



agence de la  
biomédecine

**2005- 2006**

**Human embryo & embryonic stem cell  
research in France:**

**State of the art and analysis**

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Scientific and medical  
department

# **Embryo and embryonic cell research**

**Application decree**

## Sum up of the main parts of the law:

*(art. L. 2151-1 and following, Public Health Code)*

- Any kind of experiment on human embryo is forbidden by the law of 6<sup>th</sup> August 2004 (2004-08-06) (*art. L. 2151-2*)

- Any research with human embryo or hESC is forbidden (*art. L.2151-5 al. 1*)

✓ Principle in force since « les lois de bioéthique de 1994 » & maintained with the bioethics law (LBE?) of 2004

- 2 possibilities of « derogation » : studies & research projects

- 3 types of authorizations can be applied for:

✓ **studies or research** protocols (embryo, embryonic cells)

✓ **import / export**: embryonic or foetal tissues or cells

✓ hESC: **conservation/storage**

➤ « **Research** » **projects on human embryo and embryonic cells** (art. L. 2151-5 al. 3)

- « *major therapeutic progresses* » : especially research, the therapeutic aim of which is the treatment of:

- particularly serious or incurable diseases,
- affected embryos or foetuses

- (art. R. 2151-2) : besides the conditions of the art. L. 2151-5, the CEO of the Agence guarantees:

- the feasibility of the protocol and the durability of the organisation and its research team,
- the title, degrees, and experience of the team director,
- the research location, equipment, facilities, processes, techniques,
- the safety, quality, and traceability of embryos and cells

➤ **Authorisation (up to 5 years) given by the *Agence* after consulting the « Conseil d'Orientation », and taking into account:**

- the scientific pertinence of the project,
- feasibility and skills required in respect of the ethical principles of the LBE,
- its added value for public health.

## **Follow up of projects**

- Yearly report on the research progress and any modifications (*art. R. 2151-8*)
- yearly inspection

## **-2 registries** (*art. R. 2151-11*) :

- **1** local registry held by the organisation involved in the research
- **1** national registry held by the Agence de la biomédecine
  - ✓ Coded identification & embryos & ESCh made anonymous
  - ✓ Information required to ensure traceability, quality and safety

