

# FACT International Standards & Accreditation

## FACT-JACIE & NetCord-FACT



January 4, 2007



# Foundation for the Accreditation of Cellular Therapy - FACT

- Co-founded in 1996 by:
  - American Society for Blood and Marrow Transplant
  - International Society For Cellular Therapy
- Purposes:
  - Establish and promote standards for quality medical and laboratory practice in hematopoietic progenitor cell transplantation and other cellular therapies
  - Implement voluntary inspection & accreditation program



# Joint Accreditation Committee EBMT- ISCT (JACIE)

- Established 1999
- Adopted FACT Standards 1999
- Joint inspector training 2000, 2001, 2002
- Joint review of 2002 FACT Standards (2<sup>nd</sup> Ed)
- Joint development of 3<sup>rd</sup> Edition Standards 2006

## Countries participating:

Austria	The Netherlands
Belgium	Norway
Denmark	Spain
Finland	Sweden
France	Switzerland
Germany	United Kingdom
Italy	



# FACT-JACIE International Standards

## Scope and Content

- Standards apply to:
  - Hematopoietic progenitor cells from any tissue source
  - Therapeutic cells (nucleated cells other than HPC)
- Cover all phases of collection, processing, administration (excluding collection and banking of cord blood cells)
- Require all clinical, collection and laboratory facilities to:
  - Develop and maintain a comprehensive Quality Management Plan
  - Evaluate and report outcomes
  - Comply with Applicable Law



# FACT-JACIE International Standards

## Third Edition - Significant Changes

- Restructured document to make sections (Clinical, Collection, and Laboratory) parallel.
- Expanded quality management throughout
- Regulatory requirements (FDA and EU Directive)
  - Label Tables including Biohazard and Warnings detailed
  - Core GTP, donor eligibility, documentation requirements
- Redefined numbers requirements:
  - Clinical - reduced number of autologous transplants
  - Collection and Laboratory – minimum numbers added
- Expanded requirements for pediatric competencies
- Incorporate recommendation for *ISBT128* terminology and labeling



# FACT and JACIE Accreditation

## » FACT

- Accreditation to date US and Canada; Australia - 2007.
- Australian Therapeutic Goods Administration adopted Collection and Laboratory FACT Standards (2<sup>nd</sup> ed)
  - Clinical Standards outside purview of the TGA
  - Children's Oncology Group requires FACT Accreditation – 2007

## » JACIE

- Standards identical (joint); accreditation separate.
- Accreditation process similar to FACT, not identical.
- In language of the applicant
  - More dependence on individual / regional inspectors



# FACT Accreditation

## January 2007

- Voluntary; based on written submissions, on-site inspection
- First accredited programs in North America – March 1998
- HPC Facilities registered 183 (~92%)
  - ACCREDITED 151  
(US and Canada)
- HPC Renewal Accreditations 109



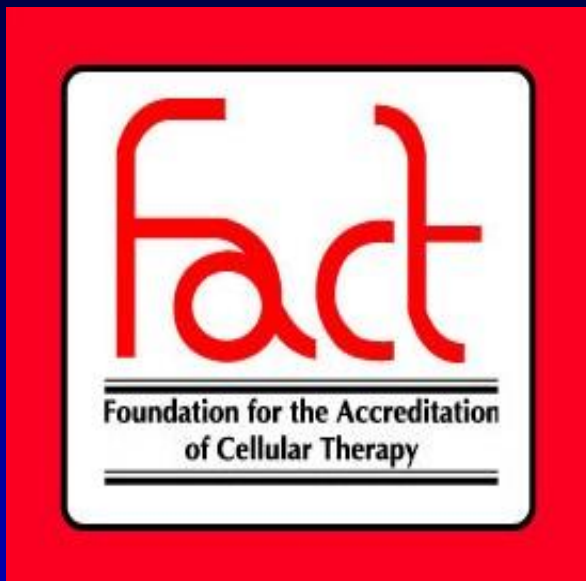
# JACIE Accreditation January 2007

- HPC Facilities registered 90
  - 12 Countries
- Facilities inspected 38
  - **ACCREDITED** 34
    - Australia, Finland, France
    - Italy, Netherlands, United Kingdom, Switzerland





# FACT: History



- *1996: FACT Standards for Hematopoietic Progenitor Cells*
- *2000: International Standards for Cord Blood Banking*
- *2002: International Inspection and Accreditation Program started*
- *2006: Third Edition of Standards published*

