

# Harmonising Standards in HSCT: AHCTA Initiatives

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**ahcta** | **alliance for harmonisation of  
cellular therapy accreditation**

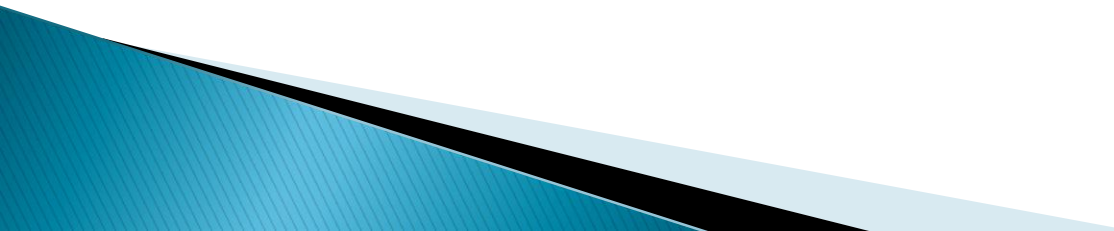
# WBMT Mission of AHCTA

Function is to recommend to the Executive Committee policies, programs, or actions in the area of any/all issues pertaining to regulatory and accreditation matters, practices and codes with both inter- and intra-national implications. This involves all aspects of cellular therapy (or stem cell transplant) procedures related to Recipient, Donor, Graft Processing. The committee will coordinate efforts with the Dissemination and Education Standing Committee activities where applicable.

# Member Organizations

- AABB
  - Asia Pacific Blood and Marrow Transplantation Group
  - American Society for Blood & Marrow Transplantation
  - Eastern Mediterranean Blood and Marrow Transplantation
  - European Federation for Immunogenetics
  - European Group for Blood & Marrow Transplantation
  - Foundation for the Accreditation of Cellular Therapy
  - International NETCORD Foundation
  - International Society of Blood Transfusion
  - International Society for Cellular Therapy (Europe)
  - Joint Accreditation Committee ISCT (Europe)-EBMT
  - National Marrow Donor Program
  - World Marrow Donor Association
- 



# Projects to date

- Position papers and consensus documents
  - Comparison of Cellular Therapy Standards “crosswalk”
  - Survey on country specific import/export requirements (through WMDA)
    - New survey on cell processing staff training
  - Resources Compendium on web site
- 



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## Documents

Title	Updated	Link
<a href="#">Mission statement</a>		
<a href="#">Towards a Global Standard for Donation, Procurement, Testing, and Distribution of HSC and Related Cellular Therapies Position Paper (revised 27 May 2008)</a>	27-05-2008	

## Comparison of Cellular Therapy Standards

### Crosswalk documents.

**Note:** These crosswalks were prepared for the purpose of providing basic information on organizational activities for global comparison and gap analysis. They are NOT intended to be used as a reference or source document and are not endorsed by any of the participating organizations. All standards are undergoing revision at the time of web posting. Efforts will be made to update the information as soon as possible. Users are directed to each organization's standards and accreditation policies for reference and the crosswalk should not take the place of a thorough line-by-line review of the Standards.

1 Donor standards	29-10-2010	
2 Background etc	03-01-2009	
3 Regulation & Inspection	13-09-2010	
4 Quality Management standards	03-01-2009	
5 Cell Collection standards	03-01-2009	
6 Labelling & Coding	07-06-2010	
7 Cell Processing	03-01-2009	

## Surveys

### Import & Export Requirements



This [import- and export survey](#) was originally started in 2003. In 2009 WMDA began updating the data and you are invited to participate [here](#).

# Resources



## Resources

This is a compendium of resources prepared by the organisations collaborating within AHCTA. Each organisation is responsible for the contents of their materials.

