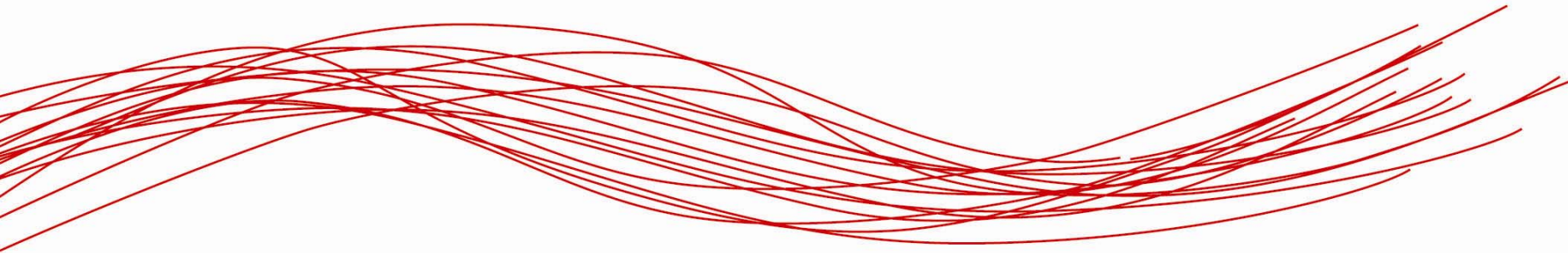


# EU Support for Stem Cell Research

EMA, London, 10 May 2010



**European Commission  
Research DG  
Charles Kessler**

# Outline of presentation

- **Main features of EU research programmes**
- **EU support to stem cell research**
  - ▶ Framework for support
  - ▶ hESC research
  - ▶ SME participation
  - ▶ Examples of projects
- **Future perspectives**

# FP7 Health Programme

- **Main Policy Drivers**

- ▶ Improving **health** of European **citizens**
- ▶ Increasing **competitiveness** of European health-related **industries** and businesses
- ▶ Addressing **global health** issues, including emerging epidemics

- **Scope**

- ▶ **Basic and applied** research, including **discovery** activities, **translational** research and early **clinical trials** (normally phase I and II, exceptionally phase III)

- **Budget**

- ▶ **€6.1 billion** over 7 years (2007-13) - EC manages about 6% of total EU public R&D spending



# EU research projects

- **Networks (min 3 countries; av 7 partners)**
- **Multidisciplinary**
- **Competitive calls for proposals, peer review**
  - ▶ Scientific excellence
  - ▶ Potential impact
- **Industry/SMEs**
- **75% funding for public bodies, SMEs; 50% others**
- **Third country participation**
- **Outreach/training/ethics/regulatory affairs, etc**

# Stem cell research in EU

- **Active research area relevant to our priorities; offers hope for incurable diseases; fast-moving field**
- **Uneven regulations on hESC research in MS**
- **EU programme can support hESC research subject to:**
  - ▶ Respect of national laws
  - ▶ Some exclusions, eg reproductive cloning, SCNT
  - ▶ Case-by-case scientific and ethical review
- **Evolving landscape**

# The hESCreg Europe Map of Human Embryonic Stem Cell Research



**Legend:**

- Total of hESCs provided
- Country 50
- hESCs currently available for research
- hESCs currently unavailable

