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1.0 INTRODUCTION

The Worldwide Network for Blood and Marrow Transplantation (WBMT) was formally created in 2007 by leaders from major hematopoietic stem cell transplantation (HSCT) groups and donor registries across the world, culminating in consensus on Bylaws and an organizational structure as early as 2009. With the interest and strong support of the World Health Organization (WHO), these leaders shared a mutual vision of combining efforts towards improving standardization in the global application of HSCT, cellular therapy, and related fields as well as broadening the scope of data sharing. This “Federation of Societies” began with 17 international organizations now numbering 24, all with substantial interest in HSCT (Appendix A). The WBMT was incorporated as a non-profit organization for educational, scientific, and philanthropic purposes under the laws of Switzerland with headquarters in Bern. There is no fee for Member Societies; funding support is solicited from relevant industry.

Description of the earliest years of efforts is available in previous Progress Reports available on the WBMT website (wbmt.org) as they describe how those proactive clinicians and researchers shaped the WBMT into a recognizable organization, its structure and charter, its notable achievements, and its future aims and goals. This report, however, focuses on the accomplishments of the WBMT during the calendar year 2016.

1.1 Early Development

The four founding Member Societies of the WBMT are the Asia-Pacific Blood and Marrow Transplantation Group (APBMT), Center for International Blood and Marrow Transplant Research (CIBMTR), European Society for Blood and Marrow Transplantation (EBMT), and World Marrow Donor Association (WMDA). Representatives organized themselves in 2007 to help identify goals, communicate them to all other societies with clinical or research interest or stake in HSCT or related fields, and embark on serious planning. They recognized:

- HSCT is a global endeavor.
- There was an urgent need to coordinate the activities of the different societies active in this field.
- An international organization could support and even influence thoughtful, local legislation from a global perspective.

During the earliest meetings, it was agreed the WBMT required a unique organizational structure to fulfill its goal of coordinating HSCT, stem cell donor, and cellular therapy work worldwide. It was also important that it not duplicate decades of successful efforts by other established organizations; the result was the “Federation of Societies” structure.

Since inception, the four founding Member Societies have continued to support, in a variety of ways, the infrastructure of the WBMT, including administrative support from several regions, budget and financial management, meeting and Workshop planning support, and website management. These contributions have been invaluable to the early success and achievements of the WBMT.
1.2 Current Status with the WHO

The WHO played a critical role in the WBMT from its inception by providing substantial interest in and support of this new initiative. The collaborative relationship with the WHO culminated in an invitation in 2012 to apply for non-government organization (NGO in official relations) status. The WBMT submitted a comprehensive application, including a three-year plan, which was reviewed and formally approved by the WHO Executive Committee in January 2013. In 2015, the WBMT submitted a renewal application, and the WHO extended the WBMT’s NGO in official relations status for another three years.

As noted above, the WHO strongly supported the WBMT’s early collaborative and unifying efforts. and WHO representatives continue to attend meetings as “observers”, assist in planning activities, and participate as forum presenters on a variety of relevant topics. Since acquiring NGO in official relations status, the WBMT is obliged to provide a set of deliverables to the WHO in constant pursuit of its educational, scientific, and philanthropic mission (Section 4.4).
2.0 COMMITTEE STRUCTURE

2.1 Board
The WBMT Board is the highest tier of decision making for all WBMT activities. The Board includes elected Executive Committee officials (Section 2.2 and Appendix B) as well as a primary and alternate representative from each of the 24 Member Societies. Each Member Society is permitted a single vote, either by the primary or the alternate representative. The Board also includes Co-Chairs of the Standing Committees (Sections 2.3 and 3.0) who also have voting privileges (again, one vote per Standing Committee).

The Board meets annually in person (alternating between the February BMT Tandem Meetings in the US and the March - April EBMT Meeting in Europe) and holds two teleconferences, mid-year and late in the year, to remain informed and to handle issues arising between the in-person sessions. Email communication is utilized as necessary between these meetings. Meeting minutes are posted on a password-protected section of the WBMT website (wbmt.org).

2.2 Executive Committee
The Executive Committee informs the Board while managing business matters between Board meetings. Membership includes the elected President, Vice-President, Treasurer, Secretary, President-Elect or Immediate Past President, and WBMT Representative to the WHO. The final role, WBMT Representative to the WHO, was added to the Executive Committee in 2016 and will be filled by a Past President. As noted above, appointed Co-Chairs of the seven Standing Committees (Sections 2.3 and 3.0) serve on the Executive Committee. The Executive Committee conducts monthly hour-long teleconferences, and minutes of these meetings are also posted on a password-protected section of the WBMT website (wbmt.org).

Following existing Nomination and Election House Rules, and with input from Board members, an ad hoc Nominating Committee, including one representative from each WHO region, also convenes as necessary. This process activated during 2016 to fill the President-Elect position since the Past President position is scheduled to outdate in April 2017; the election closed on December 31, 2016. Term duration is one year followed by a two year term as President and a one year term as Past President. Appendix B displays photos and contact information for all current, elected Executive Committee members.

2.3 Standing Committees
Seven Standing Committees (Section 3.0) focus on areas of prime importance to the mission of the WBMT, as identified by the Executive Committee. Most of these committees were created in 2008, and Co-Chairs were appointed at that time. Committee leadership positions were last reviewed in 2014, and the next review is scheduled for 2017. In 2016, the Board revised the WBMT bylaws related to the Standing Committee Co-Chairs. There is now greater emphasis on committee leader expectations and reporting committee activities. The majority of WBMT project work is accomplished by these Standing Committees:
• Accreditation [the international Alliance for Harmonization of Cellular Therapy Accreditation (AHCTA) serves in this capacity] (Section 3.1)
• Donor Issues (Section 3.2)
• Education and Dissemination (Section 3.3)
• Graft Processing and Cellular Therapy (Section 3.4)
• Nuclear Accident Management (Section 3.5)
• Patient Advocacy / Advisory (Section 3.6)
• Transplant Center / Recipient (Section 3.7)

Two or three Co-Chairs lead each committee. These Co-Chairs also participate in the ongoing work and decisions of the Executive Committee as noted above. Any interested individual belonging to any one (or more) of the Member Societies is eligible to join these committees; membership is solicited or refreshed periodically.

Because all WBMT committees are project driven, they meet with varying frequency, usually by teleconference due to international participation. WBMT committees also take advantage of relevant, international HSCT meetings for in-person dialog as they are attended by many of their members; these international meetings are conducted in both the US (February) and the EU (March - April) annually.
3.0 STANDING COMMITTEE ANNUAL REPORTS AND 2016 ACCOMPLISHMENTS

3.1 Accreditation Committee* (AHCTA)

*(managed by the Association for the Harmonization of Cellular Therapy Accreditation; AHCTA)

Committee Mission

The mission of the Accreditation Committee is to recommend to the Executive Committee policies, programs, and actions pertaining to regulatory matters, practices, and codes with both national and international implications. This involves procedures related to all activities of the other Standing Committees. In its vigilance to avoid duplication of efforts, WBMT members agreed early (2009) that AHCTA would fulfil the role of the WBMT Accreditation Committee.

Leadership

The Chair of this committee is:

- Kathy Loper (Member Society, AABB)

Meetings / Teleconferences

The Accreditation Committee generally meets by teleconference about once per month (the first Wednesday of the month) and in person once or twice per year, as international conference attendance permits. During 2016, this committee met in person on April 5 in Valencia and held six committee calls as well as several project team calls.

Completed Projects

During 2016, the Accreditation Committee completed the following projects:

- Updated resources on website, ahcta.org.
- Communicated via a new LinkedIn group for AHCTA (launched in late 2014).
- Updated crosswalk materials on AHCTA website comparing requirements from different standards setting organizations.
- Contributed to planning for the 2017 Workshop in Riyadh (Section 4.2.2.4).

Ongoing Projects

This committee continues to work on the following projects:

- Translate AHCTA resources into Spanish for the Latin American Blood and Marrow Transplantation Society (LABMT) website.
- Collaborate with and support LABMT by assisting with webinars and educational program development.

Future Plans

During 2017, the Accreditation Committee hopes to identify new projects that would serve the HSCT community and align with the mission of AHCTA and WBMT.

Publication

There were no publications generated by this committee during 2016.
3.2 Donor Issues Committee

Committee Mission

The mission of the Donor Issues Committee is to recommend to the Executive Committee policies, programs, and actions pertaining to the identification of stem cell donors (bone marrow, peripheral blood, and cord blood), harvesting procedures, product transportation, donor safety practices, and outcomes / long term follow-up within a member collection center; this includes the conduct of individuals and processes related to these procedures and practices.

Leadership

The Co-Chairs of this committee are:

- Joerg Halter (Member Society, EBMT)
- Vanderson Rocha (Member Society, WMDA)

Meetings / Teleconferences

This committee met in person on April 5 in Valencia. There were no scheduled teleconferences.

Completed Projects

During 2016, the Donor Issues Committee completed the following projects:

- Conducted the 4th Donor Outcome Workshop. Held September 22-23 in Tel Aviv, with Menachem Bitan serving as the local organizer, this workshop focused on the suitability of donors with infectious diseases or living in areas of endemic infectious diseases. This very productive group of eight participants included individuals from Latin America, North America, the Middle East, and Europe as well as collection centers, registries, transplant centers, and the European Centre for Disease Prevention and Control (ECDC).
- Contributed to planning for the 2017 Workshop in Riyadh (Section 4.2.2.4).

Ongoing Projects

This committee continues to work on the following projects:

- Develop donor suitability criteria for pediatric or elderly donors and donors with health disorders. The broad project aims to provide recommendations on donor suitability criteria for donors who would not qualify as healthy, volunteer, unrelated donors.
  - This initiative began during a Donor Outcome Workshop in Vienna in September 2013. Two papers on non-infectious health disorders and pediatric donors have already been published.
  - Work on recommendations related to infectious diseases started during the workshop in Tel Aviv in September 2016. The manuscript is being prepared for publication by the participants on this workshop in close collaboration with experienced colleagues working in regions with endemic diseases (e.g. Latin America and Asia), the WMDA, infectious disease specialists involved in the HSCT field, and ECDC.
• Initiate a global survey of the use of cord blood grafts. This project aims to understand the use of cord blood grafts and exchange of cord blood grafts among different countries, cord blood banks, and donor registries. It involves many WBMT Member Societies, such as Eurocord, EBMT, WMDA, and CIBMTR as well as the National Marrow Donor Program (NMDP) and others. The targeted date of completion is the end of 2017. The project incorporated two conference calls among NetCord, WMDA, and Eurocord Member Societies. Since 2016, NetCord and WMDA have discussed the fusion between the two organizations; therefore, this project was not a priority. Project leaders plan to reactivate this project this year and hope to finish it during 2017.

Future Plans

The Donor Issues Committee identified the following projects for initiation during 2017:

• Author recommendations for cord blood graft selection. Recently, the British Society of Blood and Marrow Transplantation under the leadership of this WBMT committee’s Chair, published the recommendations of cord blood grafts and their place among other alternative donors in the United Kingdom (UK). The Donor Issues Committee aims to use this paper as a backbone for its own global recommendations. This committee will circulate this paper among relevant WBMT Member Societies and other experts seeking opinions on how best to select and place cord blood grafts in comparison to other stem cell donors.