***The Agence de la biomédecine is a member of an European funded project of hESC registry***

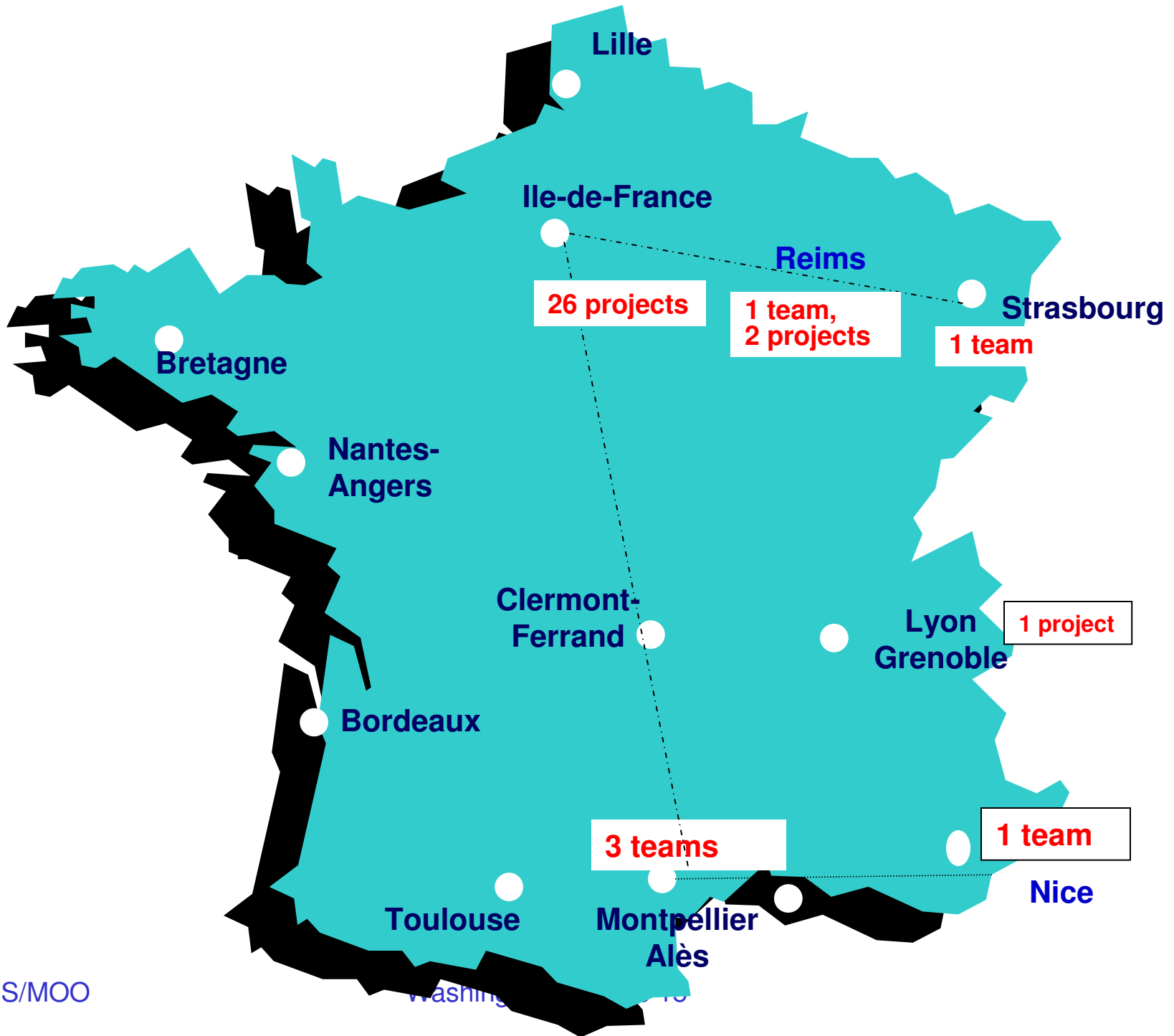
# Homonculus, the Little Man, 1694



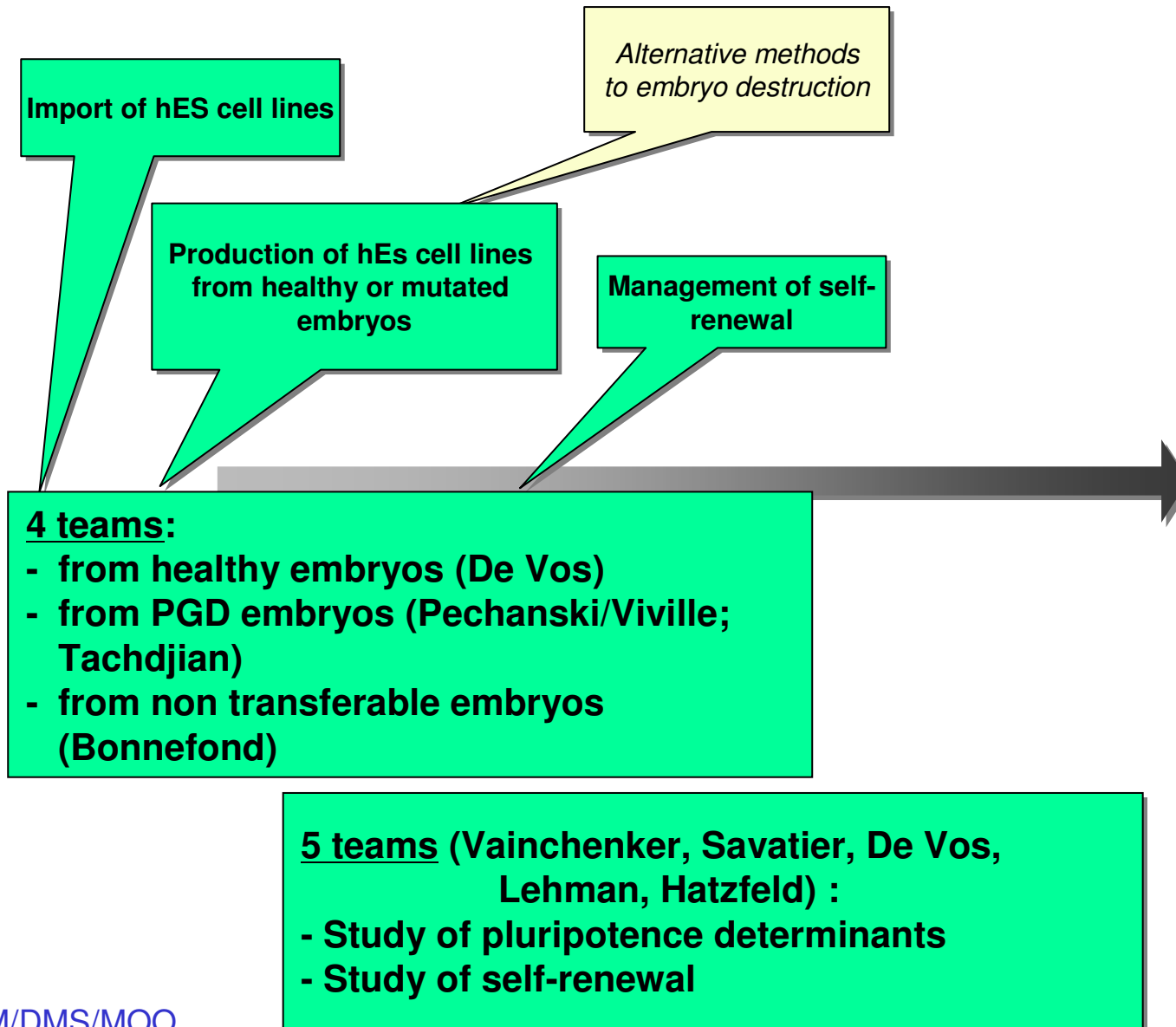
Nicolaas Hartsoeker  
Washington 2007 06 15