Last updated: 15 July 2010

## Assessment/Inspection Tools

- AABB**
  - [AABB Information](#) (*member access restricted*)
  - [AABB Assessment tool](#) (*member access restricted*)
- FACT**
  - [FACT-JACIE Cellular Therapy Accreditation Manual](#) (*Free*)
- JACIE**
  - [Inspection Checklist](#) (*look for JACIE Inspection Checklist 4th ed ver [X].xls*)
- National Marrow Donor Programme**
  - [NMDP network website](#) (*requires login*)
- NETCORD**
  - [Netoord-FACT Cord Blood Accreditation Manual](#) (*Free*)
- WMDA**
  - [WMDA Accreditation Handbook](#)

## Educational programs

- AABB**
  - [AABB Resources](#) (*some member restricted/discounted*)
  - [Circular of Information](#)
  - [Learning Centre](#)
- FACT**
  - [FACT Inspector Training Webinars](#) (*Free to inspectors, for sale to non-inspectors*)
  - [FACT Tutorials](#) (*Free to inspectors, for sale to non-inspectors*)
  - [Donor History Questionnaire](#)
  - [FDA Cellular Therapy Liaison Meetings](#) (2005-2009)
- ICCBBA (cellular therapy)**
  - [ISBT 128 Information](#)
- ISCT**
  - [ISCT Resources](#) (*some member restricted/discounted*)
  - [Laboratory Resources](#)
- JACIE**
  - [Link to Events](#)
- National Marrow Donor Programme**
  - [NMDP network website](#) (*requires login*)

## Quality Plan Information

- AABB**
  - [Quality Plan Publications](#)
- FACT**
  - [Quality Management Webinar Series](#)
- JACIE**
  - [Quality Management Guide](#) (2008)
- National Marrow Donor Programme**
  - [NMDP network website](#) (*requires login*)

## Publications (books, videos, slide sets)

- AABB**
  - [Publication \(book\) on Methods](#)
  - [Publication \(book\) on Stem Cell Transplant](#)
  - [Quality Plan Publications](#)
- National Marrow Donor Programme**
  - [NMDP network website](#) (*requires login*)
- Product Assistance for Cellular Therapies (FACT)**
  - [Cell Therapy: cGMP Facilities and Manufacturing](#)

## Sample procedures

- AABB**
  - [AABB Commendable practices](#)
- ISCT**
  - [Laboratory resources](#) (*Free*)
- JACIE**
  - [Quality Management Guide](#) (2008)
  - [Sample Quality Management Materials](#)
  - [Suggested list of Policies and Standard Operational Procedures \(SOPs\)](#)
- National Marrow Donor Programme**
  - [NMDP network website](#) (*requires login*)
- Product Assistance for Cellular Therapies (FACT)**
  - [SOP Requests](#)

## Standards

- AABB**
- ASHI**
- EFI**
- FACT/JACIE**
- ICCBBA (cellular therapy)**
- NETCORD**
- NMDP**
- WMDA**

## Other resources

- International Society for Stem Cell Research (ISSCR)**
  - [International, national and local regulations, guidelines and resources](#)
- National Marrow Donor Programme**
  - [NMDP network website](#) (*requires login*)
- NMDP Radiation Injury Treatment Network**

## Organisations & Associations

- [American Association of Blood Banks](#)
- [American Society for Blood & Marrow Transplantation](#)
- [Asia Pacific Blood and Marrow Transplantation Group](#)
- [European Federation for Immunogenetics](#)
- [European Group for Blood & Marrow Transplantation](#)
- [Foundation for the Accreditation of Cellular Therapy](#)
- [International NETCORD Foundation](#)
- [Joint Accreditation Committee ISCT \(Europe\)-EBMT](#)
- [International Society of Blood Transfusion](#)
- [International Society for Cellular Therapy](#)
- [National Marrow Donor Program](#)
- [World Marrow Donor Association](#)

# Aligns with Mission of WBMT

Promote excellence in stem cell transplantation and cellular therapy including stem cell donation on a global scale