Publication

The following paper was e-published by Biology of Blood and Marrow Transplantation in 2015 and reported in the 2015 WBMT Progress Report. It was published in print in January 2016. See Appendix G for a complete list of WBMT publications.


3.3 Education and Dissemination Committee

Committee Mission

The mission of the Education and Dissemination Committee is to recommend to the Executive Committee policies, programs, actions and materials pertaining to the development or design of resources prepared for the express purpose of educating a populace about HSCT. This committee collaborates with all partners within the WBMT - but particularly the European School of Haematology (ESH) - and assists in “single voice” preparation of opinion or advisory materials for the WBMT and/or WHO. It plays an important role in Workshop program design.
Leadership

The Chair of this committee is:

- Eliane Gluckman (Member Society, European School of Hematology, ESH, and Eurocord)

Meetings / Teleconferences

The Education and Dissemination Committee did not meet in person during 2016 but steadfastly participates in various projects related to seminars and printed materials related to HSCT.

Completed Projects

During 2016, the Education and Dissemination Committee completed the following projects:


- Conducted an ESH-EBMT training course in Budapest in May 2016. More than 200 participants attended this meeting, which included an interactive course on HSCT with main lectures and clinical case discussions as well as breakfast and dinner meetings with the speakers and attendees.

- Participated in planning for the 2017 Workshop in Riyadh (Section 4.2.2.4).

Ongoing Projects

This committee continues to work on the following projects:

- Prepare an educational book on hemoglobinopathies.

- Organize an ESH conference on hemoglobinopathies.

Future Plans

The Education and Dissemination Committee identified the following projects for initiation during 2017:

- Develop new educational tools (e.g., e-learning program, webinar conferences).

- Develop online training programs.

- Participate in the creation of an International Continuing Medical Education (CME) accreditation plan.

- Establish contacts and identify obstacles for setting up new transplant centers in emerging and underdeveloped countries.

Publications

The following book was accepted for publication in 2016 and published in early January 2017.

3.4 Graft Processing and Cellular Therapy Committee

Committee Mission

The mission of the Graft Processing and Cellular Therapies Committee is to recommend to the Executive Committee policies, programs, and actions pertaining to the handling of a harvested product: storage, preparation and manipulation equipment, product transportation practices, and documentation within a member cell processing center; this includes the conduct of individuals and processes related to these procedures and practices. The committee also focuses on cellular therapy, which is increasingly important in haemato-oncology, transplantation, and regenerative medicine, as this pertains both to graft source and graft processing and manipulation.

Leadership

The Co-Chairs of this committee are:

- Mickey Koh (Member Society, International Society of Blood Transfusion, ISBT)
- Paul Eldridge (Member Society, Foundation for the Accreditation of Cellular Therapy, FACT)

Carolyn Taylor, who served as Co-Chair of this committee since its inception and the founding of WBMT, retired in 2016. The WBMT and, in particular, this committee are deeply appreciative of her hard work and dedication, which helped make this committee successful.

Meetings / Teleconferences

During 2016, the Graft Processing and Cellular Therapy Committee met in-person on April 4 in Valencia during the EBMT Annual Meeting. The Co-Chairs also held a teleconference on August 23 to not only introduce the committee to the new Co-Chair, Paul Eldridge, but also to outline the projects and plans for the committee.

Completed Projects

During 2016, the Graft Processing and Cellular Therapy Committee participated in the following projects:

- Organized and participated in the Joint International Session during the EBMT Annual Meeting in Valencia. This session focused on quality, accreditation, and access to transplantation worldwide. Mickey Koh served as a panelist during the discussion.
- Co-authored a manuscript on the WHO initiative, Medical Products of Human Origin (MPHO). The manuscript was ratified by WBMT, ISBT, International Council for Commonality in Blood Banking Automation (ICCBBA), and The Transplant Society (TTS). It was initially submitted for publication to The Lancet but was rejected. The manuscript is currently being revised by the principal author, Philip O’Connell (TTS), for re-submission.
- Reviewed and provided comments on the WHO MPHO document entitled “Principles for the Donation and Management of Medical Products of Human Origin.”
- Participated in planning for the 2017 Workshop in Riyadh (Section 4.2.2.4), including a roundtable discussion regarding graft processing and HLA.
Ongoing Projects

This committee continues to work on the following projects:

- Partner with the International Society of Cellular Therapy (ISCT) on the *ISCT Presidential Task Force on the Use of Unproven Cellular Therapies* project (Section 4.4.2.3). Phase 2 of this project commenced in November, and monthly teleconferences are expected. Mickey Koh was appointed one of three Vice Chairs in this project. He also participated in one of the teleconference calls for the WBMT Patient Advocacy and Advisory Committee as it was felt they could offer valuable contribution to this project.

- With Mickey Koh as the lead, support the Ethiopia project (Section 4.5.1), which aims to set up capabilities for HSCT in Addis Ababa. The WBMT team assists the local team in developing an HSCT program.

Future Plans

The Graft Processing and Cellular Therapy Committee identified the following projects to initiate during 2017:

- Create a map of Cell Processing laboratory facilities worldwide.

- Collate the practices and results of various centres who have dispensed with cryopreservation in autologous stem cell transplants. This relies on non-cryopreserved stem cells being stored in the fridge for a finite period of time. The Co-Chairs thought it would be important to analyze the data and clinical results from this practice, which is not typically recommended.

- Collaborate with the EBMT Cellular Therapies Working Party and other organizations to produce an activity survey of cellular therapies worldwide.

Publication

There were no publications independently generated by this committee during 2016; however, this group contributed substantially to the manuscript on MPHO.

3.5 Nuclear Accident Management Committee

This committee was first suggested in 2014, and organizing meetings and planning sessions took place in 2015. In Fall 2015, committee leaders presented during the WBMT session at the APBMT annual meeting. Highlights of this session focused on the number and types of radiologic response exercises being conducted worldwide; all emphasized the need to engage and educate the HSCT community of their potential involvement in a nuclear disaster and to continue these practice exercises.

Committee Mission

The mission of the Nuclear Accident Management Committee is to promote worldwide awareness of radiation disaster preparedness and the role of HSCT teams in the management of medical emergency and casualties. Committee objectives include the following:

- Establish coalitions within member countries to share information following radiological incidents.
• Increase preparedness in countries with WBMT members.
• Develop international consensus guidelines for triage and treatment of casualties that require haematopoietic support.

Leadership
The Co-Chairs of this committee are:
• Cullen Case (Radiation Injury Treatment Network, RITN)
• David Ma (Member Society, APBMT)
• Ray Powles (Member Society, EBMT)

Meetings / Teleconferences
During 2016, the Nuclear Accident Management Committee did not meet but communicated via email to further develop this committee.

Completed Projects
During 2016, this committee completed the following projects:
• Identified goals.
• Developed committee objectives.
• Created a committee charter.

Ongoing Projects
This committee continues to work on the following projects:
• Receive Board approval for the committee charter.
• Create long-term strategic goals for the committee.
• Form partnerships with the EBMT, AABB, Disasters Task Force, and other appropriate organizations.

Future Plans
The Nuclear Accident Management Committee identified the following projects to initiate during 2017:
• Gain recognition as a formal / affiliated member of the WHO’s Radiation Emergency Medical Preparedness and Assistance Network (REMPAN).

Publication
• There were no publications generated by this committee during 2016.

3.6 Patient Advocacy / Advisory Committee
Creation of this committee was first suggested in early 2015, and the first in-person session was held in December 2015. Fifteen people representing several regions and disease advocacy groups attended, and all offered strong support for this initiative. Because it is, indeed, also a global venture, in-person meetings are a challenge. WBMT tries to take advantage of the two major annual HSCT meetings (one held in the US, the other in the EU) to maximize the number
of interested parties who can attend in-person meetings. There is heavy use of teleconferencing as well.

A first goal for 2016 was to design a survey so the committee can glean exactly what exists already worldwide. However, during that first meeting, an important question was raised: “How do we define patient advocacy? Is it personal advocacy navigating one patient through the HSCT process, or is it the broader concept of social and governmental advocacy towards larger numbers of patients – or both”. This committee will focus on clarifying this fundamental question as well.

Committee Mission

The mission of the Patient Advocacy / Advisory Committee is to recommend to the Executive Committee policies, programs, and actions pertaining to the establishment and / or support of international patient advocacy groups and activities. This includes projects in collaboration with international disease or treatment specific organizations that are scientifically or practically related to stem cell transplantation (pre- and post-transplantation issues) particularly those with emphasis on patient, donor, family, and / or caregiver subject matter. There will be mentorship and harmonization in the development and / or distribution of (access to) patient / public educational materials.

Leadership

The committee leadership represent a unique model in which one of the Co-Chairs is a past-patient rather than a physician.

The Co-Chairs of this committee are:

- Menachem Bitan (Member Society, EBMT)
- Leonie Walsh (Australian Bone Marrow Donor Registry)

Core Group

The core group is a collection of very interested persons from a variety of world regions who lead the committee with the Co-Chairs. They participate in the teleconferences and in-person meetings mentioned below.

- Jessica Gillis-Smith (US)
- Kathy Goris (Belgium)
- Megan Hogg (Australia)
- Miki Imada (Japan)
- Yoshihisa Kodera (Japan)
- Elizabeth Murphy (US)
- Dietger Niederwieser (Germany)
- Helene Schoemans (Belgium)
- Susan Stewart (US)
- Jeffrey Szer (Australia)
- Guy Tavori (Israel)
- Anita Waldmann (Germany)
Meetings / Teleconferences

During 2016, this committee met in person on April 5 at the EBMT Annual Meeting in Valencia. The Core Group also held three teleconferences: June 7, September 6, and November 29.

Completed Projects

During 2016, the Patient Advocacy / Advisory Committee completed the following projects:

- Elected patient and physician Co-Chairs.
- Distributed an invitation letter to several patient groups in Europe and the Far-East.
- Invited regional WBMT Member Societies [LABMT, APBMT, Eastern Mediterranean Blood and Marrow Transplantation (EMBMT), and African Blood and Marrow Transplant group (AFBMT)] to support this committee and propagate the invitation letter in their region.

Ongoing Projects

This committee continues to work on the following projects:

- Develop a survey (based on a NMDP/Be The Match survey) of needs and expectations, to be distributed to patient groups.

Future Plans

The Patient Advocacy / Advisory Committee identified the following projects to initiate during 2017:

- Participate in patient activities during the BMT Tandem Meetings and EBMT Annual Meeting, such as the Patient’s Day at the EBMT Annual Meeting.
- Determine the role of this committee in World Marrow Day, which typically takes place in September.
- Continue to expand the committee’s global network of patient groups.
- In collaboration with the Transplant Center / Recipient Committee, launch a project to assess drug cost fluctuations worldwide and particularly evaluate price hikes of critical drugs needed for transplantation (Section 4.3).
- Increase the committee’s presence on the WBMT website (wbmt.org).
- Communicate via an in-person meeting at the EBMT Annual Meeting in Marseille and teleconferences every three months.

Publication

- There were no publications generated by this committee during 2016.

3.7 Transplant Center / Recipient Committee

Committee Mission

The mission of the Transplant Center / Recipient Committee is to recommend to the Executive Committee policies, programs, or actions pertaining to the performance of hematologic transplantation and other cellular therapies / procedures within a member transplant center; this includes recording recipient outcomes, maintenance of records, and the conduct of
individuals and processes carrying out these procedures and practices. As of 2015, this committee also administers activities related to the global transplant activity (GTA) reports and GTA data use proposal reviews / deliberations (Section 4.1).