## Research licence for human embryos and embryonic stem cells

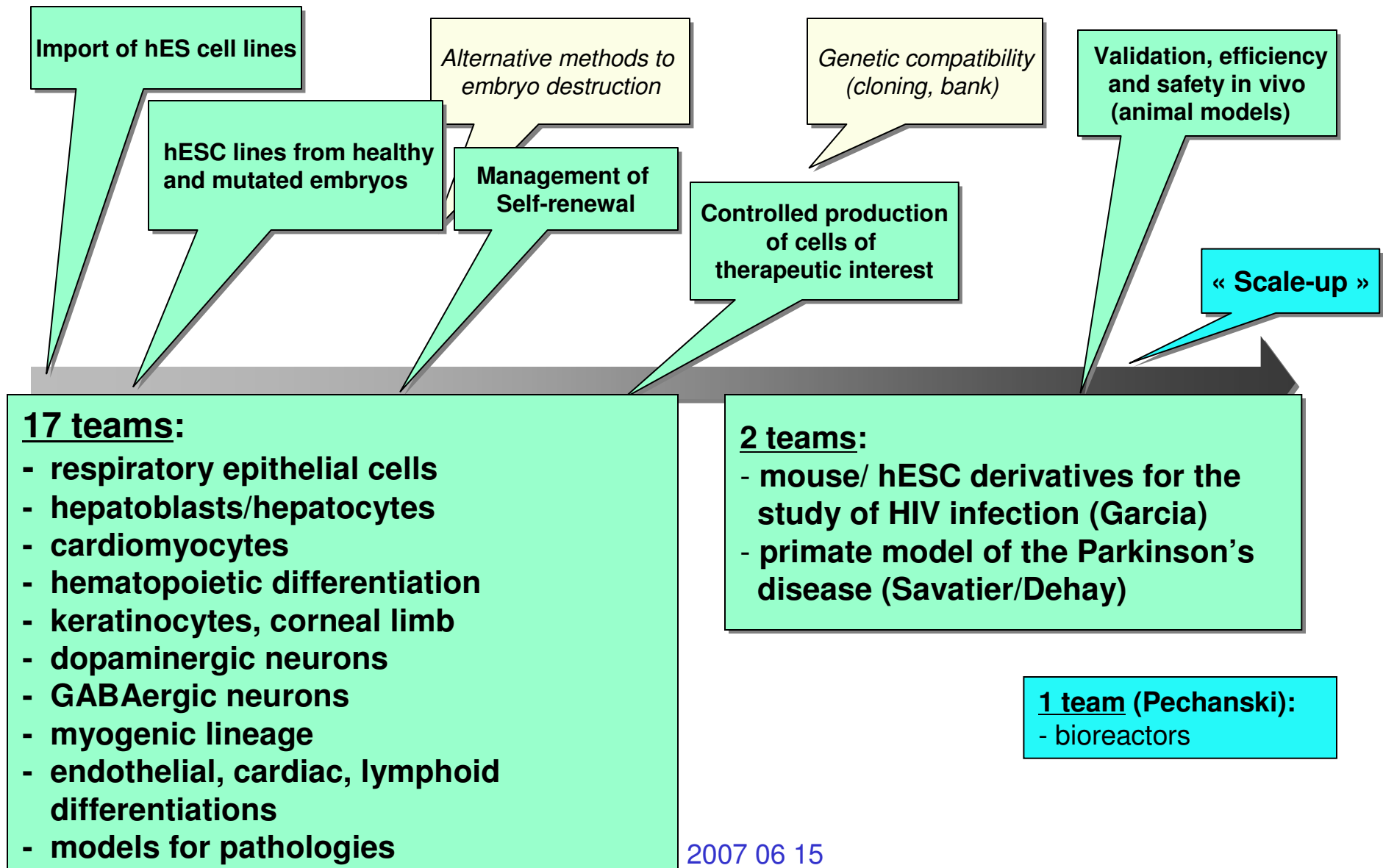
Agency	Total number	Number of teams	Directors
<b>INSERM</b>	<b>22</b>	<b>13(+4)</b>	<b>(Aberdam, Bonnefond, Coulombel, Bennaceur 2/Melki/Turhan/Tachdjian, Pechanski/Viville 6, Puchelle 2, Pucéat, Gherardi, Maurel, Onteniente, Savatier, Vainchenker 2; Weber</b>
<b>CNRS</b>	<b>3</b>	<b>3</b>	<b>Hatzfeld, Lehmann, Pucéat</b>
<b>CHU</b>	<b>2</b>	<b>1</b>	<b>De Vos/Hamamah</b>
<b>St-Louis Hospital</b>	<b>1</b>	<b>1</b>	<b>Larghéro</b>
<b>Univ. Paris VI</b>	<b>1</b>	<b>1</b>	<b>Douay</b>
<b>Pasteur Institute</b>	<b>1</b>	<b>1</b>	<b>Garcia</b>
<b>SME</b>	<b>2</b>	<b>2</b>	<b>AbCys, Mabgene</b>
	<b>32</b>	<b>22*</b>	



