

# Overview of Standards Setting in HCT

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WBMT

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



# 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.

# AABB Standards and Accreditation Program

- Standards developed by committee of technical and clinical experts, ethicists, public members and external representatives (e.g., CIBMTR and NMDP)
- Public comment period
- Revised on a 24-month cycle
- Process for interim and emergent standards
- Policy to manage conflicts of interest

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



# Scope and Activity

- AABB Standards are broadly applicable to virtually any cellular therapy product
  - All aspects of procurement, processing, and transplantation
  - International transfer of products
- Continued evolution and expansion to address novel cellular therapies
- Clinical standards cover clinical use of these products and patient care

Activity	Number
HPC	83
CB	76
Somatic	7
Clinical	1
Applications pending	25

# 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

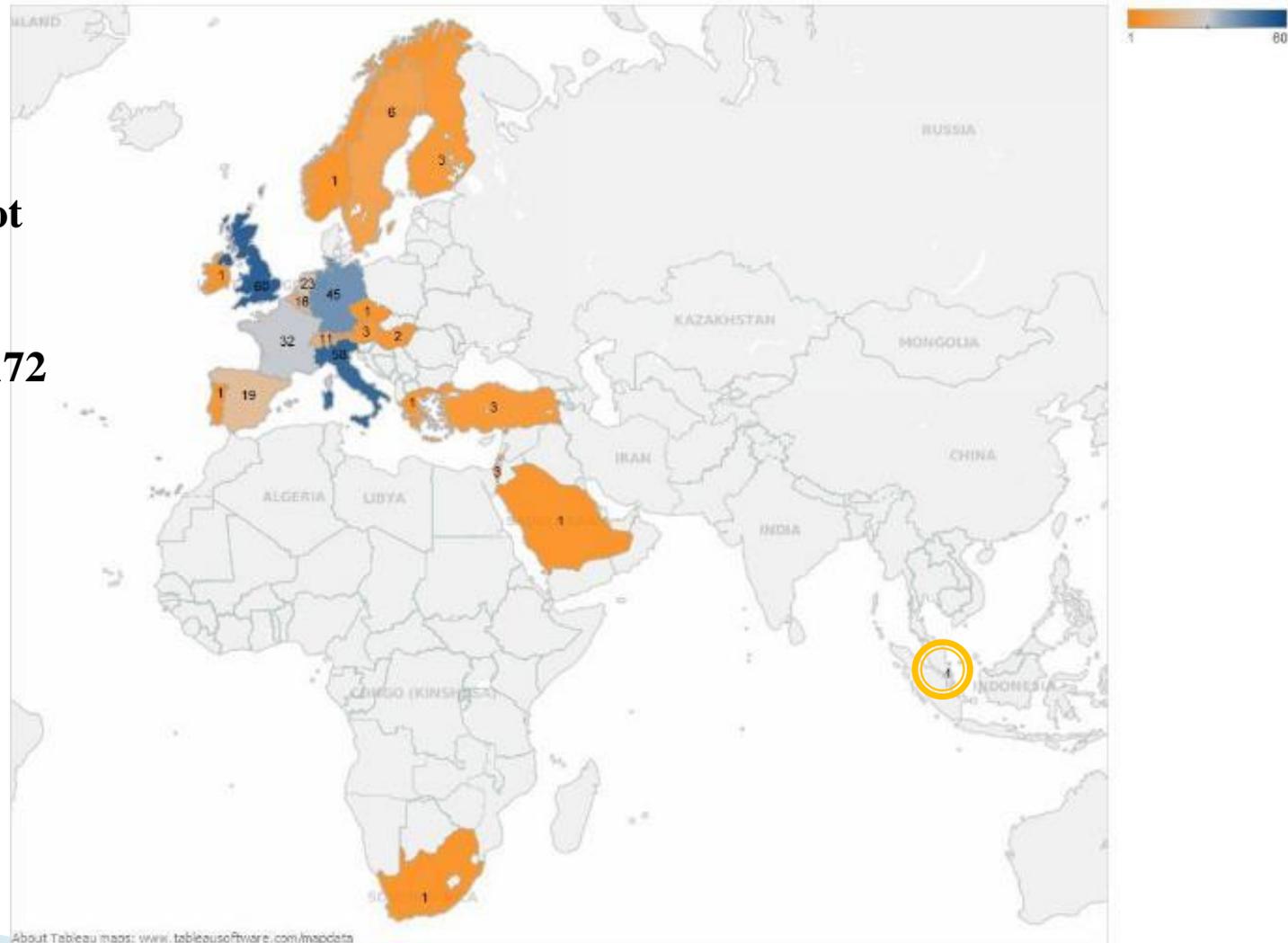
# JACIE



- Joint Accreditation Committee – ISCT & EBMT
- Established 1998
- Part of European Group for Blood & Marrow Transplantation (EBMT)
- Common standards with FACT
- Applications from over 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
- More information, visit [www.jacie.org](http://www.jacie.org)

# Total Initial Applications to JACIE by Country since 2000

Applications by country



## Accreditation Snapshot

Total applications since 2000: **322**

Facilities accredited\*: **172**

Countries: **23**

\*- valid today

# 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.
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# 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
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# 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

# **Alliance for Harmonization for Cellular Therapy Accreditation (AHCTA)**

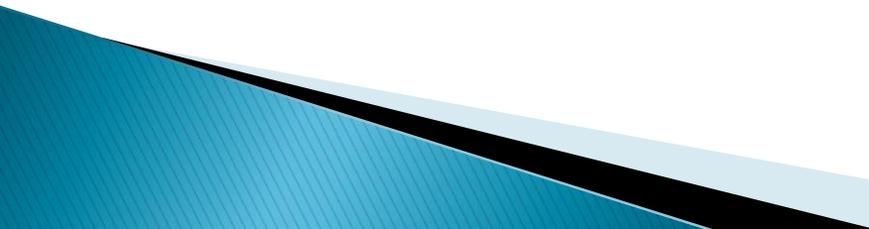
# WBMT Mission of AHCTA

## Committee of WBMT

Function is to recommend policies, programs, or actions in the area of any/all issues pertaining to regulatory and accreditation matters

Involves all aspects of cellular therapy related to recipient, donor, graft processing

# Member Organizations

- AABB
  - Asia Pacific Blood and Marrow Transplantation Group
  - American Society for Blood & Marrow Transplantation
  - American Society for Apheresis
  - 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
  - Latin American Society for Blood and Marrow Transplant
  - National Marrow Donor Program
  - World Marrow Donor Association
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# Aligns with Mission of WBMT

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



# Acknowledgements

- Eoin McGrath – EBMT/JACIE
  - Supports web site
- AHCTA Committee members
- Organizations for supporting efforts
- Committee members for work on numerous projects and resources (posted online and free)

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

