Implementing Standards Across International Borders The european experience

June 27, 2007

Foundation for the Accreditation of Cellular Therapy

JACIE joint accreditation committee isct-ebmt

Australian Government

Department of Health and Ageing

Therapeutic Goods Administration

JACIE: Joint Accreditation Committee of EBMT and ISCT

Ineke Slaper-Cortenbach
JACIE President and chair European LRA Committee

JACIE

- Founded in 1998 by EBMT and ISCT
- 63 audits since inspections began in 2004
- 20 countries represented on Board of National Representatives
- > 100 qualified inspectors: multiple languages
- European system of training of inspectors and quality management for centres
- Shared standards in Europe, North America, Australia

Aims /Role of JACIE

1.Accreditation of Individual Centres

- Assistance
- Inspection
- Certification

2.Information / Education

- QM courses
- Training courses
- Sample documents

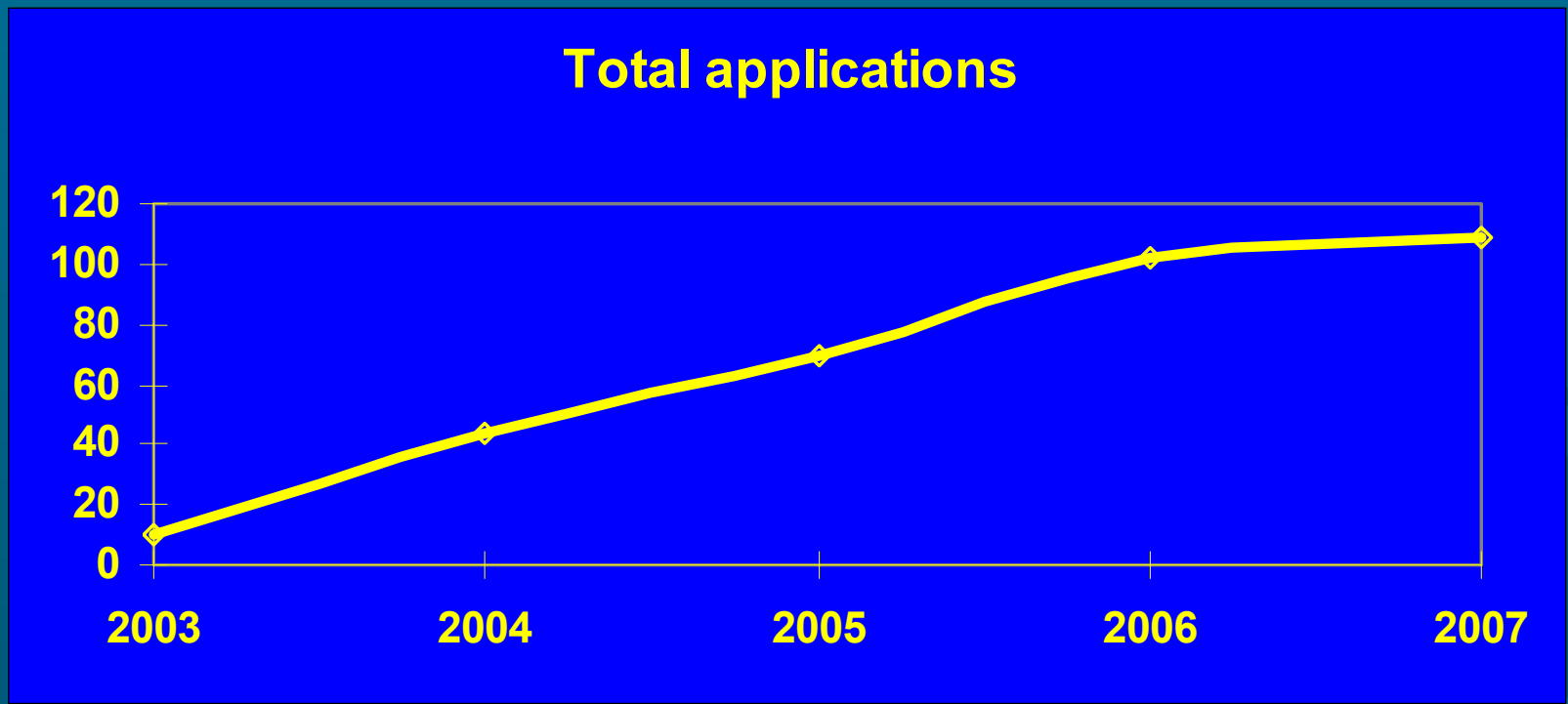
3.Regulatory Issues

- updating standards
- adjust to regulations
- International harmonisation

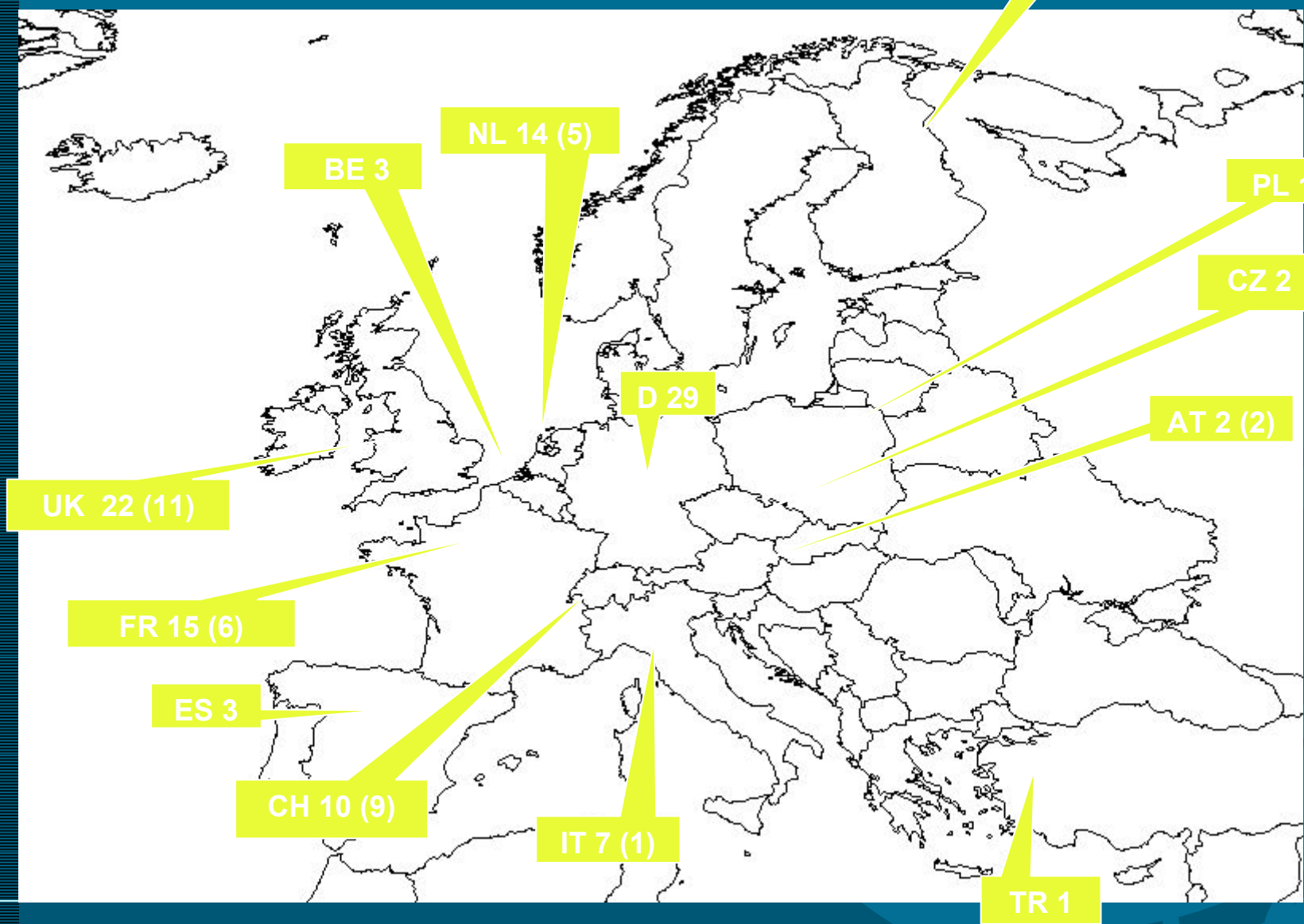
Current status (May 2007)