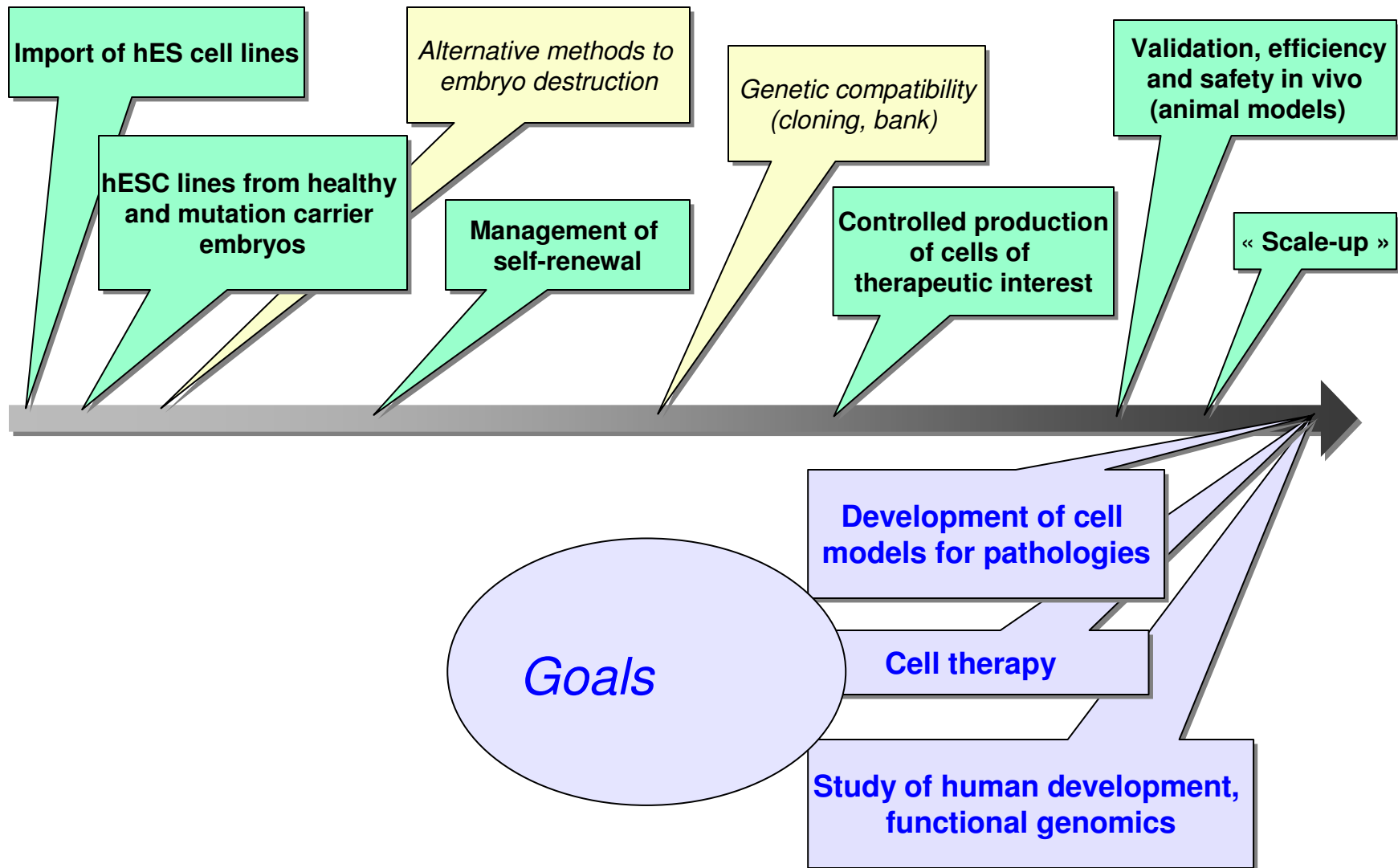
# Human embryonic stem cells research : How? What for?