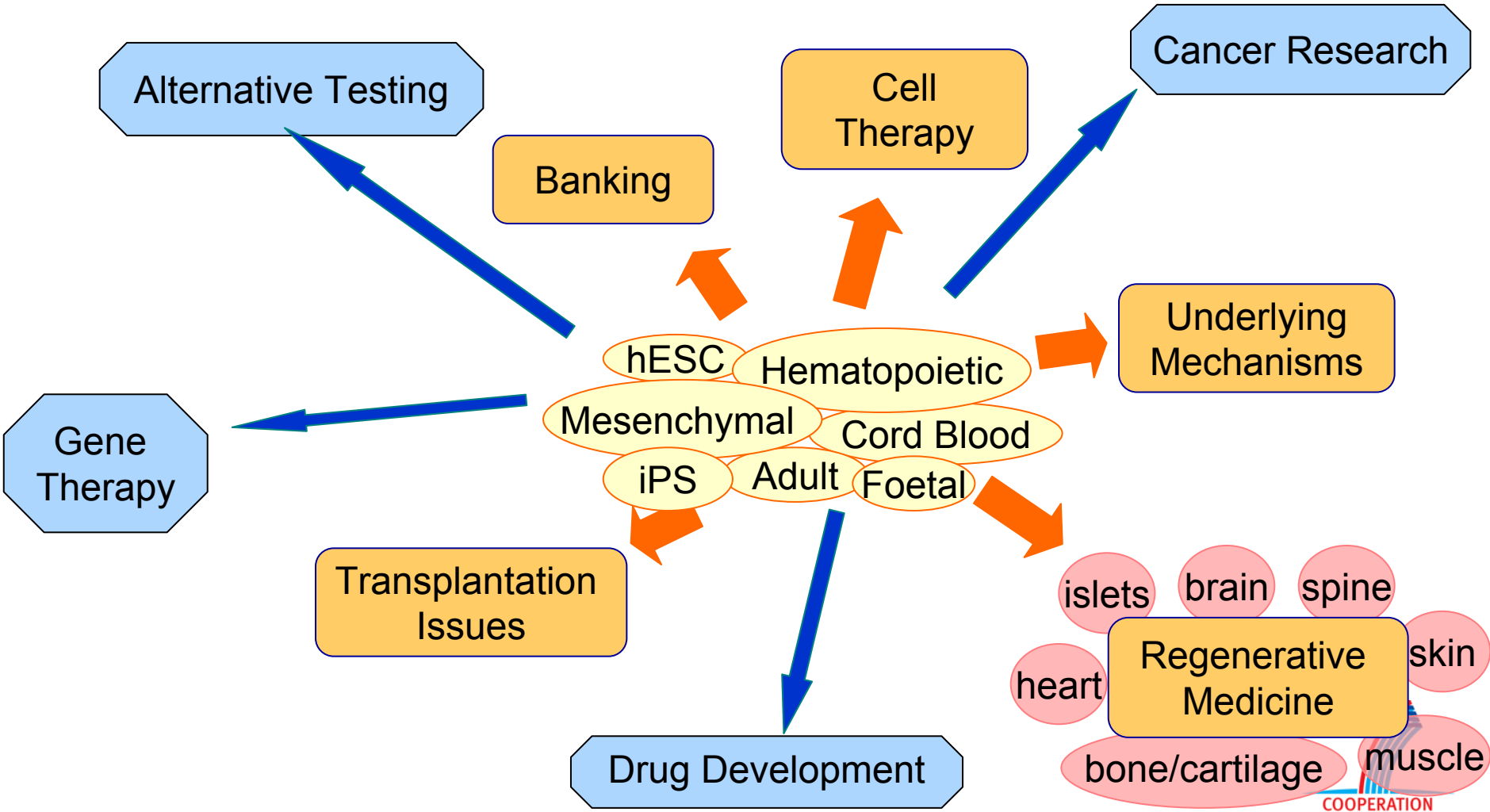
Source: hESCreg database, March 2009

# EU stem cell research projects FP7

(to May 2009)

● <b>Cooperation</b>	<b>27</b>
▶ Health	23
▶ NMP	3
▶ Socio	1
● <b>Ideas</b>	<b>31</b>
● <b>People</b>	<b>43</b>
● <b>TOTAL</b>	<b>101, approx €187 million</b>
● <b>hESC</b>	<b>16, approx €49 million</b>

# EU Stem Cell Research





# Examples of stem cell projects (FP7) I

## EuroStemCell portal:

- [www.eurostemcell.org](http://www.eurostemcell.org)

## Translation to the clinic:

- **OptiStem:** Optimization of stem cell therapy for clinical trials of degenerative skin and muscle diseases [www.optistem.org](http://www.optistem.org)
- **NeuroStemCell:** European consortium for Stem Cell Therapy for neurodegenerative diseases [www.neurostemcell.org](http://www.neurostemcell.org)



