Report on the CTCLAG activities
A year end review 2010

Ineke Slaper-Cortenbach

i.slaper@umcutrecht.nl

Cellular Therapy Coding & Labeling Advisory Group

Second consensus statement

In 2005 the Boards of AABB, ASBMT, ASFA, EBMT, FACT, ICCBBA, ISBT, ISCT, JACIE, NMDP and WMDA issued a consensus statement in support of the use of *ISBT 128* in the coding of hematopoietic progenitor cell and other therapeutic cell products and announced the establishment of a co-sponsored International Cellular Therapy Coding and Labeling Advisory Group.

Since that time the Advisory Group has been meeting regularly and has established a well structured terminology for hematopoietic progenitor cells which has been adopted as the formal terminology in the accreditation standards of AABB, FACT, and JACIE. In addition a number of cellular therapy laboratories have implemented the *ISBT 128* Standard for coding and labeling of their products. The Asia Pacific Blood and Marrow Transplantation Group has recently joined the Advisory Group.

Recognizing:

- the need for a common and consistent means of coding and labeling for all cellular therapy products;
- the importance of globally unique identification for cellular therapy products as an essential element of effective traceability;
- the importance of an agreed common structured terminology to describe cellular therapy products;

ISBT 128
More than Identification

Second consensus statement

The Boards of the above organizations:

- acknowledge the substantial progress that has been made by the Cellular Therapy Coding and Labeling Advisory Group;
- encourage cell therapy facilities to move forward with the implementation of *ISBT 128* coding and labeling;
- request the Cellular Therapy Coding and Labeling Advisory Group to extend the terminology to cover non-hematopoietic cellular therapy products, working with other technical advisory groups as appropriate;
- encourage other relevant professional bodies, accreditation bodies, regulators and health authorities to support this drive for global standardization.

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Members of CTCLAG

Name	Affiliation
Slaper-Cortenbach, Ineke (Chairperson)	JACIE representative
Allman, Sallie	NMDP representative
Ashford, Paul	ICCBBA representative
Distler, Pat (Secretary)	ICCBBA representative
Janssen, William	ASBMT representative
Koh, Mickey	APBMT representative
Lankester, Alan	Technical expert
Larsson, Stella	Technical expert
Loper, Kathy	AABB representative
Miller, John	WMDA representative
Querol, Sergio	EBMT representative
Sims-Poston, Leigh	ISCT representative
Szczepiorkowski, Zbigniew	ASFA representative
Warkentin, Phyllis	FACT representative

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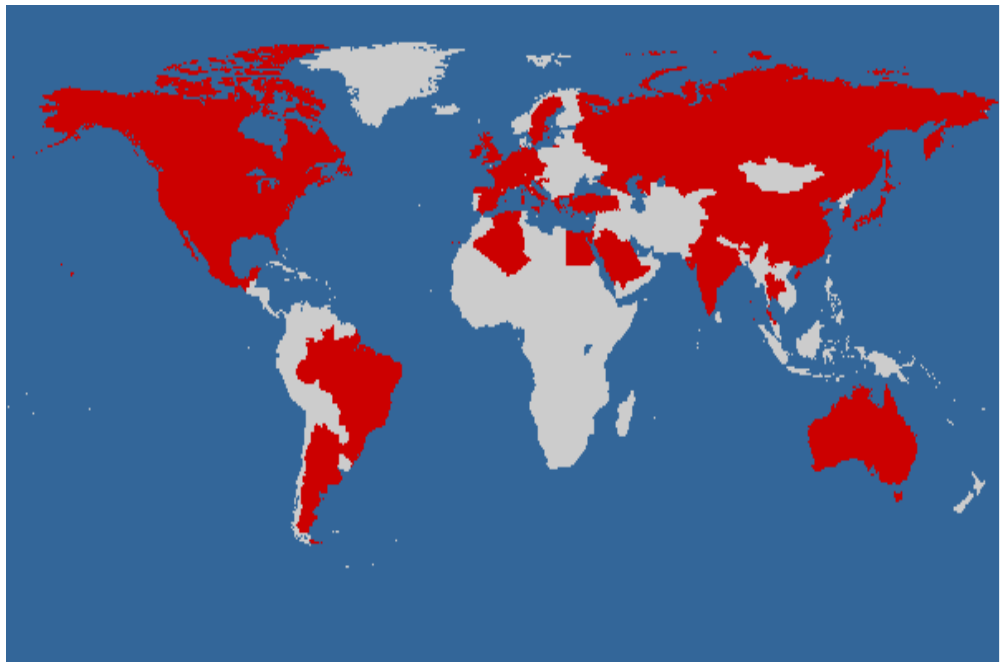
CT annual Report

During the five years since the inception of CTCLAG, a great deal of progress has been made.