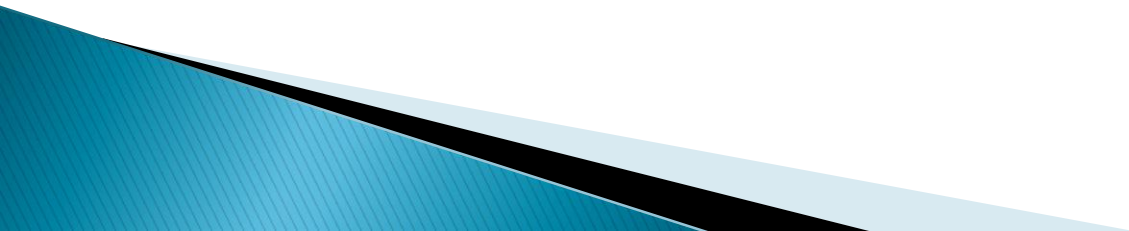


# Committee Members

- ▶ Alok Srivastava
- ▶ Amal Al Seraihy
- ▶ Andrea Harmer
- ▶ Carolyn Keever Taylor
- ▶ Christina Celluzzi
- ▶ Chun-Rong Tong
- ▶ Cristina Navarrete
- ▶ Dennis Confer
- ▶ Derwood Pamphilon
- ▶ Eduardo Nunes
- ▶ Ellen Lazarus
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- ▶ Etienne Baudoux
- ▶ Fawzi Abdel-Rahman
- ▶ Fran Rabe
- ▶ Francesco Lanza
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- ▶ I Slaper-Cortenbach
- ▶ Irene Andersen
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- ▶ Jean Sanders
- ▶ Lisa Phillips-Johnson
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- ▶ Machteld Oudshoorn
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- ▶ Phyllis Warkentin
- ▶ Shinichiro Okamoto
- ▶ Thomas Bart
- ▶ Yoshihisa Kodera
- ▶ Safa Karandish



# **Standards Setting Organizations**





# WMDA is founded to facilitate the international exchange of HSC products

- Global standards
- Global recommendations and guidelines
- Promoting international exchange of information
- **WMDA Website: [www.worldmarrow.org](http://www.worldmarrow.org)**



## Donors

## Recipients

### Registry

- Donor/cord unit database & search algorithm
- Coordination of process at national & international level

### Donor Center

- Recruitment volunteer adult donors
- Education & counseling of donors
  - Health screening of volunteers
- Follow-up on donor health after donation

### Collection/Harvest Center

- Medical screening of selected donors
- Harvest of hematopoietic stem cells

### Cord Blood Bank

- Collection, processing & storage of cord blood
  - Consenting of maternal donors
- Health screening of mother and unit

### Cell Processing/Cell Therapy Laboratory

- Protocol specific processing of HSC

### Transplant Center

- Care & treatment of patient
  - Selection of donor
  - Transplantation

*Division of responsibilities may vary somewhat among countries & facilities*



The National Marrow Donor Program<sup>®</sup>, which operates the Be The Match<sup>®</sup> Registry, is a non-profit organization that has been established for more than 25 years in the U.S. It is the world's largest listing of potential marrow donors and donated cord blood units. The NMDP collaborates with more than 600 partners worldwide.

[www.bethematch.org](http://www.bethematch.org)



- NMDP Standards - soon to be in its 23<sup>rd</sup> Edition – set forth basic guidelines and requirements for programs working with the NMDP. NMDP network representatives and NMDP staff form the NMDP Standards Committee.
- Standards encompass network participation criteria (requirements for transplant hospitals, recruitment centers, product collection centers, etc.); the donation process; product collection, storage, transportation, processing and labeling; adverse events, complaints and non-conforming products, materials or services; and records.
- Standards form the baseline information for more details Manuals of Operations, network policies and staff procedures.

# Foundation for the Accreditation of Cellular Therapy (FACT)

- Standards and accreditation of BMT Programs and Cord Blood Banks
- Focus on Clinical Administration and Patient Safety
- Expert Volunteer Inspectors and Committees
- Culture of Peer Review and Support
- International Scope
- Partnerships with JACIE and NetCord (joint stds)

*LEARN MORE ABOUT FACT*

*www.factwebsite.org*

Email: fact@unmc.edu

Phone: 1-402-559-1950

## Standards

- Evidence based: published literature, scientific theory, and expert consensus
- Minimum requirements: flexibility (HPC and regenerative medicine products)
- International: committee members from 15 different countries

## Accreditation

- Voluntary
- Peer-driven
- Recognized by international registries, clinical trials groups, and other key stakeholders

## 3 Pillars of Excellence

## Education

- Far reaching: online and global
- Wide ranging: quality, operations, and accreditation topics
- All encompassing: sessions for Directors, scientists, nurses, technologists, and more