- Centres registered: **110**
- Centres in progress: **47**
- Centres inspected: **63**
- Facilities accredited: **36**
- Countries: **13**

Overall applications trend

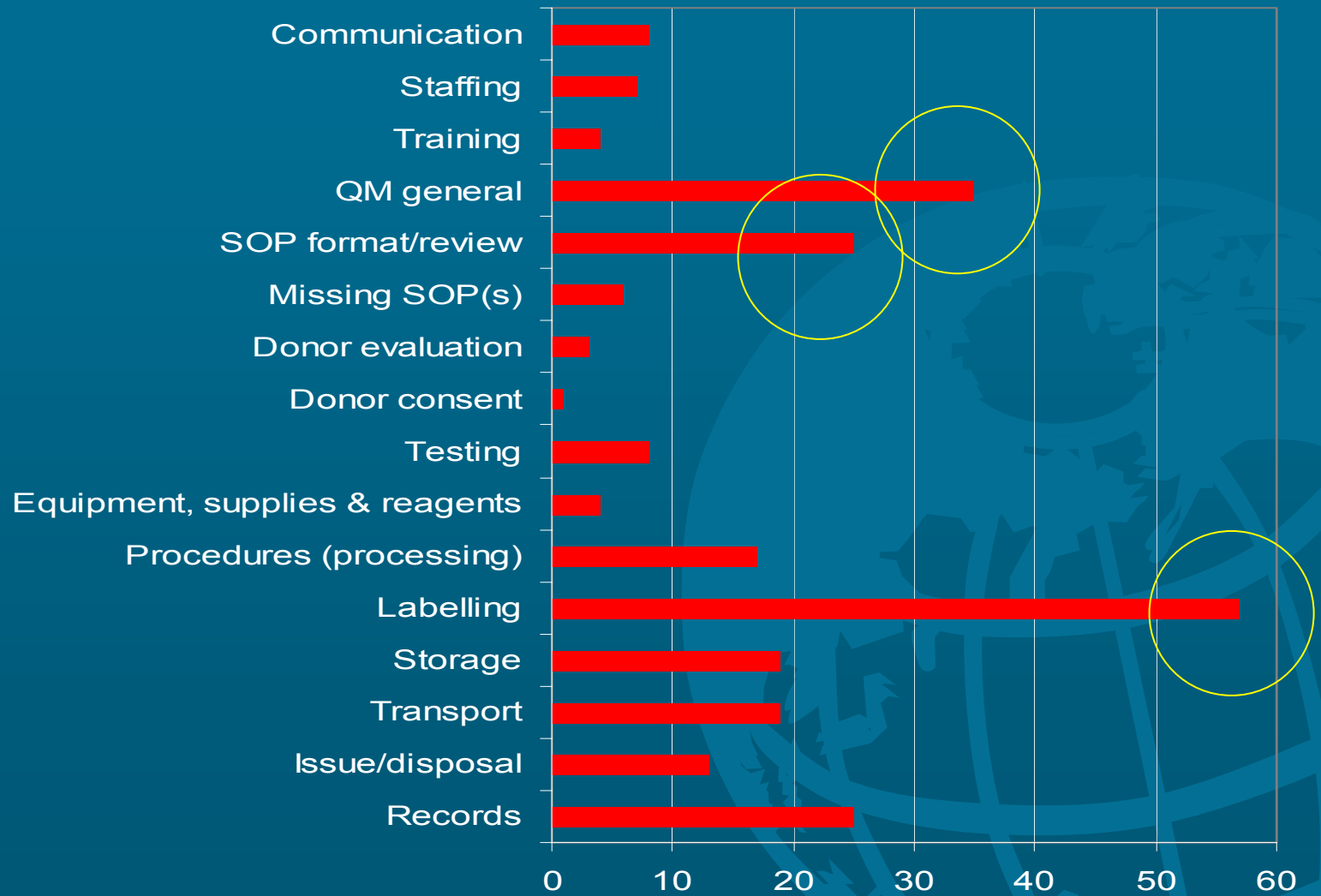


applications 110; accredited 36



Overview of deficiencies

Areas as % of total processing deficiencies



Challenges in inspecting HSC's in Europe

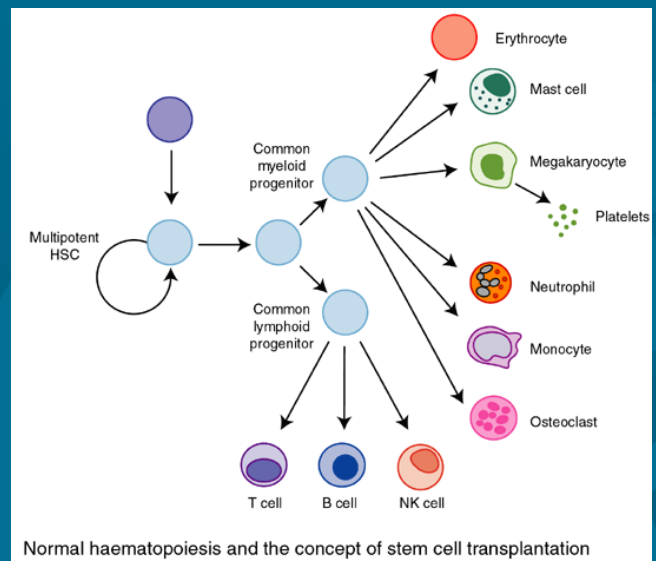
Challenges in inspecting HSC's

- The inspection of the total process
- The clinic not being used to stringent protocols
- Evaluation of the donor
- National/regional blood services v. hospital based apheresis
- Labelling
- Stand-alone lab & checking interaction with other parts
- Language differences
- Keeping inspectors trained
- compliance with european regulations

European Directive on quality and safety of tissues and cells

2004/23/EC: *Setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells*

- This Directive should apply to tissues and cells including *hematopoietic peripheral blood*, umbilical-cord (blood) and bone marrow stem cells, reproductive cells (eggs, sperm), foetal tissues and cells, and adult and embryonic stem cells
- It was published in the Official Journal of the European Union on April 7, 2004 and entered into force
- Implementation in Members States before April 7, 2006



Normal haematopoiesis and the concept of stem cell transplantation

2004/23/EC: *Setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells*

- This Directive *excludes:*
  - blood and blood products (other than Hematopoietic progenitor cells) These products are regulated in 2002/98/EC and 2004/33/EC;
  - Tissues and cells used as an autologous graft (tissues removed and transplanted back within the same surgical procedure and without being subjected to any banking;
  - Not applicable for research (animal studies) or for organs, tissues and cells of animal origin;
  - Organs or parts of organs if it is their function to be used for the same purpose as it functions in the human body.

Regulatory issues discussed with EU

March 9, 2006

- position of DLI
- Air quality: LAF cabinet in minimal class D background
- Import and export of cells
- A single European coding system

EUD on T&C and related EUD's

- 'Mother' Directive 2004/23/EC
  Effective April,7 2006
- Implementing Directive 2006/17/EC
  Effective Nov 2006
  - donation, procurement and testing of tissues and cells
- Implementing Directive 2006/86/EC
  Effective Sept 2007
  - traceability requirements
  - serious adverse reactions and events
  - coding, processing, preservation, storage and distribution of human tissues and cells