- At the end of 2010, 262 active FINs assigned to Cellular Therapy Facilities in 38 countries
- In 2010: 57 new facilities **(22%)** registered



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Number of CT Facilities/country

Country	CT Facilities as of 31 December 2010	Country	CT Facilities as of 31 December 2010
Algeria	1	Japan	1
Argentina	1	Kazakhstan	1
Australia	3	Mexico	2
Austria	13	The Netherlands	2
Belgium	6	People's Republic of China	11
Brazil	20	Poland	21
Canada	11	Portugal	1
Croatia	1	Republic of China	4
Czech Republic	1	Russian Federation	3
Denmark	1	Saudi Arabia	2
Egypt	1	Singapore	2
France	5	South Korea	1
Germany	1	Spain	8
Greece	4	Sweden	1
India	1	Switzerland	2
Iran	1	Thailand	2
Ireland	1	Turkey	4
Israel	3	United Kingdom	8
Italy	2	United States of America	109

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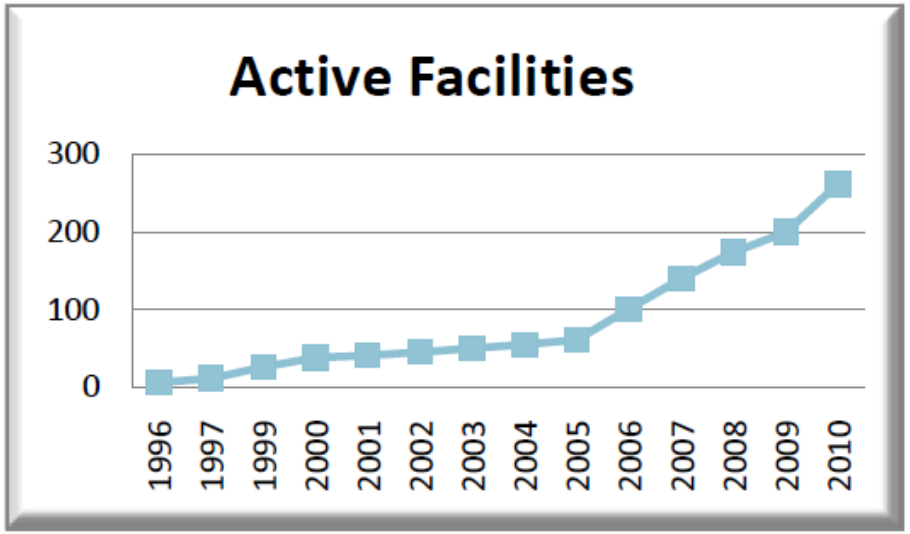
Number of CT Facilities



Guillaume Bouchet, from the cellular therapy facility, checking a HPC graft before distribution.

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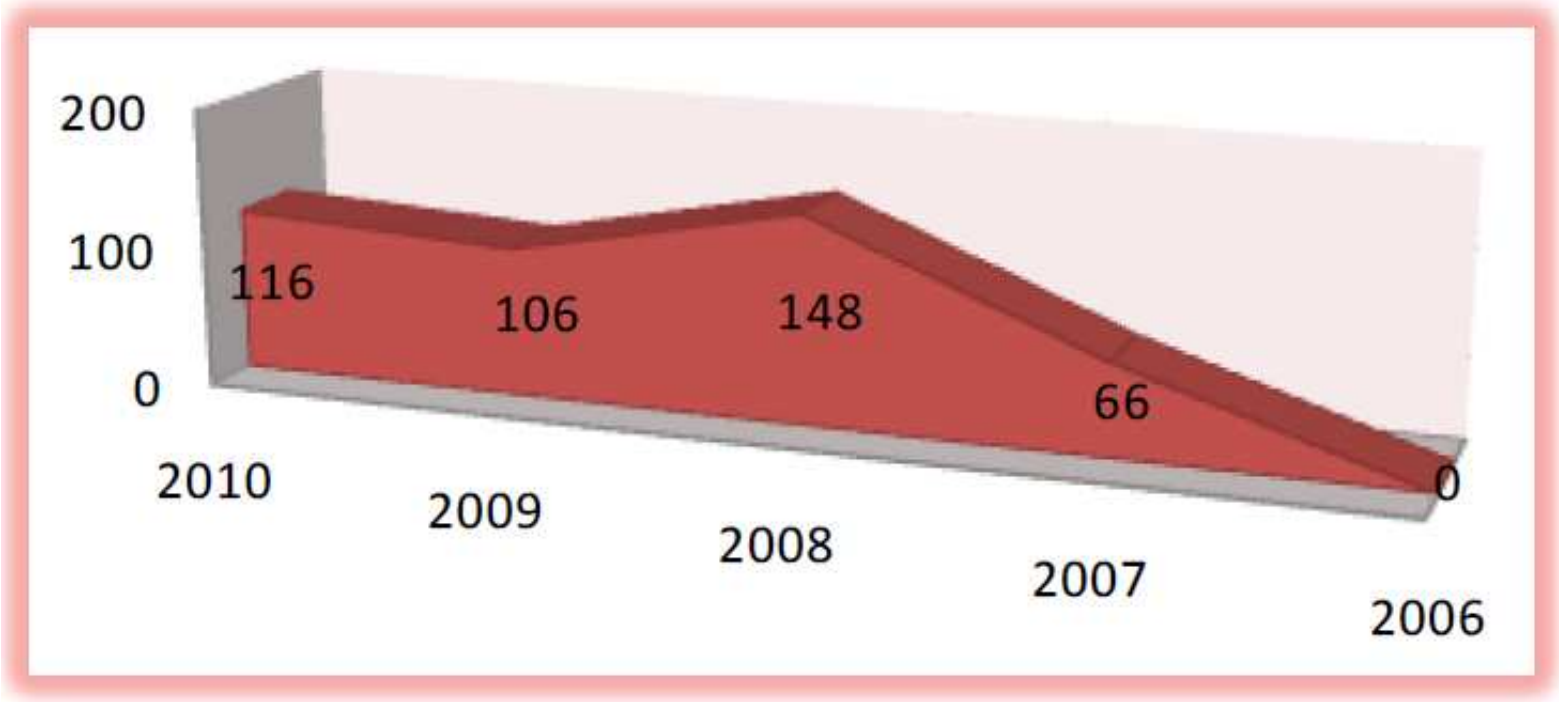
Number of CT product codes