# Examples of stem cell projects (FP7) II

## Tool development

- **STEMEXPAND:** Stem Cell Expansion – Expansion and engraftment of haematopoietic and mesenchymal stem cells [www.stemexpand.eu](http://www.stemexpand.eu)
- **PurStem:** Utilisation of the mesenchymal stem cell receptor for development of uniform, serum-free culture conditions and tools for cell characterisation [www.purstem.eu](http://www.purstem.eu)
- **LIV-ES:** Development of culture conditions for the differentiation of hES cells into hepatocytes [www.liv-es.eu](http://www.liv-es.eu)
- **ESNATS:** Embryonic Stem cell-based Novel Alternative Testing Strategies [www.esnats.eu](http://www.esnats.eu)

# Regenerative medicine Call 3

(closed Dec 2008)

- **Strategy**

- ▶ Support in-patient work, paving the way for new therapeutic products
- ▶ Remove bottlenecks and expand knowledge of mode of action
- ▶ Boost European biotech industry, incl SME
- ▶ Large-scale integrated projects (€6-12 million each)

- **Topics**

- ▶ Cell therapy for tissue and organs
- ▶ Regeneration of tissue using bio-compatible materials & cells
- ▶ Activation of endogenous cells as an approach to regenerative medicine

- **8 projects supported – approx €90 million**

# Regenerative medicine Call 3

(closed Dec 2008)

## Proposals received:

● Bone and cartilage (incl. disc, tendon, tooth)	26
● Neuro (incl. Parkinson, Alzheimer, stroke, sci)	13
● Heart/Muscle	11
● Vascular	7
● Eye	3
● Kidney/liver	3
● Skin	2
● Diabetes	2
● Several conditions	3
● Other (eg, obesity)	4
<b>TOTAL:</b>	<b>74</b>
of which, <b>SME coordinated:</b>	<b>16</b>

# Regenerative medicine

## Calls 1, 2 and 3

- **Total 17 projects supported**
- **EU contribution: c. €134 million**
- **Coordinators: 10 univ, 7 govt lab**
- **35 SMEs, of which**
  - ▶ Cell culture/production, incl repository/bank 13
  - ▶ Biotherapeutics 10
  - ▶ Cell therapy companies 4
  - ▶ Implants/tissue engineering 5
  - ▶ Instruments/vectors 3

# Future perspectives (1)

- **Next call\*** (published before summer)
- **Special emphasis**
  - ▶ Clinical trials
  - ▶ SMEs
  - ▶ 2-step submission
- **Regenerative medicine**
  - ▶ HEALTH.2011.1.4.1 Regenerative medicine clinical trials
  - ▶ HEALTH.2011.1.4.2 Tools, technologies and devices for application in regenerative medicine
  - ▶ Both, up to €6 million, >1 project/topic

\*Pending approval

## Future perspectives (2)

- **Other possibilities for cell therapy\***
  - ▶ HEALTH.2011.2.2.1-1 Investigator-driven clinical trials for **childhood onset neurodegenerative** diseases
  - ▶ HEALTH.2011.2.2.2-1 Investigator-driven clinical trials for therapeutic interventions in the **elderly** populations
  - ▶ HEALTH.2011.2.4.1-1 Investigator-driven treatment trials for **rare cancers**
  - ▶ Up to €6 million, SME focus, >1 project/topic

\* Pending approval

# Information

## Health Research

[http://cordis.europa.eu/fp7/health/home\\_en.html](http://cordis.europa.eu/fp7/health/home_en.html)

Open information day Health research 8 June 2010 Brussels

[http://ec.europa.eu/research/health/events\\_en.html](http://ec.europa.eu/research/health/events_en.html)

Register as expert evaluator

<https://cordis.europa.eu/emmfp7>

New Therapies Catalogue

<ftp://ftp.cordis.europa.eu/pub/lifescihealth/docs/new-therapies.pdf>



# Conclusions

- **EU active in supporting stem cell research**
- **Research covers many applications but therapy is the most important**
- **We encourage projects to engage with regulators**
- **Getting to the in-patient trial stage is a bottleneck and we wish to explore ways this can be overcome**
- **Further opportunities, esp for clinical trials and SMEs**

# Thank you for your attention

[Charles.kessler@ec.europa.eu](mailto:Charles.kessler@ec.europa.eu)