Regulations and proposals

- EU Directives in progress:
  - Import and Export of cells: 2008
  - Single European Coding System: september 2008
- Advanced Cell Therapy Proposal
  - Somatic Cell therapy (EUD 2001/83)
  - Gene Therapy (EUD 2001/83)
  - Tissue Engineering

EUD 2004/23/EC

('Mother Directive') Comparison with EU Directive 2004/23/EC
Draft Aug 17 2006
Requirements for HPC and TC
*will need to cross check against final version of FACT FACT-JACIE standards 3rd ed. for numbering and wording, and WMDA column to be updated

Highlighted in blue – questions.
Highlighted in yellow differences from FACT-JACIE standards

EU Directive 2004/23/EC on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells.		FACT-JACIE STANDARDS 3RD ED DRAFT FEB06 Section B Clinical and Donor Evaluation Section C Collection Facility		COMMENTS	To be updated WMDA STANDARDS-version December-15-2005	
Whereas:						
(1)	The transplantation of human tissues and cells is a strongly expanding field of medicine offering great opportunities for the treatment of as yet incurable diseases. The quality and safety of these substances should be ensured, particularly in order to prevent the transmission of diseases.		FACT-JACIE sets standards for quality and safety in all aspects of stem cell transplantation.	Consistent		WMDA sets standards for quality and safety as they related to the international exchange of hematopoietic stem cells. The standards include guidelines for health screening of donors to prevent transmission of diseases.
(2)	The availability of human tissues and cells used for therapeutic purposes is dependent on Community citizens who are prepared to donate them. In order to safeguard public health and to prevent the transmission of infectious diseases by these tissues and cells, all safety measures need to be taken during their donation, procurement, testing, processing, preservation, storage, distribution and use.		FACT-JACIE standards cover donation, procurement, testing, processing, preservation, storage, distribution and use	Consistent		WMDA standards cover health testing of donors, testing for histocompatibility, donation, international transport, and use. They do not cover processing and storage.
(3)	It is necessary to promote information and awareness campaigns at national and European level on the donation of tissues, cells		FACT-JACIE does not have a role in promoting information and awareness of donation but can assist by assuring safety of donation.	Consistent		WMDA supports registry activities that provide information and awareness of donation. WMDA standards ensure the anonymity of donors and donor

Role of JACIE in ensuring Quality Standards

- 3th version FACT/JACIE Standards are professional standards: developed and accepted by the profession
- International
- Standards take FDA & EU Directives into account and offer guidance to centres on compliance

Role of JACIE in ensuring Quality Standards

- JACIE-trained inspectors / ‘technical experts’
  - Inspections are carried out by native speakers
  - 2 day training course
  - Standard format
  - Emphasis on audit skills
  - Full-time experts / voluntary inspectors

Role of JACIE in ensuring Quality Standards

- Preparation and support of centres
  - Raising consciousness among the profession of importance of quality practice
  - Taking advantage of historically stronger quality culture in laboratories
  - Publication of a quality handbook for clinical transplant units/departments
  - Facilitiating knowledge/best practice exchange

Interaction of JACIE
& Competent Authorities (CA's)

- JACIE network of National Representatives in 20 countries
- Some countries where value of JACIE accreditation recognised by CA's or National Authorities (Switzerland, France, Spain, Italy, the Netherlands)
- JACIE represented through EBMT-CA contact group: France, Italy, Spain, United Kingdom plus other interested countries (Denmark, Germany)
- Contacts with WHO, Council of Europe
- JACIE as source of expert, international opinion on stem cell transplantation