# The International NetCord Foundation

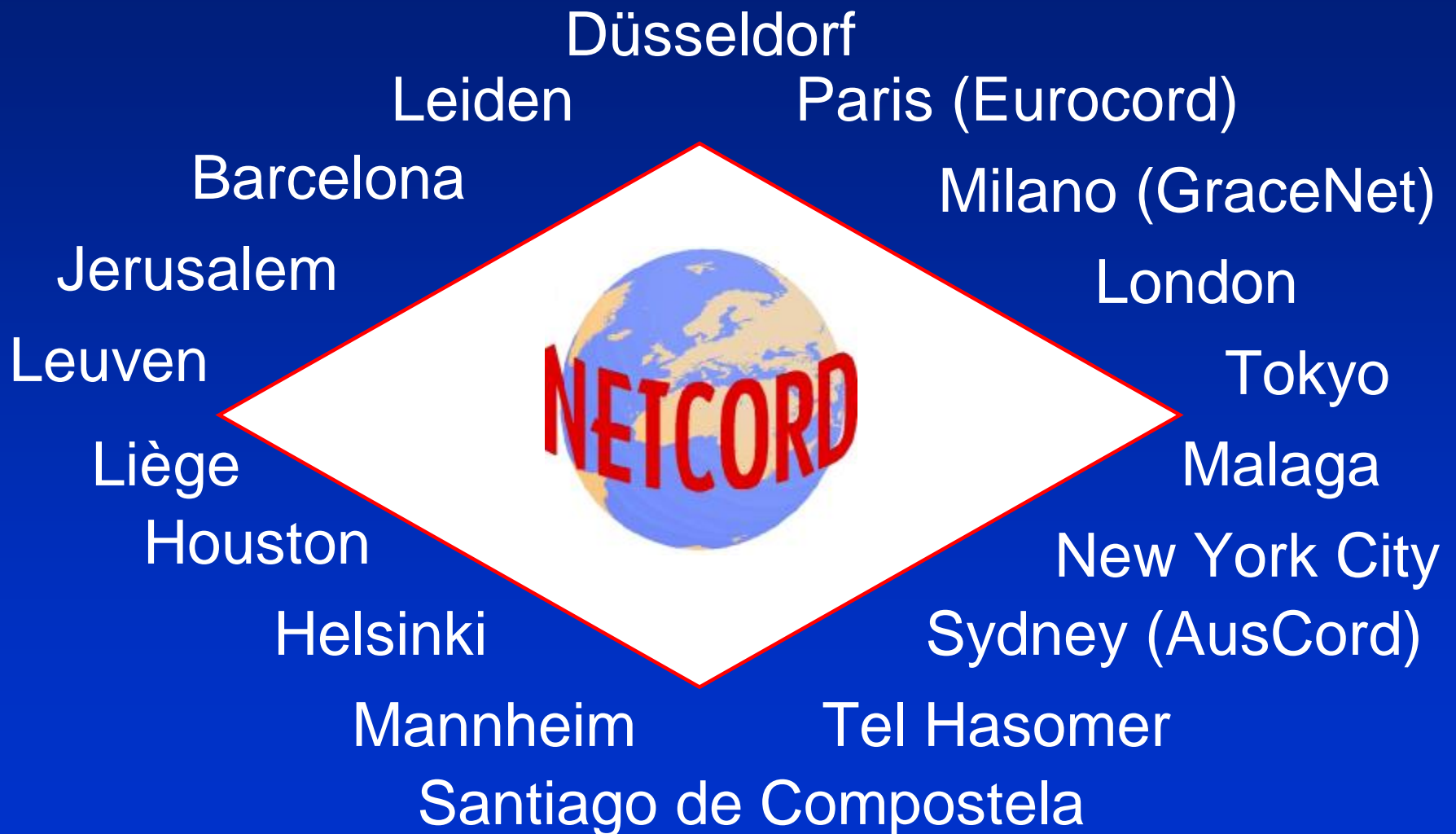
A Foundation of member cord blood banks established to globally unite supply and demand of umbilical cord blood and to construct and maintain world-wide standards and a system of quality approval in the area of umbilical cord blood.