Leadership
The Co-Chairs of this Standing Committee are:

- Jane Apperley (Member Society, JACIE)
- Marcelo Pasquini (Member Society, CIBMTR)

Meetings / Teleconferences
During 2016, this Standing Committee met in person on April 5 in Valencia and maintained regular communication throughout the year, particularly related to the “minimal requirements” project described in the Ongoing Projects below.

Completed Projects
During 2016, this Standing Committee completed the following projects:

- Participated in planning for the 2017 Workshop in Riyadh (Section 4.2.2.4).

Ongoing Projects
This Standing Committee continues to work on the following projects:

- Complete a document of “minimal requirements” for establishing an HSCT Program for publication as a manuscript in a peer-reviewed journal and as a chapter in a book.
- Prepare a trend document indicating recent changes in utilization of haploidentical transplants. This served as the basis for a Joint Session presentation at the BMT Tandem meetings in February 2016.
- Continue to lead the Research Data Activities Task Force, including overseeing review of incoming proposals for use of GTA data.

Future Plans
This Standing Committee has identified the following projects to initiate during 2017:

- In collaboration with the Patient Advocacy / Advisory Committee, launch a project to assess drug cost fluctuations worldwide and particularly evaluate price hikes of critical drugs needed for transplantation (Section 4.3).
- Develop an annual report from the GTA in the form of a slide set to be available to all member societies on the WBMT website.

Publication
- There were no publications generated by this committee during 2016.
4.0 WBMT ACTIVITIES AND 2016 ACCOMPLISHMENTS

The WBMT engages in a variety of activities including:

- Generating an annual global survey of HSCT activity (Section 4.1);
- Conducting scientific and educational conferences (Section 4.2);
- Developing consensus guidelines for optimum delivery of HSCT services and accreditation of HSCT facilities (Section 4.3);
- Collaborating and consulting with the WHO to promote excellence in HSCT, stem cell donation, and cellular therapy (Section 4.4);
- Supporting other global HSCT activities (Section 4.5);
- Developing a Website for broad communication (Section 4.6);
- Establishing research guidelines within this global HSCT community (Section 4.7).

4.1 Annual Global Survey

WBMT leaders agreed in early formative years that a first initiative should be to conduct annual global surveys of HSCT activity performed by transplant centers (Appendices C1 and C2); a minimal yet essential level of activity information is requested of participating centers. The annual survey displays volume of, and main indications for, allogeneic (related, unrelated, and graft source information) and autologous HSCT activity. The disease indications for HSCT include main- and sub-class categories. These data were previously unknown, and centers were not represented on a map. The WBMT needed these baseline data to support future projects and to assist countries in increasing their activity levels and/or in the development of new transplant programs. Reporting these global data has become an obligation to the WHO (Section 4.4.1).

The WBMT survey reporting sheet is available on the WBMT website (wbmt.org/en/wbmt-survey); it is accompanied by the disease indications classification codes to assist in completing the survey.

The WBMT continues to promote the annual survey by publishing findings biannually and presenting results periodically at international meetings (Appendix F); data are presented internationally at least once annually. The WBMT encourages other, newer groups (e.g., LABMT and AFBMT) to form their own registries to participate in the survey, and a WBMT representative presents at each Workshop and Symposium (Section 4.2.2), describing the activity data, including the collection process, and encouraging all teams to report their activity data. These data are also provided to the Global Observatory for Donation and Transplantation (Section 4.4.2.4).

A tool, Transplant Activity Survey (TAS), was designed several years ago for the WBMT Activity Survey. This tool allows the reporting of transplant activity via the web using a simple, user-friendly input form that is similar to the reports (easy, single page record) already being provided to WBMT via a regional transplant society, national registry, or individuals at the team/center level. Mathematical calculations are performed automatically, avoiding human error. Activity data can still be entered at either the country or center level.
These data do not represent an outcome registry, but the TAS is a mechanism by which each country’s annual data can be registered with the WBMT and put to further use within the reporting organization.

These activity data can be used at the team level for those countries / societies that do not have an existing data collection system (e.g. LABMT, AFBMT). If an outcome registry were to be developed, it could potentially use the TAS to identify the activity in those countries that are outside other data collection systems (e.g., CIBMTR, EBMT, etc.), providing a mechanism for follow-up.

During 2014-2015, a Research Data Task Force developed guidelines for research using these data (Appendix D1). A process was identified by which Member Societies can request use of these data for research purposes. Member Societies signed Data Transmission Agreements (Appendix D2) with the WBMT in 2016. Proposals for the use of these data are reviewed and deliberated by the WBMT Transplant Center / Recipient Committee (Section 3.7).

4.2 Scientific and Educational Conferences

4.2.1 Joint Scientific / International Symposia

Scientific conferences are an important activity of the WBMT for communicating with other clinicians and researchers. WBMT conducts an annual 90 minute Scientific / International Symposium at one or two major HSCT conferences. The Symposium is first presented during the US-based BMT Tandem Meetings [sponsored by the CIBMTR and American Society for Blood and Marrow Transplantation (ASBMT)] each February. Then the WBMT works with EBMT to have presence on the scientific program at the annual EBMT meeting in March – April. These meetings represent the premier gatherings in the US and in Europe for clinicians and researchers interested in HSCT. The focus at during the WBMT presentations is always on something of global interest, and often with different expert speakers due to logistical considerations. Appendix F lists annual Symposia programs since WBMT began coordinating them in 2009.

Planning for both of the 2017 sessions occurred during 2016.

4.2.2 WBMT Workshops and Scientific Symposia

The WBMT sponsors Workshops and Scientific Symposia in regions with constrained resources, a demonstrated need and interest, and clinicians who wish to expand existing transplant programs or to start a new program. These activities are aimed at regions where resources and unique factors present challenges to clinicians wanting to provide improved access to their peoples in need of this treatment modality. The WBMT leverages the skills and expertise of its Education and Dissemination Committee and the ESH along with all other Standing Committees in planning these programs. Since 2011, the WBMT conducted three Workshops and Symposia: in Hanoi, Vietnam, in 2011 (Section 4.2.2.1); Salvador, Brazil, in 2013 (Section 4.2.2.2); and Cape Town, South Africa, in 2014 (Section 4.2.2.3). In 2016, the WBMT assisted the EMBMT in completing plans for the fourth Workshop and Symposium in Riyadh, Saudi Arabia, in January 2017.
4.2.2.1 2011 Hanoi, Vietnam

In late 2011, the WBMT conducted its first two-day Workshop and associated one-day Scientific Symposium in Hanoi, Vietnam, in cooperation with the WHO and in partnership with the APBMT and a local Vietnamese Organizing Committee.

One important result of the Hanoi Workshop was the suggestion that WBMT conduct training programs for physicians who lead transplant programs abroad. Since then, several teaching fellowships materialized during 2013 and increased in number through 2015. Trainees included practitioners from Vietnam (Hanoi and Ho-Chi-Minh City), Mongolia, Qatar, the Philippines, and Cambodia cross-training in Japan, Korea, Belgium, and Germany. Another important aspect of this Workshop was networking. For instance, representatives from Myanmar, Indonesia, and Bangladesh established an HSCT program under the guidance of WBMT members who participated in the 2011 Workshop.

4.2.2.2 2013 Salvador, Brazil

With a commitment by the WBMT Board to support the LABMT, a new WBMT Member Society in 2013, and strong interest from a local organizing committee, the WBMT hosted a second two-day Workshop and one-day Scientific Symposium in late 2013 in Salvador da Bahia, Brazil. Participants indicated this was a successful and valuable collaborative venture, but the most visible measurement of success is the high level of regional organization and productivity since the Workshop, as demonstrated by the active output of the LABMT.

The LABMT now holds regular monthly and annual meetings and continues to actively develop standing committees modelled after WBMT committees. Within two years of the Workshop, LABMT investigators published in peer-reviewed journals and presented oral abstracts at the prestigious American Society of Hematology (ASH) meetings. These achievements are even more impressive since the LABMT members admitted during the 2013 Workshop that they had never met previously as an integrated group.

4.2.2.3 2014 Cape Town, South Africa

The WBMT held its 3rd Workshop and Scientific Symposium November 14-16, 2014, in Cape Town, South Africa, in collaboration with the WHO and a local, South African planning committee. With the largest audience yet, attendees represented 34 countries, 20 of which were African. More than 200 individuals registered for the Workshop, and, for the first time, participants completed evaluations. About 45% of attendees completed the evaluations, providing primarily positive responses and sound suggestions for improvements to future Workshop programs.

The WBMT customized the scientific program to address blood transfusion safety, a special problem on the continent, and logistically included far more open dialog time than in previous Workshop programs. Since the WBMT placed a strong emphasis on the value of activity reporting and formation of local databases, an increase in reporting to the WBMT from the African continent may be a measurable outcome of this 3rd Workshop.

As was true for both previous Workshops, a broad spectrum of expert planners and presenters were from Europe, the Far East, Mediterranean region, and the US, augmenting a cadre of
regional speakers. Programs for all three Workshops are available on the WBMT website (wbmt.org).

Similar to the LABMT and the Workshop in Salvador, Brazil, the WBMT encourages and strongly supports a more formal structure and activity level of the AFBMT. This group met for a first time in Lagos, Nigeria, in 2011. The WBMT received and approved a formal application for status as a WBMT Member Society in February 2015, and the AFBMT hosted a business meeting in Istanbul in March 2015 during which officers were elected. Bylaws development is still in progress.

4.2.2.4 2017 Riyadh, Saudi Arabia

The fourth Workshop and Symposium, this one co-organized with the EMBMT, was delayed from November 2016 to January 2017. Although Dubai was first designated as the Workshop site, it was moved to Riyadh, Saudi Arabia, for logistical reasons. Planning activities by both the WBMT and the EMBMT spanned the entire 2016 calendar with WBMT Officers and Standing Committee Co-Chairs participating on the Riyadh-based Planning Organization. The program format followed those established previously, with a two-day Workshop followed by a one-day Scientific Symposium. A substantial change this year, however, permitted extended program time dedicated to longer, open discussion periods, as suggested on prior Program evaluation forms. By the end of 2016, almost 800 participants registered for this Workshop; this is substantially more than previous Workshops.

4.2.2.5 Future Workshops and Symposia

Also during 2016, the WBMT Executive Committee reviewed and revised existing criteria and application forms for future Workshops. To date, two regions have indicated early interest in future Workshops though no formal applications have been received for a possible late 2018 or early 2019 program. The WBMT idea for future Workshops is to focus more on smaller regions, as opposed to entire continents; however, the aim is still to assist in the creation of new programs and supporting expansion and/or improvement of existing programs.

4.2.3 Donor Outcome Workshops

In 2016, the WBMT Donor Issues Committee (Section 3.2) sponsored its fourth successful Donor Outcome Workshop. Previous workshops took place in 2009, 2011, and 2013. The committee held the workshop September 22-23 in Tel Aviv, Israel. Menachem Bitan, Co-Chair of the WBMT Patient Advocacy / Advisory Committee served as the local organizer. The workshop focused on the suitability of donors with infectious diseases or living in areas of endemic infectious diseases. The very productive group of eight participants included individuals from Latin America, North America, the Middle East, and Europe as well as collection centers, registries, transplant centers, and the ECDC. Workshop participants continue to prepare for publication recommendations related to infectious diseases and HSCT.