Product codes requested by Canada, France, the Netherlands, Singapore, Scotland, Sweden & the USA

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Technical issues

- New class definitions
- Different sources for TC-MSC
- MUD products and anonimity.
- Tissue engineered products
  - Chondrocytes: starting material is tissue and processed material can be TC-chondrocytes, but end product will be engineered tissue
  - How to go forward?

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New Class Definitions:

- NC, Menstrual Blood: Nucleated cells collected from menstrual blood, with undefined therapeutic use at the time of collection.

- NC, Adipose Cells: Nucleated cells collected from adipose tissue, with undefined therapeutic use at the time of collection.

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Terminology

TC, Marrow (existing)	Bone marrow collected as a source of nucleated cells intended for therapeutic use other than HPCs.
TC, Adipose Tissue	Adipose tissue collected as a source of nucleated cells Intended for therapeutic use other than HPC.
TC, Cord Blood (existing)	Umbilical cord blood and/or placental blood collected as a source of nucleated cells intended for therapeutic use other than HPCs
TC, Wharton's Jelly	Mucous connective tissue of the umbilical cord collected as a source of nucleated cells intended for therapeutic use other than HPCs.
TC-MSC MD	A therapeutic cell product containing mesenchymal stromal Cells derived from the marrow for therapeutic use.
TC-MSC AD	A therapeutic cell product containing mesenchymal stromal cells derived from adipose tissue for therapeutic use. Adipose tissue derived.
TC-MSC CBD	A therapeutic cell product containing mesenchymal stromal cells derived from cord blood for therapeutic use.
TC-MSC WJD	A therapeutic cell product containing mesenchymal stromal cells derived from Wharton's Jelly for therapeutic use.

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Progress in implementation of ISBT 128 for Cellular Therapy

It was decided that:

- ISBT 128 terminology is mandatory for FACT-JACIE accredited facilities and for CT facilities accredited by AABB

- the ISBT 128 coding and labelling is for most CT facilities in an implementation phase;

- Implementation plan for ISBT 128 coding and labelling will be mandatory in the 5th version of the FACT/JACIE standards and in AABB

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Publications in 2010

Ashford, Paul. "Traceability." *Cell and Tissue Banking,* 2010, Volume 11, Number 4, Pages 329-333
http://www.springerlink.com/content/l8q785495x7t42w4/fulltext.pdf

Distler, Pat. "ISBT 128: A Global Information Standard." *Cell and Tissue Banking*, 2010, Volume 11, Number 4, Pages 365-373
http://www.springerlink.com/content/08ru28526212762g/fulltext.pdf

Sims Poston, Leigh. "ISBT 128 Labeling for Cellular Therapy Products" *Blood and Transplant Matters,* Spring 2010, Issue 30, Page 14
http://hospital.blood.co.uk/library/pdf/bm30.pdf

Slaper-Cortenbach, Ineke. "ISBT 128 Coding and Labeling for Cellular Therapy Products." *Cell and Tissue Banking,* 2010, Volume 11, Number 4, Pages 375-378
http://www.springerlink.com/content/65n1372431n0r711/fulltext.pdf

Slaper-Cortenbach, Ineke. "ICCBBA and ISBT 128 – Value for Money?" *Blood and Transplant Matters,* Spring 2010, Issue 30, Page 13
http://hospital.blood.co.uk/library/pdf/bm30.pdf

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