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## A few remarks:

- A significant number of licence applications is granted and many teams are concerned

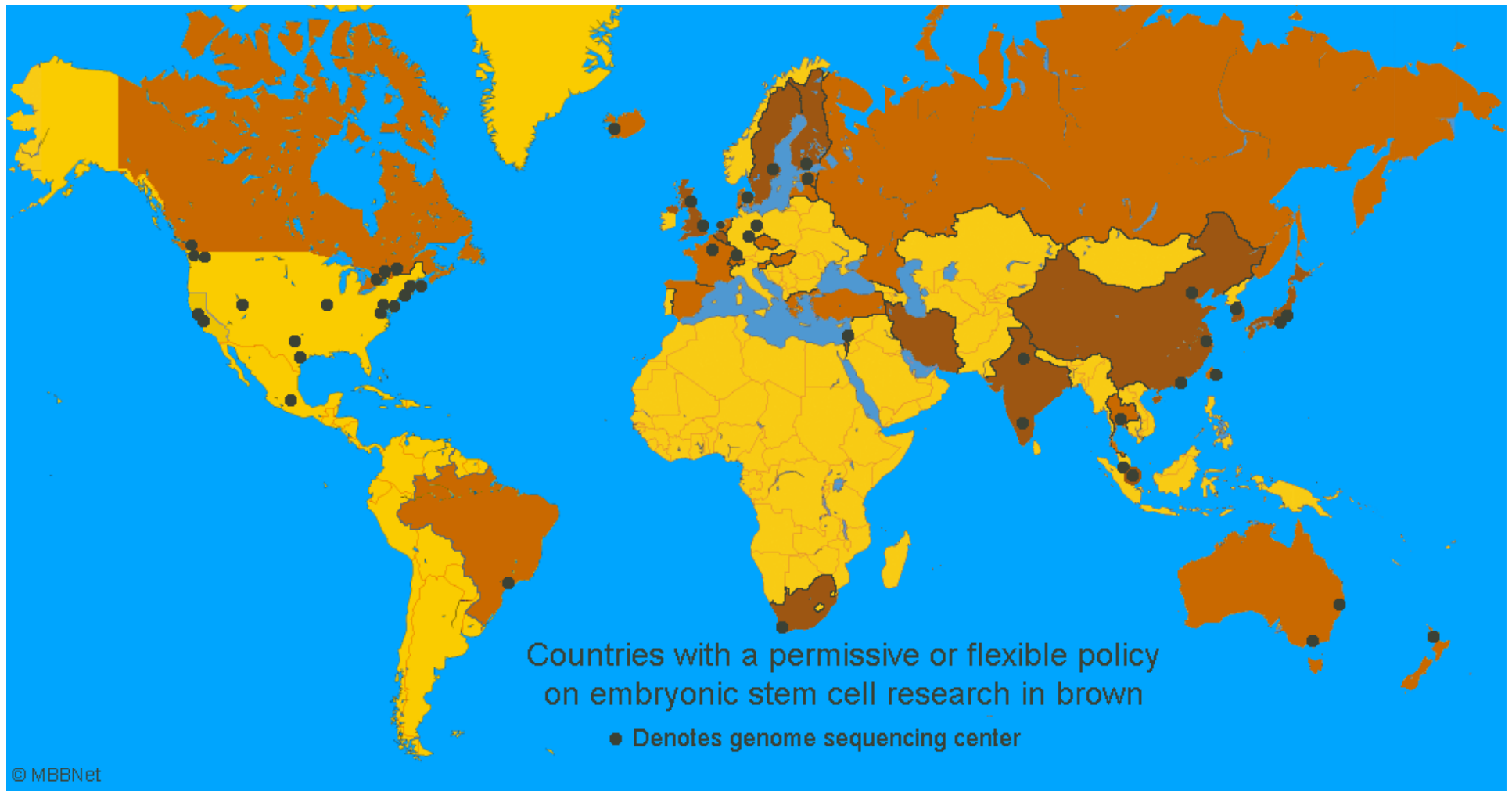
- projects oriented to therapeutic issues\* (effects of the law)
- only recently some few teams focused on epigenetics
- no project on the immunogenic capacity of hESC