4.3 Consensus and Guideline Initiatives

The primary purpose of the WBMT is to serve as a single voice – at a global level – for HSCT and related issues. With the support of its Board, the WBMT publicizes its sentiments on controversial or critical matters on its website and/or collaborates with other likeminded
groups in opinion solidarity. Previously this included WBMT positions on support of standardized product labelling and rejection of financial reimbursement for donation of cellular products; details are provided in previous Progress Reports, and formal statements are available on the WBMT website (wbmt.org). The position regarding reimbursement for donors, published in February 2012, is also available on the Be The Match News Releases webpage (bethematch.org/news/news-releases/).

More recently, current and previous Standing Committees authored substantial works, either independently or collaboratively, on standardization of practice topics (e.g., minimal requirements, training best practices, etc.) associated with respective committee mandates (Section 3.0 and Appendix G). An ongoing example is the Transplant Center / Recipient Committee; throughout 2016, this committee created a table of minimal requirements for establishing a new HSCT program. All elements were rated then reviewed by committee volunteers; both a manuscript for submission to a peer-reviewed journal and a book chapter are in progress. This fundamental information was used, in part, by a WBMT group who visited Ethiopia in December 2015 to assess their existing situation and to document what they require to move forward with their five-year HSCT program plan. A final report was created in spring 2016 and provides the basis for the ongoing work in Ethiopia.

In late 2016, members of the WBMT Executive and Patient Advisory / Advocacy Committees identified the issue of dramatic cost escalations and shortages of some critical medications affecting a variety of countries across the globe. Recent medications of concern include melphalan and BCNU. With its structure, the WBMT can provide a global approach to advocating for this issue and offer advice regarding the best alternatives when key drugs are unavailable. In 2017, the WBMT intends to launch a project to assess cost fluctuations worldwide and particularly evaluate price hikes of critical drugs needed for transplantation. This project will incorporate a survey of transplant centers regarding the availability and costs of drugs and the establishment of a task force. The task force will review and summarize the findings and develop a set of recommendations to the WHO.

4.4 Collaboration with the WHO

As noted previously, a WHO representative has been involved with WBMT activities since the earliest concept development meetings. The WBMT maintained a “working relationship” with the WHO for almost four years before being officially invited to apply for NGO in official relations status with the WHO. The WHO approved the WBMT’s initial application as of January 2013 and an application for continued status as of January 2016. This status provides the WBMT with the opportunity to continue its work on a more formal basis in partnership with the WHO in promoting global excellence in HSCT, stem cell donation, and cellular therapy. This partnership brings with it additional responsibilities, including participation in other WHO initiatives, in pursuit of mutual educational, scientific, and philanthropic missions. Because of the importance of this collaboration, the WBMT created in 2016 a Board position specifically designated to represent the WBMT to the WHO.
4.4.1 Platform for WBMT Collaborative Projects

The 2012 NGO status application process distinguished those collaborative projects already in progress (or completed) at that time from those projected for the subsequent three-year period (should WBMT be approved as an NGO partner). With the awards of official NGO partnership status in 2013 and continued status in 2016, the WBMT is now obligated to continue its work on specific identified projects.

Those activities in progress or already completed in 2012 were:

- Collect and share data (Section 4.1 and 4.4.2).
- Conduct Workshops (Sections 4.2.2 and 4.2.3).
- Provide technical and scientific support (Sections 4.1-4.4 and 4.5.1).
- Foster and shepherd development of regional HSCT societies (Section 4.5.2).

Those activities to which the WBMT committed in its NGO applications and which form the foundation for its continued work are:

- Work with the Global Observatory on Donation and Transplantation (Section 4.4.2).
- Promote access to HSCT – stem cell donation (Section 4.2).
- Develop a donation guidance document (Section 4.3).
- Promote access to HSCT – stem cell transplantation (Sections 4.2.4-5).
- Provide technical and scientific input on safety and quality of HSCT (Sections 4.2.4-4).
- Provide global consultation on ethics, safety, and access to HSCT (Sections 4.2.4-4).
- Contribute to the initiative for global vigilance and surveillance of adverse reactions and events (Section 4.4.2).
- Provide consultation services (Section 4.0).

Groups from three categories collaborate with the WHO: those in collaboration as a WHO department, those in collaboration as a governmental organization, and those in collaboration as an NGO. The WBMT fits into the latter category. There are several projects in which the WBMT is engaged in partnership with the WHO. They are as follows:

4.4.2 Collaborative Projects

4.4.2.1 NOTIFY Project

WBMT members participate in the NOTIFY Project since a first meeting in Bologna in 2011. The NOTIFY Project, a vigilance initiative, was launched as a joint venture by WHO and the Italian National Transplant Center. Also in collaboration with the European SOHO V&S project (Vigilance and Surveillance of Substances of Human Origin), this major global initiative was organized to provide a global interface for the vigilance and surveillance of substances of human origin (organs, tissues, and cells for transplantation and assisted reproduction). A sub-project of the broader NOTIFY Project is referred to as BIG V&S (Bologna Initiative for Global Vigilance and Surveillance), coordinated by the WHO and the Italian National Transplant Center. Adverse reactions associated with MPHO can be reported to this group.

An important accomplishment of the NOTIFY group of experts was the development of the NOTIFY Library, a large database launched in 2013, which provides global access to reports of
adverse outcomes. WBMT was in a unique position to make important recommendations to this group, including changes in cell type taxonomy data items and keywords specifically related to cellular therapies. WBMT representatives also recommended improving website navigation processes and the formation of an editorial board including more specialists in hematopoietic progenitor cell therapies. Experts in this “Blood Working Group” will eventually join existing editorial working groups, and, as the work develops, an Editorial Group will be established for Transfusion Reactions.

4.4.2.2 Medical Products of Human Origin

WBMT is one of four WHO NGOs assigned to the MPHO project. A draft paper produced by these four NGOs is completed and awaiting publication. The WHO circulated another draft paper, entitled “Principles of donation and management of MPHOs”, to the WBMT for comments. This paper focuses on donor concerns, including development of an overarching set of guiding principles to ensure ethical and safe practice in the management of donors of MPHO and derived products. The principles will cover the different aspects of donation and MPHO management to the point of product allocation and should include, inter alia, safety, ethics, transparency, traceability, and informed consent. It is anticipated these principles will be a central plank for future regulation of MPHO.

4.4.2.3 Unproven Cellular Therapies

Another initiative in which WBMT members have been involved is that of cellular therapy tourism, now entitled “Unproven Cellular Therapies”. The ISCT initiated this project, which is now in the second phase under the ISCT Presidential Task Force on Unproven Cellular Therapies. WBMT is a key partner in this task force with Mickey Koh serving as one of the Vice Presidents. The aim of the task force is to educate both the public and the medical community regarding the appropriate use of cellular therapy and the importance of engaging in clinical trials as most of these novel cellular therapies are still investigational products.

4.4.2.4 Global Observatory on Donation and Transplantation

Data on international use of HSCT procedures are gathered inconsistently across the globe but usually by registries and professional societies. The Department of Essential Health Technologies of the WHO and the Spanish National Transplant Organization (Organización Nacional de Transplantes) established the Global Observatory on Donation and Transplantation (transplant-observatory.org) in 2007. These collaborative activities help to meet the requirements of the 2004 57th World Health Assembly Resolution WHA57.18. This resolution suggests the collection of global data on the practices, safety, quality, efficacy, and epidemiology of transplantations as well as their global availability for all those concerned, including professionals, patients, politicians, and the general public, are recognized as a prerequisite for global improvement of, and better access to, transplantations (Organs, Tissues and Cells, (2), 91-94, 2007). One goal of the Observatory is the development of a global database on donation and transplantation. WBMT Member Societies, particularly the WMDA, contributed substantially by providing unrelated donor information from their own databases to this Observatory databank.
The WBMT provided its first HSCT activity contribution to the Global Observatory in 2012 with Global Survey data from 2006-2008 and now updates these data as they become available. The 2013 data were provided by the WBMT in the first half of 2016 and updated and refreshed in late 2016.

4.5 Supporting Other HSCT Global Activities

4.5.1 Ethiopia – A New HSCT Center

The WBMT not only supports existing HSCT programs seeking improvement but also assists in establishing new HSCT programs of high quality. In November 2014, representatives from Ethiopia (a Minister of Health office representative, individuals representing blood banks, hemato-logists, and others) met with WBMT leaders and requested support and technical assistance in establishing an HSCT program in their country. These preliminary discussions led the WBMT to create a task force of interested parties to assess and assist in this venture. A Co-Chair of the WBMT Graft Processing and Cellular Therapies Committee, Mickey Koh, was identified as the WBMT Project Leader and he maintained frequent communication with the Ethiopian team throughout 2015. Planning became more focused in the second half of 2015, and a comprehensive onsite visit by four WBMT HSCT clinicians (some with substantial blood transfusion expertise) followed in December 2015. In the first part of 2016, the team prepared a full report, which was approved by the WBMT Executive Committee and distributed to the Ethiopian clinician team as well as the Dean of the adjacent medical school and the Minister of Health. Throughout the year, Mickey Koh conducted regular discussions via email with the Ethiopian team, and this project will continue in 2017. Though challenges exist, the WBMT is impressed with the eagerness and engagement of local planners who are strongly supported by their current government.

4.5.2 Regional HSCT Societies

As previously mentioned (Section 4.2.2.2), the WBMT has been instrumental in supporting the development of the now highly successful LABMT. The LABMT first met as an integrated group in 2013; now it has a Board and bylaws, and it holds regular monthly and annual meetings. The WBMT continues to support this organization, and the LABMT continues to actively develop, including creating standing committees modelled after WBMT committees.

Similarly, the WBMT was very supportive of establishing the AFBMT (Section 4.2.2.3). A small, interim Executive Committee existed early in the building process; elected officers are now in place. The WBMT approved the AFBMT’s formal application for Member Society status in February 2015 and continues to place high focus and expectations on this organization; it represents the single remaining continent that has not uniformly reported transplant activity or outcome data. In September 2017, the AFBMT plans to conduct an in-person meeting in Morocco.

Both groups are encouraged to commit to participate in the WBMT annual global survey of HSCT activity (Section 4.1). A positive outcome of the Workshop in Latin America is the numerous new transplant centers providing activity data to this survey. The same result is anticipated since the Workshop in Africa as several participants indicated on evaluations a
willingness to begin reporting HSCT activity data. This is an important step forward in addressing the current gap in acquisition of data from these regions.

In 2016, the WBMT engaged heavily with the EMBMT in planning the Workshop and Symposium in Riyadh, Saudi Arabia, in January 2017 (Section 4.2.2.4). The EMBMT was incredibly proactive and organized. They took the lead on designing the scientific program and procuring sufficient funding; they also handled almost all of the logistics, including making arrangements for ancillary activities. The WBMT looks forward to continued collaboration with this engaged and highly motivated organization.

4.6 Website Development

The WBMT website, launched in 2010, is hosted and serviced in Bern, Switzerland, by the Swiss Blood Stem Cells group. Identifying itself via the internet was an important first step in the evolution of WBMT branding. Substantial effort is continually placed on posting current documents, such as meeting minutes, information regarding Workshops and Symposia programs, and important newsworthy items (e.g., one millionth transplant announcement in early 2013, consensus statements, etc.)