CB inventory (October 2006) >124,000 units





# The International NETCORD Foundation



# NetCord-FACT Standards: Scope and Content

- Cover all phases of cord blood collection, processing, testing, banking, selection, release
- Require all cord blood banks to:
  - Maintain comprehensive Quality Management Program
  - Utilize validated methods, supplies, reagents, equipment
  - Maintain product tracking
  - Maintain details of clinical outcome
  - Comply with Applicable Law
- CBB must have a process to address every Standard



# NetCord-FACT Standards 3<sup>rd</sup> Ed, 2006

## Significant Changes

- Provisions for private (directed) banking:
  - Most Standards are identical – quality units required
  - Non-fixed collection sites, contracts with donor families, documented agreement of trained health care professional to perform collection
- Documented informed consent for collection (at least) required prior to collection
- Requirements in event of cessation of operations:
  - Maintain inventory, capacity to distribute
  - Document continued competency of staff prior to restart
  - Maintain contractual obligations with donor families



# NetCord-FACT Standards 3<sup>rd</sup> Ed, 2006

## Significant Changes

- Inclusion of QM / other standards to meet regulatory requirements – FDA, EU
  - Relevant GTPs, labeling
  - Donor eligibility determination, documentation
- Clarify testing requirements
  - Mat. ID testing required: HIV, HTLV, HCV, HBV, CMV, Syphilis
  - CB unit ID testing recommended
  - CB unit assays: NC, NRBC, viability, ABO/Rh, Microbial culture, HLA-A,B, DRB1 (HLA-C,DQB rec), hemoglobinopathy screen, CFU
- CB unit storage temperature < -150°C



# FACT-NETCORD

## Cord Blood Bank Accreditation

### January 2007

CBB Applicants 44

US, UK, Europe, Asia

**ACCREDITED 11**

**Non-US 7**

Additional inspected 7

Non-US 4





# FACT/NetCord Accredited Cord Blood Banks



- Banc de Cordó de Barcelona Barcelona, Spain
- Besançon Cord Blood Bank of the Etablissement Français du Sang Besançon, France
- Carolinas Cord Blood Bank Durham, North Carolina, USA
- The Finnish Cord Blood Bank Helsinki, Finland
- José Carreras Cord Blood Bank Düsseldorf, Germany
- Liege Cord Blood Bank Liege, Belgium
- London Cord Blood Bank Edgware, Middlesex, United Kingdom
- MD Anderson Cord Blood Bank Houston, Texas, USA
- Milano Cord Blood Bank Milano, Italy
- National Cord Blood Program New York, New York, USA
- StemCyte, Inc. Arcadia, California, USA





# Non-U.S. Cord Blood Banks In FACT-NetCord Accreditation Process

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- Sydney, New South Wales, Australia
- Melbourne, Victoria, Australia
- Tokyo, Japan
- Pavia, Italy

# FACT-NetCord Standards International Acceptance

- Eleven CBB inspected - US, UK, Europe, Asia
- **Italy**
  - NETCORD-FACT Standards translated into Italian 2002
  - Published by Istituto Superiore di Sanità for clinical guidance
  - Accepted as a recommendation by the Italian Ministry of Health



# FACT-NetCord Standards International Acceptance

- **Australia**

- Therapeutic Goods Administration, Office of Devices, Blood and Tissues, regulates CB under Australian code of GMP and NetCord-FACT Standards

- **WMDA** – voluntary organization to establish international guidelines for collection and transfer of hematopoietic stem cells

- Adopted NetCord-FACT Standards for CBB
- Deemed status for accreditation

- **AsiaCord**

- Adopted NetCord-FACT Standards



# Applicable International Regulations

- European and UK Banks licensed according to Human Tissue Act (2004) and EU Directive
  - UK: Human Tissue Authority (HTA) regulates and inspects
  - Banks are inspected generally every two years
  - Many started in national blood service or use these functions
- Germany – Cord Blood is regulated as a pharmaceutical, with “GMP” regulations and inspections.
- Finland – EU Directive and HTA apply.
  - CBB is part of Finnish Red Cross Blood Services; is also regulated and inspected by governmental National Agency of Medicines.



# Applicable International Regulations

- Australia – CBBs are inspected and licensed by the Therapeutic Goods Administration (TGA)
- Non-US CBBs test maternal serum for infectious diseases using kits and / or reagents that are “CE marked”. Often are the same tests as used for blood donor screening.
  - In some cases (Germany, Australia), CB must also be tested, although there is no test specifically approved for this use. Use the same tests/kits used for blood donors.
  - UK – kits are also evaluated by a “Kit Evaluation Group”
- May be additional tests required nationally – eg, Parvovirus 19 testing in Finland.



# International Accreditation Issues

- Language when CBB does not function in English:
  - Inspection issue and role of translations
  - Record retention issue
- Testing for diseases uncommon in a specific country or that is not part of the routine for normal blood donors
  - Eg – Finland - No NAT testing or HIV-Ag, CMV not routine
  - South Africa – do not want to test for HTLV
- Labeling differences, particularly the use of the Biohazard label.



# Contact Information

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