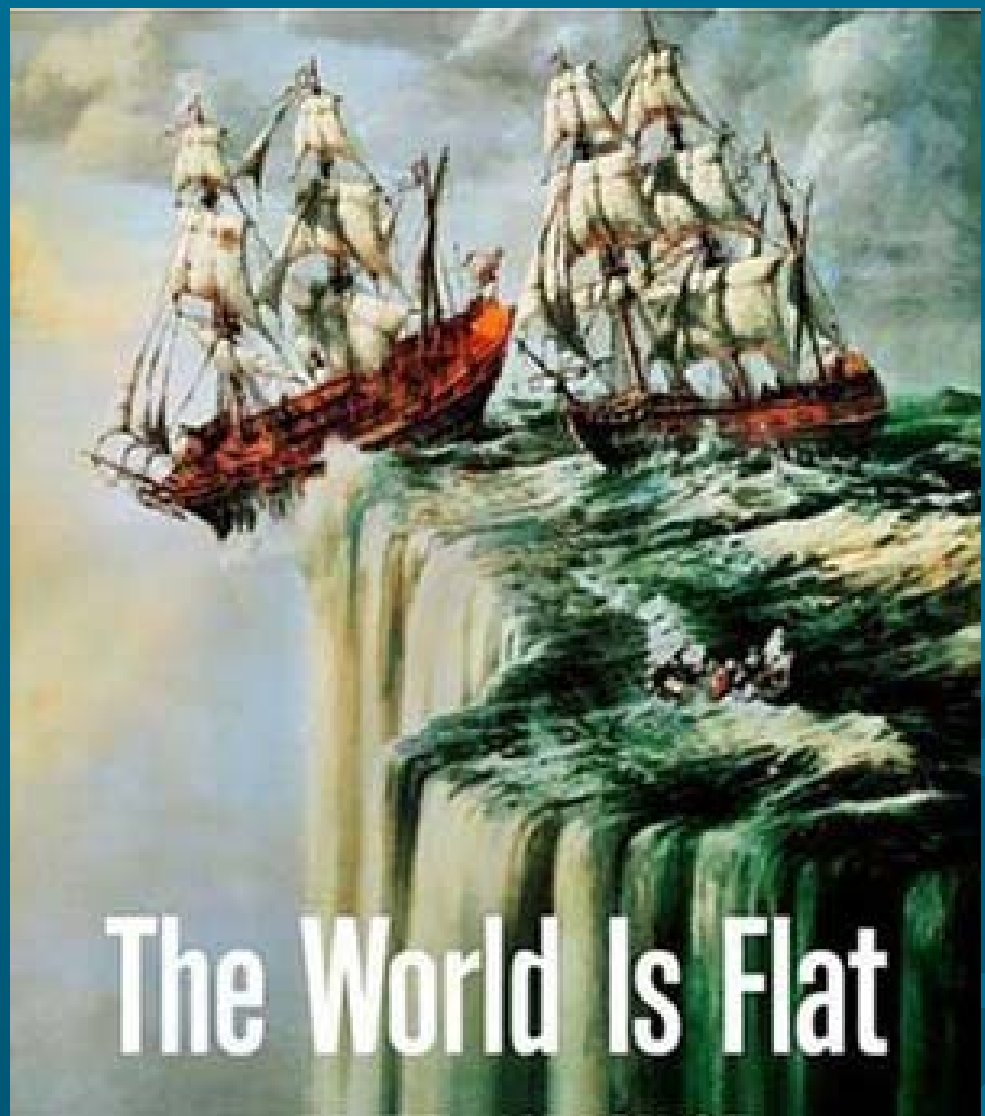
Role of JACIE in ensuring Quality Standards

Ongoing efforts to coordinate with international colleagues e.g.:

- Alliance for Harmonisation of Cellular Therapy Accreditation (AHCTA): www.ahcta.org
- Close cooperation with ICCBBA on Coding and labelling of cellular products: www.iccbba.com

Perspective on JACIE

- Designed to improve standards of health care
- Standards set by professional consensus / Peer review
- 3 year standards cycle
  - Flexible, can respond to changes in practice
  - Include regulatory issues into our own standards relatively rapidly
- Voluntary system in most EU countries
- Cost efficient, but still need support from EBMT
- Inspectors are working in the field
- Multiple language skills: inspectors and board members
- Currently in line with EU Directive on tissues & cells
- International cooperation with FACT a.o. in AHCTA


The World Is Flat