During 2016, the WBMT website was particularly important in disseminating notices, programs, and registration processes for the 2017 Saudi Arabian Workshop and Scientific Symposium.

4.7 Research Data Task Force

The WBMT Board mandated development of a Task Force in 2013 for the purpose of developing guidelines for management and use of the WBMT GTA data as well as guidelines for how general research should be managed in collaboration amongst WBMT Member Societies. These documents (Appendices D1 and D2) were approved in 2015, and all Member Societies signed data transmission agreements in early 2016. As of 2015, the Transplant Center / Recipient Committee (Section 3.7) administers all activities related to the GTA survey, including providing reports and reviewing proposals for use of these data.
5.0 FUTURE AIMS

The WBMT continues to evolve, and though it has identified many activities with which it wants or needs to be involved, limited resources and availability of this volunteer group of leaders and committee members affect the selection of projects for its portfolio. In addition to the plans identified in Section 3.0 by each of the Standing Committees, the Executive Committee is assessing priority activities for 2017 and beyond. They are to:

- Establish a more durable mechanism for soliciting and sustaining high level financial support.
- Continue the close collaboration with the WHO on global projects relevant to HSCT and fulfilling WBMT responsibilities as an NGO in official relations with the WHO, including the ongoing WHO-sponsored project, the ISCT Presidential Task Force on Unproven Cellular Therapies (Section 4.4.2.3).
- Continue to offer Workshops and Scientific Symposia in regions with constrained resources (Section 4.2.2).
- Launch a project to assess cost fluctuations worldwide and particularly evaluate price hikes of critical drugs needed for transplantation (Section 4.3).
  - Survey transplant centers regarding the availability and costs of drugs.
  - Establish a task force to review and summarize the findings and develop a set of recommendations to the WHO.
- Continue efforts in support of AFBMT (Section 4.5.2).
- Continue support of transplant center twinning and/or other cross-training activities;
- Continue the mission of the Research Data Task Force for identification of proper procedures for research coordinated by the WBMT (Section 4.7).
- Further organize and operationalize the WBMT Nuclear Accident Management Standing Committee (Section 3.5) in collaboration with existing nuclear accident committees to extend the concept of “speaking with one voice”.
- Further develop the WBMT Patient Advocacy / Advisory Committee (Section 3.6) to mentor patient groups and harmonize patient educational materials across the globe.
6.0 PUBLICATIONS AND ABSTRACTS HISTORY

Some works are published on behalf of the WBMT whereas others are credited to a WBMT Standing Committee. Appendix G displays the complete WBMT publication portfolio while identifying which entity is credited.

There were no abstracts generated or submitted by the WBMT during 2016; see previous annual Progress Reports for those submitted and accepted in prior years.

For more information about items included in this report or for general queries, please contact any WBMT Officer (Appendix B).
## APPENDIX A: MEMBER SOCIETIES

<table>
<thead>
<tr>
<th>Member Society</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>AABB</td>
<td>AABB, formerly known as the American Association of Blood Banks, is an international non-profit association committed to advancing the practice and standards of transfusion medicine and cellular therapies to optimize patient and donor care and safety.</td>
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<tr>
<td><a href="http://aabb.org">aabb.org</a></td>
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<tr>
<td>African Blood and Marrow Transplantation Group (AFBMT)</td>
<td>AFBMT represents transplantation programs and activity on the entire African continent; it is new since December 2014 and now organized with officers and bylaws. It currently reports activity data to the WBMT however long term goals include transplant outcomes reporting.</td>
</tr>
<tr>
<td>American Society for Apheresis (ASFA)</td>
<td>American Society for Apheresis (ASFA)</td>
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<tr>
<td>American Society of Blood and Marrow Transplantation (ASBMT)</td>
<td>American Society of Blood and Marrow Transplantation (ASBMT)</td>
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<tr>
<td>American Society for Histocompatibility and Immunogenetics (ASHI)</td>
<td>ASHI is a non-profit association of clinical and research professionals that is dedicated to advancing the science and application of histocompatibility and immunogenetics as well as advocating the highest standards of laboratory testing in the interest of optimal patient care.</td>
</tr>
<tr>
<td><a href="http://ashi-hla.org">ashi-hla.org</a></td>
<td></td>
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<tr>
<td>Asia Pacific Blood and Marrow Transplantation (APBMT)</td>
<td>A Founding Member: APBMT is an international organization of HSCT researchers that allows physicians in Asian countries involved in HSCT to share their experience and develop cooperative studies.</td>
</tr>
<tr>
<td><a href="http://apbmt.org">apbmt.org</a></td>
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<tr>
<td>Australasian Bone Marrow Transplant Recipient Registry (ABMTRR)</td>
<td>ABMTRR promotes HSCT research and helps provide access to and information about HSCT to people in Australia and New Zealand.</td>
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<tr>
<td><a href="http://abmtrr.org">abmtrr.org</a></td>
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<td>Member Society</td>
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<tr>
<td>Bone Marrow Donors Worldwide (BMDW) bmdw.org</td>
<td>BMDW is a voluntary collaborative effort of stem cell donor registries and cord blood banks whose goal is to provide centralized information on the HLA phenotypes and other relevant data of unrelated stem cell donors and cord blood units and to make this information easily accessible. As of January 1, 2017, all of the activities of BMDW are provided through WMDA.</td>
</tr>
<tr>
<td>Center for International Blood and Marrow Transplant Research (CIBMTR) cibmtr.org</td>
<td>A <em>Founding Member</em>: The CIBMTR collaborates with the global scientific community to advance hematopoietic cell transplantation and cellular therapy research worldwide. A combined research program of the National Marrow Donor Program® and the Medical College of Wisconsin, the CIBMTR facilitates transplant outcome research that has led to more than 800 peer-reviewed publications. These publications have contributed to increased survival and an enriched quality of life for many transplant patients.</td>
</tr>
<tr>
<td>Eastern Mediterranean Blood and Marrow Transplantation (EMBMT) embmt.org</td>
<td>EMBMT promotes all aspects of patient care, academic, and research activities associated with HSCT in eastern Mediterranean countries with the goal of sharing experience, initiating cooperative trials, and establishing common strategies to advance the field of HSCT.</td>
</tr>
<tr>
<td>Eurocord eurocord-ed.org</td>
<td>Eurocord promotes national and international collaborations and disseminates HSCT knowledge. The Eurocord registry operates on behalf of the EBMT, and Eurocord works in close collaboration with NetCord cord blood banks and EBMT centers and database.</td>
</tr>
<tr>
<td>European Federation for Immunogenetics (EFI) efiweb.eu</td>
<td>EFI aims to promote research in immunogenetics, histocompatibility testing, and HSCT. It promotes the advancement of immunogenetics in Europe and supports research and training in the field.</td>
</tr>
<tr>
<td>European Group for Blood and Marrow Transplantation (EBMT) ebmt.org</td>
<td>A <em>Founding Member</em>: EBMT aims to improve outcomes of HSCT and provide information to the public about developments in the field by sharing the experience of European centers and encouraging cooperative research among scientists and physicians in the HSCT field.</td>
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<tr>
<td>Member Society</td>
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<tr>
<td>European Leukemia Network (ELN)</td>
<td>The European Leukemia Network is a research network of 194 participating centers in 39 countries all cooperating in the Network. The goal is a cure of leukemia by integration of European leukemia research. The website delivers information (in various European languages) for physicians, patients (e.g. patient organizations in Europe), ongoing clinical trials and further information about leukemia.</td>
</tr>
<tr>
<td>European Marrow Donor Information System (EMDIS)</td>
<td>The EMDIS system integrates the databases of European blood and marrow donor registries allowing data exchange from and to heterogeneous systems and nation-wide area networks.</td>
</tr>
<tr>
<td>European School of Hematology (ESH)</td>
<td>ESH is a non-profit institution for continuing education that promotes and facilitates access to research in hematology and related disciplines in Europe, North America, North Africa, and the Middle East. ESH also develops tools for continuing education produced in collaboration with international experts in the field.</td>
</tr>
<tr>
<td>Foundation for the Accreditation of Cellular Therapy (FACT)</td>
<td>FACT is a non-profit organization that establishes standards for high-quality medical and laboratory practices in cellular therapies for the purposes of voluntary inspection.</td>
</tr>
<tr>
<td>International Council for Commonality in Blood Banking Automation (ICCBBA)</td>
<td>ICCBBA is a not-for-profit, tax exempt, NGO responsible for management of the ISBT 128 Information Standard for Blood and Transplantation, a global standard for the terminology, identification, labeling, and information transfer of human blood, cell, tissue, and organ products across international borders and disparate health care systems. It ensures the highest levels of accuracy, safety, and efficiency for the benefit of donors, patients, and ISBT 128 licensed facilities worldwide. The system features a unique, highly flexible, and comprehensive coding method for every collected product and provides international consistency to support the transfer, transfusion, or transplantation of blood, cells, tissues and organs.</td>
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<tr>
<td>Member Society</td>
<td>Description</td>
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</tr>
<tr>
<td><strong>International Society of Blood Transfusion (ISBT)</strong></td>
<td>ISBT is an international professional society that facilitates knowledge about transfusion and transplantation science and medicine.</td>
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<tr>
<td>isbtweb.org</td>
<td></td>
</tr>
<tr>
<td><strong>International Society of Cellular Therapy (ISCT)</strong></td>
<td>ISCT is a global association that promotes cellular therapies research by fostering international translational research, driving commercialization strategies, and providing education.</td>
</tr>
<tr>
<td>celltherapysociety.org</td>
<td></td>
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<tr>
<td><strong>Joint Accreditation Committee – ISCT (Europe) &amp; EBMT (JACIE)</strong></td>
<td>JACIE is a non-profit organization that assesses and provides accreditation in the field of HSCT. Its primary aim is to promote high-quality patient care and laboratory performance in hematopoietic stem cell collection, processing and transplantation through an internationally recognized system of accreditation. It partners with EBMT, ISCT, and FACT.</td>
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<tr>
<td>jacie.org</td>
<td></td>
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<tr>
<td><strong>Latin American Bone Marrow Transplantation group (LABMT)</strong></td>
<td>The purpose of this group is to provide a mechanism through which Latin American Blood and Marrow Transplant and Hematology groups can collaborate and engage in scientific and educational activities and endeavours to promote excellence in stem cell transplantation, stem cell donation, cellular therapy and hematologic practices. Activities include data collection and sharing outcome information.</td>
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<tr>
<td>wbmt.org</td>
<td></td>
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<tr>
<td><strong>NetCord</strong></td>
<td>The International NetCord Foundation is a non-profit association of umbilical cord blood banks whose members comprise the largest source of high-quality cord blood grafts for patients in need of HSCT. As of January 1, 2017, the all of the activities of NetCord are provided by WMDA.</td>
</tr>
<tr>
<td>netcord.org</td>
<td></td>
</tr>
<tr>
<td><strong>World Marrow Donor Association (WMDA)</strong></td>
<td><em>A Founding Member:</em> WMDA is a global association whose mission is to assure that high-quality stem cell products are available for all patients in need, while maintaining the health and safety of the volunteer donors.</td>
</tr>
<tr>
<td>worldmarrow.org</td>
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</tbody>
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APPENDIX B: EXECUTIVE COMMITTEE ELECTED OFFICERS

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APPENDIX C1: CENTER SITES THAT CONTRIBUTE DATA TO THE ACTIVITY SURVEY

WBMT: maximum number of reporting teams per country: 1,635
APPENDIX C2: COUNTRIES THAT HAVE CONTRIBUTED DATA

<table>
<thead>
<tr>
<th>WHO Region</th>
<th>Country</th>
<th>Number of Teams</th>
<th>*Maximum number of teams in any one survey year</th>
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<tr>
<td></td>
<td><strong>82</strong> (increased from 79 last year)</td>
<td><strong>1,643</strong> (increased from 1,610 last year)</td>
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APPENDIX D1: WBMT RESEARCH GUIDELINES

WBMT RESEARCH GUIDELINES

This document is developed by the Worldwide Network for Blood and Marrow Transplantation (WBMT) and outlines the guiding principles of research performed directly by this entity through the global survey data or indirectly by fostering collaboration among member societies with the intent of dissemination of information for advancement of the hematopoietic cell transplantation field.