# JACIE



- Joint Accreditation Committee – ISCT & EBMT
- Established 1998
- Dependency of European Group for Blood & Marrow Transplantation (EBMT) and International Society for Cellular Therapy (ISCT)
- Common standards with FACT (USA)
- Applications from almost 300 facilities/centres in 23 countries in Europe and elsewhere
- JACIE accreditation part of regulations and guidelines in several European countries
- Inspections in language of the centre
- Option to receive orientation visit
- More information, visit [www.jacie.org](http://www.jacie.org)



# JACIE Accredited Centres

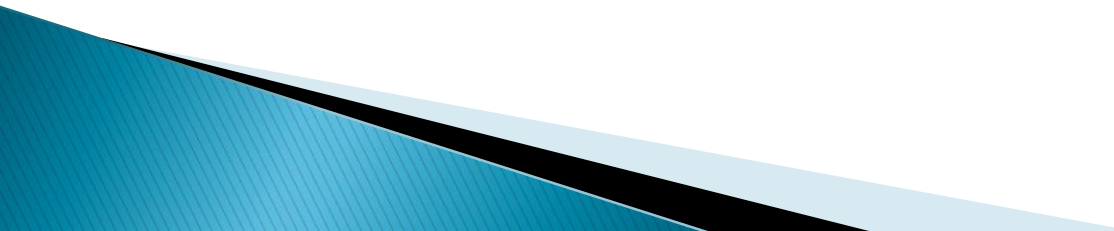


[www.jacie.org/accredited-centres-map](http://www.jacie.org/accredited-centres-map)

# European Federation for Immunogenetics (EFI)

- Scientific Society for Histocompatibility and Immunogenetics
- Clinical Services, Research, Education
  - To support the development of Immunogenetics and promote research and training in this field
  - To develop recommendations for the standardisation of techniques, quality control and criteria for accreditation **and to support their implementation.**

# Why Standardise?

- Transplantation crosses borders
  - Haematopoietic Stem Cell Transplantation
    - HLA matching is critical for patient outcome
    - Search donor registries for unrelated donor
    - HLA typing is THE key information to identify donor
  - Quality and accuracy of test results must be of a minimum standard to support exchange
  - Apply same standards across different countries
- 

# EFI Standards

- Cover technical and clinical requirements
- Under constant review by Standards Committee
- Originally based on ASHI standards
- Basic requirements still comparable
  - Europe and North America work to very similar minimum requirements
  - Supports exchange of stem cells and organs
- EFI Accreditation: accredits to these standards

# Other Member Organizations

## **Organization and Bylaws:**

- Founded in 2008
  - Founding Members: All HSCT Ctrs in EMRO region
- Members:
  - Full, Associate and Corporate
- Goal:
  - A cooperative platform for physicians, scientists and healthcare providers in the Eastern Mediterranean region for sharing experience, initiating cooperative trials and establishing common strategy for optimization of HSCT

## **Purpose:**

- To promote all aspects of patient care, academic and research activities associated with HSCT, including trends, patterns and status of HSCT in the EMRO region
- To steer & regulate HSCT Registry in the region.
- To share knowledge & resources in HSCT
- To collaborate with other int'l HSCT organizations
- To support regional Unrelated Donor Registry and cord blood banks
- To establish standardization for CQI & accreditation

## **Mission:**

- To learn and share the HSCT activities, outcomes, education and research by means of integrated teamwork

## **Vision:**

- To become one of the leading international groups for HSCT and Research by close cooperation among regional centers, physicians, scientists, healthcare workers and patient advocates for optimization of patient care

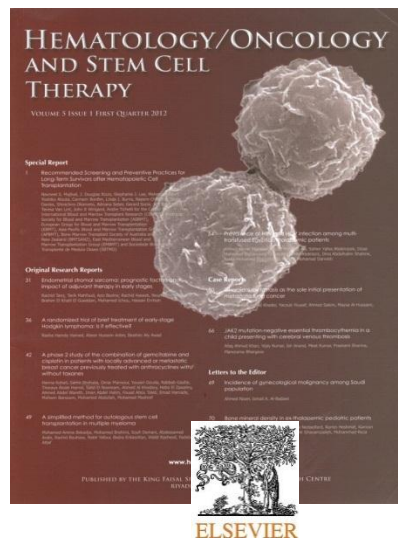
## Working Committees:

- Hemoglobinopathies
- Plasma Cell Disorders
- Lymphoma
- Pediatric Cancer
- Bone marrow failure disorders
- Acute Leukemia
- Alternate Donor Transplantation, Histocompatibility, Donor health
- Immune Deficiencies/Inborn Errors
- Chronic Leukemia
- Infection/Immune Reconstitution
- HSCT/Graft vs. Host Disease and Transplantation related toxicity
- Late effects, Supportive care and Quality of Life
- Biomarkers and HSCT Translational Research

## Recent Publications:

- [Hematopoietic stem cell transplantation practice variation among centers in the Eastern Mediterranean Region \(EMRO\): Eastern Mediterranean Bone Marrow Transplantation \(EMBMT\) group survey.](#) W Rasheed, A Ghavamzadeh, R Hamladji, et al. *Hematology/Oncology and Stem Cell Therapy* Vol 6 (1):, Mar 2013, Pages 14–19.
- [Allogeneic matched-sibling hematopoietic cell transplantation for AML: comparable outcomes between Eastern Mediterranean \(EMBMT\) and European \(EBMT\) centers.](#) A Bazarbachi, M Labopin, A Ghavamzadeh, et al. *Bone Marrow Transplant* (2013) 48, 1065–1069.
- [Hematopoietic Stem Cell Transplantation in the Eastern Mediterranean Region \(EMRO\) 2008-2009: Report on behalf of the Eastern Mediterranean Bone Marrow Transplantation \(EMBMT\) Group.](#) Mohamed SY, Fadhil I, Hamladji RM, et al. *Hematol Oncol Stem Cell Ther* 2011; 4(2): 81-93.
- [Special issues related to hematopoietic SCT in the Eastern Mediterranean region and the first regional activity report.](#) MD Aljurf, SZ Zaidi, H El Solh, et al. *Bone Marrow Transplant.* 2009 Jan;43(1):1-12.
- [Status of Hematopoietic Stem Cell Transplantation in the WHO Eastern Mediterranean Region \(EMRO\).](#) Mahmoud Aljurf, Syed Z Zaidi, Fazal Hussain, et al. *Transfusion and Apheresis Science* 42 (2010) pp. 169-175
- [Trends of Hematopoietic Stem Cell Transplantation in the Eastern Mediterranean Region, 1984-2007.](#) S.O. Ahmed, A. Ghavamzadeh, S. Zaidi, et al. *Biology of Blood and Marrow Transplantation.* Volume 17, Issue 9, Sep 2011, Pages 1352–1361.

## EMBMT Official Journal:



## Website:

- [www.embmt.org](http://www.embmt.org)

International Society for Cellular Therapy

ISCT



## TRANSLATIONAL FOCUS

### ACADEMIA

#### SCIENTIFIC COMMITTEES:

- MESENCHYMAL STEM CELL
- GENE THERAPY
- HSC & UCB
- CARDIOVASCULAR
- NEUROLOGY
- IMMUNOTHERAPY
- PULMONARY

### REGULATORY AND QUALITY/OPERATIONS

#### GRP STEERING COMMITTEE:

- LRA NORTH AMERICA
- LRA SOUTH & CENTRAL AMERICA
- LRA EUROPE
- LRA ASIA
- LRA AUSTRALIA

#### LAB PRACTICES

### COMMERCIALIZATION

#### COMMERCIALIZATION COMMITTEE:

- PRODUCT AND PROCESS  
DEVELOPMENT
- REIMBURSEMENT
- BUSINESS MODELS  
AND COGs
- INDUSTRY EDUCATION

THREE PILLARS OF VALUE





To drive the translation of all cellular therapies for the benefit of patients worldwide.



# American Society for Blood and Marrow Transplantation

American Society for Blood and Marrow Transplantation is an international professional membership association of physicians, investigators and other healthcare professionals promoting blood and marrow transplantation and cellular therapy research, education, scholarly publication and clinical standards.

[www.asbmt.org](http://www.asbmt.org)



# The International NetCord Foundation

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 hematopoietic stem cell transplantation.

[www.netcordfoundation.org](http://www.netcordfoundation.org)

# Acknowledgements

- Eoin McGrath – EBMT/JACIE
  - Supports web site
- AHCTA Committee members
- Organizations for supporting efforts
- Christina Celluzzi, PhD - AABB
- Dietger Niederwieser, MD, Chair WBMT

[www.ahcta.org](http://www.ahcta.org)

