager, at edenze@nmdp.org.

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Blood and Marrow Transplant Clinical Trials Network

By Amy Foley, MA

The BMT CTN, with its 20 core and approximately 100 affiliate centers, has enrolled more than 8,800 patients since 2003. The CIBMTR shares administration of the BMT CTN Data and Coordinating Center with NMDP/Be The Match and The Emmes Corporation. Together, these three



**BLOOD AND MARROW
TRANSPLANT
CLINICAL TRIALS NETWORK**

organizations support all BMT CTN activities.

The BMT CTN Steering Committee is currently under the leadership of Chair Steve Devine, MD (Ohio State University). Rick Jones, MD (Johns Hopkins) continues to serve as Vice-Chair, and Fred Appelbaum, MD (Fred Hutchinson Cancer Research Center) is now serving as Immediate Past-Chair.

NEW! Upcoming Clinical Trials

The BMT CTN encourages widespread transplant community participation in clinical trials. If your center is interested in participating, please visit the [BMT CTN website](#).

There are six studies that will be activated within the year:

Non-Malignant Blood Diseases

- 1502 - Optimizing cord blood and haploidentical aplastic anemia transplantation (CHAMP)
 - Protocol anticipated to be released in June
- 1503 - Comparison of bone marrow transplantation to standard care (biologic assignment) in adolescents and young adults with severe sickle cell disease
 - Protocol anticipated to be released in May
- 1507 - RIC before haploidentical BMT in children and adults with symptomatic sickle cell disease
 - Protocol anticipated to be released in June

AML Maintenance Therapy

- 1506 - Randomized, double-blind, placebo-controlled Phase III trial of the FLT3 inhibitor administered as maintenance therapy following allogeneic HCT for patients with FLT3 / ITD AML
 - Protocol anticipated to be released in May

GVHD Treatment

- 1501 - Randomized, Phase II, open label, study comparing sirolimus to prednisone in patients with refined Minnesota standard risk, Ann Arbor 1/2 confirmed acute graft-versus-host disease
 - Protocol anticipated to be released in April

Novel Agent in Lymphoma Treatment

- BMT CTN 1201 / Alliance A051301 - Randomized Phase III study of Ibrutinib during and following autologous HCT vs placebo in patients with relapsed or refractory diffuse large B-cell lymphoma of the activated B-cell subtype (Note: this study is managed by Alliance; BMT CTN has endorsed the study and will provide accrual credit to BMT CTN centers)
 - Protocol anticipated to be released this summer via the CTSU

Current Clinical Trials

There are 11 BMT CTN trials released to centers or open to accrual. The four open to additional center participation are indicated with purple font.

- BMT CTN 07LT - Continued, long-term follow-up and **lenalidomide maintenance therapy** for patients who have enrolled on BMT CTN 0702
- BMT CTN 1101 - Phase III study comparing HLA-haploidentical related donor bone marrow vs. double umbilical cord blood (**haplo vs. double cord**) with RIC for patients with hematologic malignancy
- BMT CTN 1102 - Biologic assignment trial comparing RIC HCT to hypomethylating therapy or best supportive care in patients aged 50-75 with intermediate-2 and high risk **myelodysplastic syndrome**
- BMT CTN 1202 - Prospective cohort of biologic samples for the evaluation of **biomarkers** predicting risk of complications and mortality following allogeneic HCT
- BMT CTN 1203 PROGRESS I - Randomized Phase II study of **novel approaches for GVHD prophylaxis** compared to CIBMTR controls
- BMT CTN 1205 - **Easy-to-read Informed consent** for HCT clinical trials
- BMT CTN 1301 PROGRESS II - Randomized, Phase III trial of **calcineurin Inhibitor-free Interventions for prevention of graft-versus-host disease**
- BMT CTN 1302 - Phase II double-blind placebo controlled trial of **maintenance ixazomib after allogeneic HCT for high risk multiple myeloma**
- BMT CTN 1304 / DFCI 10-106 - Phase III study comparing conventional dose treatment using a combination of RVD to high-dose treatment with PBSC transplant in the **Initial management of myeloma** in patients up to 65 years

(Note: this study is managed by Dana Farber Cancer Institute, but BMT CTN has endorsed the study and is providing accrual credit to BMT CTN centers)



- BMT CTN 1401 Myeloma Vaccine - Single autologous HCT followed by lenalidomide maintenance for multiple myeloma with or without **vaccination with dendritic cell / myeloma fusions**
- BMT CTN 1505 RECRUIT - Randomized intervention trial to increase **minority patient recruitment**

BMT CTN Publications

There are 57 BMT CTN published articles, including 16 primary analyses. The following manuscripts were recently published.