BACKGROUND:
The idea of creating guidelines for research endeavors generated by WBMT Member Societies laterally, or on behalf of the parent organization (WBMT), was first presented during the 2013 annual, in-person Board meeting in Salt Lake City, USA. The Board agreed that guiding principles for the conduct of research by or within the WBMT was an important topic to be explored and formed a Research Activity Task Force to 1) develop a guidelines document on developing, conducting, and disseminating results of studies involving data and/or investigators from multiple Member Societies and 2) promote collaboration among the WBMT Member Societies / registries through the establishment of a framework for the conduct of research.

During the deliberations of the Research Activity Task Force, it was decided to cover this topic of research in two different fronts, first to develop the guiding principles of collection, presentation, dissemination, and sharing of the Global Activity Survey data, herein defined as Global Transplant Activity data. Second, the Research Activity Task force would develop guiding principles to provide general guidelines for the conduct of international collaborative research, with the intent to serve as reference for research procedures and for fostering collaboration among member societies.

SECTION 1: OVERARCHING WBMT GUIDING PRINCIPLES OF RESEARCH

Overarching Guiding Principle #1

The Worldwide Network for Blood and Marrow Transplantation (WBMT) has the responsibility to collect, store, and disseminate information related to global hematopoietic cell transplantation activity. This is done through the annual global activity survey. WBMT will be responsible for safe keeping of this data and oversight of its utilization.

Overarching Guiding Principle #2

The WBMT shall not duplicate or compete with research actively being conducted by its Member Societies and/or registries. Each WBMT Member Society conducts research in its unique manner, independent from the WBMT.
**Overarching Guiding Principle #3**

The WBMT will foster collaboration through its member societies for the development of collaborative research to address global questions in transplantation, encourage the analysis of regional differences, and offer a global perspective on transplantation. Furthermore, this collaborative research shall fulfill the WBMT mission, including increase global awareness of the importance of transplantation, improve access to transplant, optimize safety for patients and donors, and improve the quality of all activities associated with hematopoietic cell transplantation.

**SECTION 2: GLOBAL TRANSPLANT ACTIVITY (GTA)**

**Global Transplant Activity Guiding Principle #1**

The WBMT is required to survey transplant activity globally in an annual basis to maintain its Non-Government Organization (NGO) status with the World Health Organization (WHO).

**Commentary on GTA Guiding Principle #1**

Since the January 2013 award of NGO status by the WHO, there are important and continuing obligations for the WBMT. One such criterion is referred to as "Global Database on Donation and Transplantation". The WHO, along with the Spanish National Transplant Organization established the Global Observatory on Donation and Transplantation and one of several goals is the development of a global database on donation and transplantation. WBMT has facilitated access to its global survey data for input into this Observatory database since 2006 and remains an ongoing project.

The current process for collecting these Global Activity data is performed by a WBMT paid consultant. All GTA related communication (e.g., requests to centers and registries) is managed by this individual. The data is collected through a survey and represents the number of first transplants performed by a center during a calendar year. Data for a particular year activity is collected from November of the subsequent year through February. For example, submission related to the activity for 2013 will be due starting November 2014 through February 2015. This data will be compiled and released to the WHO and to the public by fall of 2015.

Any transplant center is eligible to provide data to the WBMT through its Member Society. The only requirement for participation is that each Member Society has a standing agreement with the WBMT to share transplant activity data. The WBMT will have the autonomy in using these data according to its mission and share with third parties for specific projects (Guiding Principles #2 and #3).

One important exception in the relationship between the WBMT and a Member Society involves transplant activity data from regions were the regional Member Society is still in development. In these instances, direct communication from a transplant center and the WBMT is allowed, condition upon having a standing agreement in place. The transplant center
is required to include in the survey whether or not it has an active affiliation (i.e. data reporting) with an outcomes registry (APBMT, CIBMTR, or EBMT). Additionally, the regional Member Society in question needs to be aware of this direct relationship between its transplant center and the WBMT. In case of data being shared from a transplant center directly with the WBMT, the WBMT will share this activity information with the regional Member Society.

WBMT Global Transplant Activity data reports (Insert 1) capture disease indications (malignant and non-malignant) for allogeneic (related and unrelated) and autologous stem cell transplantation, donor type, and stem cell sources. They do not include outcome data. Data are provided to the WBMT by transplant program sites, national, and/or outcome registries.

The data from an outcomes registry member society (APBMT, CIBMTR, EBMT, EMBMT, and ABMTRR as well as, in the future, LABMT and AFBMT) that are shared with the WBMT can be utilized by the same Member Society for other uses without restrictions.

Collection forms are available on the WBMT website (wbmt.org) and may be submitted in paper format or electronic mail.

**Global Transplant Activity Guiding Principle #2**

| The WBMT will be responsible for the dissemination of the Global Transplant Activity report. |

**Commentary on GTA Guiding Principle #2**

The responsibilities with the GTA include report annually to the WHO and share the activity with Member Societies. A summary slide set, updated annually, outlining annual and cumulative activity will be uploaded to the WBMT website for public use. Activity reports in the form of a manuscript will be published at least once every other year.

**Global Activity Survey Guiding Principle #3**

| The WBMT has ownership of the GTA data and any use needs to be approved by the WBMT. This includes data requests and proposals for scientific studies that seek to utilize these data for analysis. |

**Commentary on GTA Guiding Principle #3**

The GTA consists of transplant center level data on volume of transplant activity indications and donor and stem cell sources. These data, in aggregate, demonstrate important trends in activities and practices globally. Additional uses of these data are possible by any WBMT Member Society. In addition to annual reports of global activities, any individual on behalf of a Member Society can request specific information by contacting the WBMT data consultant. If the use is for research purposes, the proponent is required to complete a proposal form (Insert 2), which needs to be approved by his or her Member Society Representative before it can be submitted to the WBMT. This proposal will then be reviewed by the Transplant Center /
Recipient Standing Committee before the data can be released. When a proposed study is approved, any Member Society that provided data to be used for that study will be notified by the approval committee. For data requests outside of Member Societies, GTA data can only be released with approval from the WBMT Board. In these situations, charges may apply.

Data from a Member Society that are shared with the WBMT can be utilized by the same Member Society (which also has ownership of its data) without restrictions.
### WBMT SURVEY ON TRANSPLANT ACTIVITY 2016

**PLEASE REPORT THE NUMBER OF PATIENTS RECEIVING THEIR FIRST TRANSPLANT ONLY FOR THE YEAR 2009/2010/2011/2012 SEPARATELY ON EACH SURVEY SHEET**

**Country/Hospital:**

**Contact E-mail:**

**No. Teams reporting:**

**No. Teams known to transplant but do not report:**

---

**NUMBER OF PATIENTS RECEIVING FIRST TRANSPLANTS ONLY**

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<th>Autologous</th>
<th>Total</th>
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</thead>
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<td>Family total</td>
</tr>
<tr>
<td></td>
<td>BM PBSC Cord</td>
<td>BM PBSC Cord</td>
<td>BM PBSC</td>
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- **Total Leukemia**
  - Total AML
    - AML 1st CR
    - AML non 1st CR
  - Total ALL
    - ALL 1st CR
    - ALL non 1st CR
  - Total CML
    - CML 1st cP
    - CML non 1st cP
  - Other Leukemia
    - Total MDS/MPS (incl. combined MDS/MPS)
      - Total MDS incl. SAA AL MPS
      - CLL incl. PLL
  - Total LPO
    - Total Plasma Cell Disorder
      - PCD - Myeloma
      - PCD - other
  - Total Lymphoma
    - HD
    - NHL
  - Other LPO
    - Total Solid tumors
      - Neuroblastoma
      - Germ cell tumor
      - Breast Cancer
      - Ewing
      - Other solid tumor
    - Total Non-malignant dis.
      - Total Bone Marrow Failure
        - BMF - SAA
        - BMF - other
      - Hemoglobinopathy
      - Primary Immune Deficiency
      - Inherited Dis of Metabolism
      - Auto Immune Disease
      - Other Non Malignant Disease
      - Other
    - TOTAL PATIENTS (1st HSCT)

**TOTAL NUMBER OF TRANSPLANTS PERFORMED THIS YEAR:** includes 1st, 2nd, 3rd, etc.

**ALLO:**

**AUTO:**

**TOTAL:**

---

EBMT CIC No. / CIBMTR Code / APBMT (if member): .............................................
Insert 2: Global Transplant Activity (GTA) Study Proposal Form

Prepare a brief description of the proposed study as you envision it. This should be no more than three pages, using standard 8½" X 11" paper with 1” margins. Use the outline below and send your description to the WBMT administrative office or a known Executive Committee Officer.

I. Study Title

Include the name(s) and institution(s) and WBMT Member Society of the individual(s) proposing the study.

II. Specific Aims

State the primary purpose(s) of the study as concisely and clearly as possible. A reader should have a clear idea of the purpose for which the data will be analyzed.

III. Scientific Justification

Summarize the rationale of the study, citing relevant previous work. This should convey the importance of the intended study.

IV. Study Design (Scientific Plan)

Describe how the specific aims would be addressed using information from the WBMT. It should include the specific statistical methodology planned, with discussion of limitations, if relevant.
General Research Guiding Principle #1

Any collaborative research is required to follow all basic principles for ethical conduct of research in addition of being inclusive to all participating parties, being fair, minimize bias, avoid conflicts of interest, and strictly adheres to the WHO guiding principles on cell, tissue, and organ transplantation.

Commentary on General Research Guiding Principle #1

International collaborative research is herein defined as biomedical research that includes sharing of data or biologic specimens (“biospecimens”) among different organizations or groups that are located in separate countries.

The rules and guiding principles for collaborative research are no different from any biomedical research, as the majority of biomedical research requires some level of collaboration. This guiding principle mostly apply to complex collaborative, involving different organizations situated in different countries that abide to similar but not equal rules and regulations towards the practice of research. This first guiding principle is broad and applies to biomedical research involving human subjects. The ethical principles of conduct of research are derived from the Belmont Report (hhs.gov/ohrp/humansubjects/guidance.belmont.html) and include respect for persons, beneficence, and justice. The inclusiveness to all participating parties is an essential component for the conduct of international collaborative research in order to acknowledge all who are involved. This statement would apply when the collaborative parties are large complex organizations or when the number of collaborative parties is large. Fairness applies to all levels of research, development, conduct, interpretation, and dissemination. Additionally, this guiding principle is referring to fairness among the collaborative parties. Bias is inherent in research, and minimizing bias strengthens research. Finally, conflict of interest at any level, from commercial to self-promotion, is deleterious to research as it clouds the conduct and manipulates the message or conclusion of a project.