*\*Consequences of a specific funding focused on adult stem cells  
INSERM 2001-2005: 3 Mi€ dedicated to projects and networks*

- What funding?

- Recurrent funding by universities and institutes, financial support from the European Commission,
- Charity funding, ex: AFM - 3 Mi€ over two years for hESC
- from regions and poles of competitiveness (ex: Medicen/Ingecell)
- Some funding but No real dedicated national support policy

# Stem Cell Research: Global Competition



<http://mbbnet.umn.edu/scmap.html>

Countries colored in brown represent more than 3.5 billion people, about half the world's population. All have banned human reproductive cloning.

## Comparison with neighbour countries

### France:

**2004-2006 : 32 research licences**

*(4 of which are intended for derivations)*

**Germany:** *more restrictive law, but genuine research support policy*

**- 20 licences for SC line imports and researches granted since 2002;**

**United Kingdom:** *HFEA, more permissive law, strong research support*

**33 projects 2001-2006 comprising:**

- 15 projects for derivations of new stem cell lines
- 2 projects of cell nuclear replacement
- 2 projects dedicated to parthenogenesis

*Estimated total investment: £80M-£100M*

## Experience gained after 2 years

- Authorisations :quite a complex and long process
- Knowledge and memory kept from the transitory year : 2005 as an apprenticeship
- Raising awareness to ethical and traceability issues of this research
- Leading to a « professionalization » of the researchers & key players of the domain (ex. INSERM)
- Some fragile or unforeseen points of the LBE/decrece :
  - *What framework applies to the differentiated derivatives of the hESC lines?*
  - *What rules for the banking of stem cell lines?*



ABM/DMS/MOO

Washington 2007 06 15

## Ad hoc committee 2004-2006: 14 import licences

### •AUSTRALIA

ES Cell International: **HE2S**

### •BELGIUM

Vrije Universiteit (Brussels): **IGOR ;DEMI;VUB05-HD; VUB06-WT**

### •UNITED-STATES

Geron Corporation: **H1; H7**

WiCell Research Institute: **(H1; H9 )2x;( H1; H7; H9; H13; H14) ; H9**

Harvard University: **HUES-1;HUES-2;HUES-3; HUES-4**

### •ISRAEL

Technion Israel Institute of Technology: **(H9;H 3; I3; I6);( H9;H13 I 3I 6)**

### •UNITED KINGDOM

UK Stem Cell Bank: **CF1**

### •SWEDEN

Cellartis AB: **Sahlgrenska 1(SA-01)2x**

## 2006: 10 applications for import licences

### UNITED-STATES

WiCell Research Institute:

**(H1; H9 , H14) 2x(Bennaceur, U602, U790, Pasteur);**

**(H1 H9)x2**

Harvard University: **HUES 1,2,3,7 (U602, U790, Pasteur)**

### Finland

**FES 21, 22, 29, 60;**

### ISRAEL

Technion Israel: **(H9;H 3; I3; I6)2x** (Pucéat, Larghéro, Mabgene)

(H1, 9, 14) : U602, U790, I. Pasteur



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