- Khera N et al. **Comparison of characteristics and outcomes of trial participants and nonparticipants: Example of Blood and Marrow Transplant Clinical Trials Network 0201 Trial.** Biology of Blood and Marrow Transplantation. Epub 2015 Jun 11.
- **Primary Result!** Anderlini P et al. **Cyclophosphamide conditioning in patients with severe aplastic anaemia given unrelated marrow transplantation: a phase 1-2 dose de-escalation study.** Lancet Haematology. 2015 Sep 1; 2(9):e367-75.
- Young JH et al. **Infections after transplantation of bone marrow or peripheral-blood stem cells from unrelated donors.** Biology of Blood and Marrow Transplantation. 2016 Feb 1; 22(2):359-370. Epub 2015 Sep 25.
- Wood WA et al. Patient-reported physical functioning predicts the success of hematopoietic cell transplantation (BMT CTN 0902). Cancer. 2016 Jan 1; 122(1):91-98. Epub 2015 Oct 6.
- Giralt S et al. **American Society of Blood and Marrow Transplantation, European Society of Blood and Marrow Transplantation, Blood and Marrow Transplant Clinical Trials Network, and International Myeloma Working Group Consensus Conference on Salvage Hematopoietic Cell Transplantation in Patients with Relapsed Multiple Myeloma.** Biology of Blood and Marrow Transplantation. 2015 Dec 1; 21(12): 2039-2051. Epub 2015 Sep 30.
- **Primary Result!** Devine SM et al. **Phase II study of allogeneic transplantation for older patients with acute myeloid leukemia in first complete remission using a reduced-intensity conditioning regimen: results from Cancer and Leukemia Group B 100103 (Alliance for Clinical Trials in Oncology)/Blood and Marrow Transplant Clinical Trial Network 0502.** Journal of Clinical Oncology. 2015 Dec 10; 33(35): 4167-4175. Epub 2015 Nov 2.
- Burns LJ et al. **Recovery of unrelated donors of peripheral blood stem cells versus bone marrow: A prespecified analysis from the Phase III BMT CTN protocol 0201.** Biology of Blood and Marrow Transplantation. Epub 2016 Mar 21.

To get up-to-date information about BMT CTN studies, meetings, and news:

-  Like us on Facebook: facebook.com/bmtctn
-  Follow us on Twitter: @BMTCTN

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[RCI BMT's New Data Capture and Management Systems](#)

By Becky Drexler

The RCI BMT recently released new data capture and management systems: Medidata RAVE and CTMS (Clinical Trial Management System). These new systems will reduce time to trial participant's first enrollment, lower resource needs, and reduce time and costs of trial management.

Starting in Fall 2014, the RCI BMT team, along with staff from CIBMTR IT, explored options for clinical trial data collection and management. Medidata RAVE was selected in large part because it is the standard electronic data capture system for all groups in the NCI National Clinical Trials Network. Since many sites that participate in RCI BMT trials are part of this network, they are already familiar with the system.

Over the second half of 2015, the RCI BMT team worked with Medidata to transfer trial information and customize the CTMS. The first trial in the RAVE system was released to sites at the end of December 2015. The second trial was released in January 2016, and staff members are currently working on the third trial. The CTMS was released to production in January 2016, and the first two trials are now being managed in the system. By May, all on-going trials will be in the CTMS.

We look forward to fully implementing these new systems and welcome your feedback. Please contact your clinical trial coordinator with questions regarding these new systems or to share your thoughts and opportunities for improvement.

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The Advisory Committee, made up of members from across the globe, maintains careful oversight of the CIBMTR research agenda. The [2016 committee members](#) are listed on the CIBMTR website, and we are pleased to welcome the newest members of the committee:

- Jane Apperley - Member at Large (Non-North America)
- Karen Ballen - Member at Large (North America)
- Paul Carpenter - Vice-Chair (North America)
- Hildegard Greinix - Member at Large (Non-North America)
- Nelson Hamerschlak - Vice-Chair (Central/South America)
- Navneet Majhail - Member at Large (North America)
- Miguel-Angel Perales - Member at Large (North America)
- Rob Soiffer - Chair Elect
- Jeffrey Szer - Member at Large (Non-North America)
- Yvonne Ybarra - Collection Center Representative

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The CIBMTR is supported by Public Health Service Grant / Cooperative Agreement 5U24CA076518 from the NCI, NHLBI, and NIAID; a Grant / Cooperative Agreement 5U10HL069294 from NHLBI and NCI; a contract HSH250201200016C with HRSA / DHHS; two Grants N00014-15-1-0848 and N00014-16-1-2020 from the Office of Naval Research; and grants from our [corporate and private contributors, which are listed on the CIBMTR website.](#)

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[Abbreviations](#)

Need an acronym defined? [Review our list of common abbreviations.](#)

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Last Updated: 4/29/2016 2:02 PM