International collaborative research in hematopoietic cell transplantation is necessary for the success of this field. The guiding principles are meant to be a general reference document for the conduct of research and assist investigators in promoting the betterment of the practice of transplantation, advancing the field by improving access and outcomes of patients, and safeguarding the health of volunteer donors.
General Research Guiding Principle #2

The process of international collaborative biomedical research requires several steps to ensure its efficiency and fairness at the same time safeguarding the patients’ data.

Commentary on General Research Guiding Principle #2

Biomedical research process applied to specific collaborative projects can be stratified into several phases: concept development, project development, data sharing, analysis, results interpretation, dissemination and conclusion. In general, these phases can be distinct or combined depending on the project, however consideration of each of these steps are relevant in order to organize the procedures and requirements.

This guiding principle proposes general procedure in each phase of a collaborative project that could be considered.

Concept Development

The inception of a project starts with the concept or idea. The concept often focuses on the hypotheses of interest to be tested in the project. This step can be part of the project development. However, often in the collaborative international research, the concept or proposal is often a necessary step for recruiting collaborators, obtain approval or to better describe a project that is intended. Understanding the availability of data already in existence or procurement of such data can also be considered in the step of the research process.

Project Development

The development of the project requires detail information on the objectives, background, population and requirement of informed consent, data sources and analyses being done. This a priori exercise sediment the proposed activities and anticipates all potential pitfalls. The most common procedure in this phase is the development of a protocol that includes all the components of the project. The development of the protocol should be a collaborative effort that ensures that all participating parties are aware of the project details.

Additionally, this phase of the project development needs to address the safeguard of the data, the protection human subjects, funding information, shared responsibilities plan and authorship guidelines, results review process and dissemination plan. Each of these components might not apply to all projects, but if presented upfront might help avoid delays during the life cycle of the project.

The section below outlines each component with proposed format and content.

1. Protocol Document: Describes in detail all the proposed scientific activities to be done with in the project. The protocol document should include the objectives of the project in a succinct and direct language; background that justifies the study and or hypotheses; description of the population of interest and the sources of data; description of the outcomes being tested; detailed of the proposed statistical analysis; relevant references and any additional information
that is relevant for the understanding of the project (i.e. demographic table, surveys, etc.). If the study involves additional informed consent of recipients, this document would be to be referenced or added to the protocol document.

2. **Data Safeguards**: This description could be incorporated in the protocol or in a separate document. However a safeguard plan would require agreements between parties if data are being exchanged. The important components for the safeguard plan include description of the data needed in the study, the expected transferring plan, who will be the responsible parties to oversee this exchange or transfer and how the transferred data will be stored, including security details, for how long and the procedures that will take place once the project is completed. In case of data, a description on whether personal health information (PHI, i.e. date of birth, gender, social security or other unique identification number among others) is required for the study and the type of PHI needs to be included. Also, if the project requires data from different databases to be merged, a description of this data merger should include the variables used for the merger, identification of an honest broker in case of datasets with PHI, storage or plans for data destruction once the project is completed.

3. **Protection of Human Subjects**: any biomedical research that utilizes data requires appropriate informed consent, which authorizes the utilization of data for a particular use or research in general. Ethical committee oversight is a vital component of biomedical research to assure that human subjects are not being harmed. The rules of ethical committee engagement vary in different countries which makes a protection of human subjects document important in collaboration international research. The components of this document should include, the type of data being utilized in the project, whether the patients or individuals who consented for the specific project in question. In case of sharing dataset that include PHI, additional oversight might be required to overview that the process is appropriately set to avoid data breeches or losses. For studies that required additional informed consent, the document should include how the consent procedure will take place.

4. **Funding Sources**: studies that are done as part of funded projects may require a document that outlines any restriction that the funding agent might impose on the project. Additionally, the funding plan might require multiple sources which should be outlined accordingly.

5. **Shared Responsibilities**: It is important to develop a leadership plan that outlines the responsibility of each member of the project and that all members are in agreement with this plan. This document should also include authorship guidelines for any publication that results from this project. The authorship guidelines might be a detailed list of each member of the project and their position in a manuscript or general rules that will be considered to choose authors and their respective position on any manuscript from this project.

6. **Results Review and Dissemination Plan**: some of the components of this section can be included in the protocol document. A detailed plan for how the results will be reviewed and disseminated might be necessary in studies that involve different outcomes databases or
research groups. This includes timeline for completion of the analysis, presentation in conferences or meetings and other public dissemination.

**Project Analysis**

Once the project is developed with approved documentation and agreements, data can be transferred. If the project requires separate informed consent, enrollment of participants may be initiated.

Prior to analyses, verification of the data for errors, outliers and follow up is important to avoid misinterpretation of results. Analyses results when completed should follow the results review and dissemination plan outline above.

**Completion of the Project**

Once the study is completed, which in some instances might be upon the publication of results or otherwise determined procedures for returning, destroying shared data or left over samples, or indefinitely storage should take place. Additional studies that include any data used in the original project need to be discussed among the original owners of the data before proceeding. This will initiate another project cycle and some of the steps described above may apply.

*This document will soon be prominently posted on the WBMT website (wbmt.org).*
APPENDIX D2: WBMT MEMBER SOCIETY REGISTRY DTA

WBMT MEMBER SOCIETY REGISTRY DATA TRANSMISSION AGREEMENT

This Data Transmission Agreement (“Agreement”), effective [Date], is entered into by and between the Worldwide Blood and Marrow Transplant Network (“WBMT”), a non-government organization with the World Health Organization and ____________________ (“WBMT Member Society”), each a “Party” and collectively, the “Parties”.

The purpose of this Agreement is to set forth terms by which the WBMT will facilitate its member societies in data submission related to the Global Transplant Activity (“GTA”) for public dissemination and research purposes.

First and foremost, and following WBMT Guiding Principle #3, “The WBMT has ownership of the GTA data and any use needs to be approved by the WBMT. This includes data requests and proposal for scientific studies that seek to utilize these data for analysis” and “The data from a Member Society that is shared with the WBMT can be utilized by the same Member Society (which also has ownership of its own data) without restrictions.”

Section 1. Data Collection and Records

- Global Transplant Activity Data: The WBMT member society shall submit information related to transplant activity from the transplant centers that are within the region of the member society or has an established relationship with the member society to provide this data. Transplant activity data collected in the Global Activity Survey Form (“GAS”) includes the volume of first transplants per patients performed at a transplant center in one year with accompanied information related to the indication, graft source and donor type.

- Data Collection. The WBMT Member Society shall compile all annual transplant activity data from their participating transplant centers and provide to WBMT with GAS compiled for the specific region as requested by the WBMT within the time frames and in the manner specified by the WBMT. The timeline for submission of the compiled regional GAS is from November to February in reference to the activity of the prior year. The GAS should be submitted directly to the WBMT offices during this specified period.

Section 2. Informed Consent

- The GAS does not include any patient specific identifiers. It represents the number of transplants performed at a given transplant center. The volume per center is not provided to the WBMT, the GAT includes the number of active centers in a particular region and the number of transplants performed annually. Informed consent is not required for collection or submission to WBMT.
Section 3. Term

- This Agreement shall commence on its effective date referenced in the first paragraph above and shall continue in force until terminated by either Party at any time, with or without cause, upon thirty (30) days written notice to the other Party. During the thirty (30) day period after such notice is sent, the Parties shall continue to act toward each other in good faith.

Section 4. Miscellaneous

- Compliance with Laws and Regulations. The WBMT Member Society shall comply with all applicable statutes and regulations specific to that country, including, but not limited to, those regarding the safeguarding of donor and patient records, privacy regulations and human subjects protection.

- Assignment and Subcontracting. The WBMT Member Society may not assign this Agreement or any of their respective rights and responsibilities under this Agreement, without the WBMT’s prior written consent. No responsibilities under this Agreement may be subcontracted without the prior written approval of the Parties.

- Amendment. Except as otherwise provided for in this Agreement, this Agreement may not be amended except by written instrument duly signed and delivered by the WBMT and the WBMT Member Society.

- Non-Assumption of Liabilities. Neither the WBMT nor the WBMT Member Society shall be liable for any of the prior existing or future obligations, liabilities or debts of the other Party.

- Governing Law. This Agreement and all transactions contemplated by this Agreement shall be governed, construed and enforced in accordance with the laws of Switzerland.

- Independent Contractors. Nothing in this Agreement is intended to create an employment or agency relationship between the Parties. Neither Party shall be deemed or construed to be an employee or agent of the other.

- Notice. Any notice required to be given by this Agreement shall be in writing and sent by: 1) mail, registered or certified, as evidenced by a delivery receipt; 2) with a private
delivery service as evidenced by a shipping receipt; or 3) by electronic mail return receipt requested.

- **Prior Agreement.** This Agreement constitutes and contains the entire Agreement between the Parties with respect to the subject matter hereof, including but not limited to the terms and conditions relating to the maintenance and transmission of data, and supersedes any prior oral or written agreements.

- **Force Majeure.** Neither Party shall be considered to have failed in the performance of this Agreement if such failure arises out of causes beyond the control and without the fault or negligence of the Party failing to perform, except that the WBMT Member Society shall not be excused from strict compliance with this Agreement under this clause due to errors, omissions or failures by its independent contractors or lower tier subcontractors.

- **Successors.** This Agreement shall be binding on and will inure to the benefit of the Parties and their respective successors and assigns.

This Agreement is executed by individuals who are duly authorized to enter into the Agreement and legally binds their respective parties to be effective on the date stated in the first paragraph above. “Duly authorized” includes the WBMT President, a registry leadership representative or a center representative as is designated by that center.

By: WBMT

By: [Registry WBMT Member Society]

By: __________________________

By: __________________________

Authorized Signature

(Typed/Printed Name)

Title: Current WBMT President

Title: __________________________

Date: __________________________

Date: __________________________
### APPENDIX E: HISTORY OF MAJOR MEETINGS

<table>
<thead>
<tr>
<th><strong>WBMT Board Business Meetings</strong></th>
<th><strong>WBMT Participant Meetings</strong></th>
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<td><strong>2016</strong></td>
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<tr>
<td>Teleconference (December)</td>
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<td>Teleconference (July)</td>
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<tr>
<td>Geneva, Switzerland – WHO (May)</td>
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<td>Valencia, Spain (April)</td>
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<tr>
<td><strong>2015</strong></td>
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<tr>
<td>Teleconference (December)</td>
<td>Addis Ababa, Ethiopia – On-site visit by select WBMT representatives (December)</td>
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<tr>
<td>Okinawa, Japan – Nuclear Accident Management Committee (October)</td>
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<tr>
<td>Teleconference (July)</td>
<td>Regensburg, Germany – Sickle Cell Disease Cure and Prevention Consortium (June)</td>
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<td>San Diego, CA, US (February)</td>
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<tr>
<td><strong>2014</strong></td>
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<tr>
<td>Teleconference (December)</td>
<td>Geneva, Switzerland – MPHO NGO meeting (September)</td>
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<tr>
<td>Teleconference (July)</td>
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<tr>
<td>Milan, Italy (March)</td>
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<tr>
<td><strong>2013</strong></td>
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<tr>
<td>Brasilia, Brazil – WBMT / NOFITY (December)</td>
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<tr>
<td>Teleconference (November)</td>
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<tr>
<td>Teleconference (July)</td>
<td>Geneva, Switzerland – WHO (May)</td>
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<tr>
<td>London, UK – Standing Committees (April)</td>
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<tr>
<td>Salt Lake City, UT, US (February)</td>
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<tr>
<td>WBMT Board Business Meetings</td>
<td>WBMT Participant Meetings</td>
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<td>------------------------------</td>
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<tr>
<td><strong>2012</strong></td>
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<td></td>
<td>Atlanta, GA, USA – WBMT / LABMT (December)</td>
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<td></td>
<td>Rome, Italy – WBMT / NOTIFY (November)</td>
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<tr>
<td>Teleconference (October)</td>
<td>Hyderabad, India – APBMT (October)</td>
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<td>St. Petersburg, Russia – WBMT / Russia (September)</td>
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<td></td>
<td>Lagos, Nigeria – WBMT / AFBMT (September)</td>
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<td>Manila, Philippines – WBMT / Philippine Society of Hematology (August)</td>
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<tr>
<td>Geneva, Switzerland (April)</td>
<td>San Diego, CA, US – WBMT / LABMT (February)</td>
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<td>Teleconference (December)</td>
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<td>Teleconference (April)</td>
<td>Paris, France – Standing Committees (March)</td>
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<td>Honolulu, HI, US* (February)</td>
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<td><strong>2010</strong></td>
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<td>Phuket, Thailand – APBMT (November)</td>
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<td>Brussels, Belgium – WHO (February)</td>
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<td><strong>2009</strong></td>
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<td>Minneapolis, MN, US (November)</td>
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<td>WBMT Board Business Meetings</td>
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<tr>
<td><strong>2008</strong></td>
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<tr>
<td>Minneapolis, MN, US (October)</td>
<td>Geneva, Switzerland – WHO (October)</td>
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<td>Firenze / Florence, Italy (March)</td>
<td>Tampa, FL (February)</td>
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<tr>
<td><strong>2007</strong></td>
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<tr>
<td>Minneapolis, MN, US (October)</td>
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<tr>
<td>Lyon, France (March)</td>
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*1st elected Board meeting*
APPENDIX F: HISTORY OF INTERNATIONAL SCIENTIFIC SYMPOSIA

2016

April, **EBMT Meeting** (Valencia)
*Global Challenges in Transplantation*
Co-Chairs: Y Kodera (Japan) and J Kuball (Netherlands)
- Economic stresses in transplantation: How are these challenging existing and new programs? (D Weisdorf, US)
- Quality measures: How to incorporate quality into existing and new sites? (H Greinix, Austria)
- EBMT-JACIE accreditation: 10 years of success (J Snowden, UK)

February, **BMT Tandem Meetings** (Honolulu)
*Haploidentical HCT – A Global Overview: Comparing Asia, EU, and US*
Co-Chairs: Y Kodera (Japan) and J Szer (Australia)
- Introduction
  - WBMT Global Activity Survey (D Niederwieser, Germany)
  - Trends in Haplo HCT (J Apperley, United Kingdom)
- The Asian Experience (X-J Huang, China)
- The EU Experience (A Nagler, Israel)
- The US Experience (E Fuchs, US)

2015

April, **EBMT Meeting** (Istanbul)*
*During these meetings, the WBMT participated in a plenary session in lieu of a traditional Joint Session.*

Co-Chairs: Y Kodera (Japan) and T Damirer (Turkey)
- Lessons after one million transplants (A Gratwohl, Switzerland)
- Which AML patient should not be transplanted in 2015? (F Appelbaum, US)

February, **BMT Tandem Meetings** (San Diego)
*Global Donor Selection Challenges: Clinical efficacy and cost performance*
Co-Chairs: Y Kodera (Japan) and D Weisdorf (US)
- Introduction (Y Kodera, Japan, and D Weisdorf, US)
- Haplo-HCT without T-cell depletion vs. unrelated vs. related (post-transplant cyclophosphamide) for developing countries (D Niederwieser, Germany)
- Regional cost differences of matched, haploidentical, and cord blood HSCT (S Giebel, Poland)
- Report from regional group – LABMT (A Seber, Brazil)
2014

April, **EBMT Meeting** (Milan)

*Hematopoietic Stem Cell Transplantation: Access and Affordability*

Co-Chairs: D Niederwieser, Y Kodera, D Confer, D Wiesdorf, H Greinix
- Non-Government Organization (NGO): Status significance and opportunities of an NGO (J Nunez)
- Cost of non-transplant therapy for hematologic malignancies (J Apperley)
- Alternative donor selection
  - Haploidentical donor (L Luznik)
  - Cord blood stem cell transplantation (M Eapen)

February, **BMT Tandem Meetings** (Dallas)

*Hematopoietic Stem Cell Transplantation: Access and Affordability*

Co-Chairs: D Niederwieser, Y Kodera, D Confer, D Wiesdorf, H Greinix
- Non-Government Organization (NGO): Status significance and opportunities of NGO (J Nunez)
- Cost of non-transplant therapy for hematologic malignancies (J Apperley)
- Alternative donor selection
  - Haploidentical donor (X-J Huang)
  - Cord blood stem cell transplantation (D Weisdorf)

2013

April, **EBMT Meeting**

*The Legacy of E. Donnall Thomas: One Million Hematopoietic Stem Cell Transplants*

Co-Chairs: D Niederwieser, Y Kodera, D Confer, H Greinix
- E. Donnall Thomas: From Cooperstown to Global (R Storb)
- Challenges to Future Growth: The Transplant Center Perspective
  - Europe (M Mohty)
  - Eastern Mediterranean (M Aljurf)
  - Africa (N Novitzky)
- Challenges to Future Growth: The Donor Registry Perspective (D Confer)
- Challenges to Future Growth: The WHO Perspective (L Noël)
- Improving Research Collaborations to Move Forward (M Horowitz)

February, **BMT Tandem Meetings**

*The Legacy of E. Donnall Thomas: One Million Hematopoietic Stem Cell Transplants*

Co-Chairs: D Niederwieser, Y Kodera, D Confer, H Greinix
- E. Donnall Thomas: From Cooperstown to Global (F Appelbaum)
- Challenges to Future Growth: The Transplant Center Perspective
  - North America (R Champlin)
  - Central / South America (C Bonfim)
  - Asia-Pacific (A Srivastava)
- Challenges to Future Growth: The Donor Registry Perspective (D Confer)
• Challenges to Future Growth: The WHO Perspective (L Noël)
• Improving Research Collaborations to Move Forward (J Apperley)

2012

WBMT Scientific Session
Chair: D Niederwieser
• WBMT Update (D Niederwieser)
• The Macroeconomics of Hematopoietic Stem Cell Transplantation (A Gratwohl)
• A Global View of Cord Blood Transplantation (V Rocha)
• The Fukushima Nuclear Accident – The Transplant Team Experience (S Taniguchi)

2011

WHO and WBMT: A Model for Optimal Collaboration Between Scientists and Health Institutions
Co-Chairs: D Confer, Y Kodera, D Niederwieser
• Update on WBMT Activity (D Niederwieser)
• Global HSCT Activity Survey 2007-2008 (H Baldomero)
• Report from the APBMT Congress: HSCT Activity and Plans for a Vietnam Meeting (Y Kodera)
• Harmonizing Standards in BMT – Improving Outcomes on a Global Scale (K Loper)
• WHO and WBMT a Model for Optimal Collaboration Between Scientists and Health Institutions (L Noël)

2010

Worldwide Network for Blood and Marrow Transplantation (WBMT) Session
Co-Chairs: D Niederwieser, M Horowitz
• Update on Progress of WBMT (D Niederwieser)
• Challenges in Establishing HSCT Outcomes Registries in Developing Countries Asia-Pacific BMT Group (Y Atsuta)
• Eastern Mediterranean BMT Group (M Aljurf)
• Ethical Issues in Donation of Hematopoietic Stem Cells (A Capron)

2009

WBMT International Session (Supported by THERAKOS, Inc.)
Co-Chairs: D Niederwieser, S Davies, Y Kodera, M Oudshoorn
• Overview of Unrelated Adult and Cord Blood Donation: the WMDA Annual Survey (M Oudshoorn)
• Unrelated Donor Outcomes and Plans for Assessing Related Donor Outcomes: A Report from the NMDP / CIBMTR (D Confer)
• Related Donor Outcomes from the Japanese Registry: The Importance of Pre-registration (Y Kodera)
• Proposal for an EBMT Donor Outcome Registry (J Halter)
## APPENDIX G: PUBLICATIONS LIST

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<th>WBMT Publications</th>
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## APPENDIX H: TERMS AND ABBREVIATIONS

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<tr>
<th>Term / Abbreviation</th>
<th>Definition</th>
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<tr>
<td>AABB</td>
<td>AABB; formerly known as American Association of Blood Banks</td>
</tr>
<tr>
<td>ABMTRR</td>
<td>Australasian Bone Marrow Transplant Recipient Registry</td>
</tr>
<tr>
<td>AFBMT</td>
<td>African Blood and Marrow Transplant Group</td>
</tr>
<tr>
<td>AHCTA</td>
<td>Alliance for the Harmonization of Cellular Therapy Accreditation</td>
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<tr>
<td>APBMT</td>
<td>Asia-Pacific Blood and Marrow Transplantation Group</td>
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<td>ASBMT</td>
<td>American Society for Blood and Marrow Transplantation</td>
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<tr>
<td>ASH</td>
<td>American Society of Hematology</td>
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<tr>
<td>BIG V&amp;S SARE</td>
<td>Bologna Initiative for Global Vigilance and Surveillance of Adverse Reactions and Events</td>
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<tr>
<td>BM</td>
<td>bone marrow</td>
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<tr>
<td>BMDW</td>
<td>Bone Marrow Donors Worldwide</td>
</tr>
<tr>
<td>CIBMTR</td>
<td>Center for International Blood and Marrow Transplant Research</td>
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<tr>
<td>CME</td>
<td>continuing medical education</td>
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<tr>
<td>EBMTR</td>
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<tr>
<td>ECDC</td>
<td>European Centre for Disease Prevention and Control</td>
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<td>European Leukemia Network</td>
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<td>European School of Hematology</td>
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<td>FACT</td>
<td>Foundation for Accreditation of Cellular Therapy</td>
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<td>GTA</td>
<td>global transplant activity</td>
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<td>HSCT</td>
<td>hematopoietic stem cell transplantation</td>
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<td>ICCBBA</td>
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<td>LABMT</td>
<td>Latin American Blood and Marrow Transplant Society</td>
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<td>MPHO</td>
<td>medical products of human origin</td>
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<tr>
<td>NGO</td>
<td>non-government organization; as an NGO in official relations with WHO</td>
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<tr>
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<td>National Marrow Donor Program</td>
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<td>Radiation Injury Treatment Network</td>
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<td>SOHO V&amp;S</td>
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<td>WBMT</td>
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<td>WHO</td>
<td>World Health Organization</td>
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<td>WMDA</td>
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