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Stem Cell Research for Regenerative Medicine and Tissue Engineering NSF, 1-2 February 2007

**“EU support for stem cell and tissue
engineering research”**

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Brussels



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Outline

- **European Research Programmes**
- **EU support for stem cell and tissue engineering research**
 - Framework for support
 - Research situation regarding hESC
 - Examples of activities
- **Future perspectives**



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Why research at European level?

Pooling and leveraging resources

- Critical mass, leverage effect, big science

Human capacity and excellence

- International mobility, S&T capability, competition

Better integration of European R&D

- Pan-European policy challenges, coordination of national policies, comparative research, dissemination of results



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Seventh RTD Framework Programme (2007-2013)

- **European Research Council** (Ideas - €7,460 million)
- **Collaborative research** (Cooperation - €32,365 million)
- **Infrastructures, SMEs,** (Research Capacities - €4,217 million)
- **Human potential, science careers** (People - €4,728 million)

Reminder:

The European Commission currently manages about 5% of total public spending in R&D in the European Union.

The EU currently invests about 1.9% of GDP in research



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Collaborative Research

9 Thematic Priorities:

	€million
• Health	6,050
• Food, agriculture and biotechnology	1,935
• Information and communication technologies	9,110
• Nanosciences, nanotechnologies, materials and new production technologies	3,500
• Energy	2,300
• Environment (including climate change)	1,900
• Transport (including aeronautics)	4,180
• Socio-economic sciences and the humanities	610
• Security and space	2,780



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EU Research Projects

- **Networks (min 3 countries; average 7 partners)**
- **Competitive calls for proposals, peer review**
- **Scientific excellence**
- **Potential impact**
- **Industry/SMEs**
- **Third country partners**
- **Up to 75% funding from EU (was 50%)**
- **Special actions for mobility, SMEs, etc**



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Collaborative research in Health

Main policy drivers:

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



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Collaborative research in health

Activities in three main areas:

- **Biotechnology, generic tools and technologies for human health**
- **Translating research for human health**
- **Optimising the delivery of healthcare to citizens**



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Stem cell research in EU

- **Active research area relevant to our priorities**
- **Uneven regulations governing hESC research in Member States:**
 - Cannot derive but can import (DE, IT);
 - Allow derivation of hESC from supernumerary IVF embryos (DK, EL, ES, FI, FR, NL), and
 - Allow somatic cell nuclear transfer (BE, SE, UK);
 - Some research, no specific law (EE, HU, LV, SL);
 - No regulation (CY, CZ, IE, LU, PT; AT, LT, MT, PL, SK).
- **EU has no legal competence to regulate this sector**
- **Respect of national rules is fundamental principle**
 - No research forbidden in a MS supported by EU there



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hESC research in FP6/7 (1)

Ethical Framework:

- **3 areas excluded from EU funding:**
 - Human reproductive cloning
 - Germ line gene therapy
 - Creation of human embryos for research and for SC procurement, eg by Somatic Cell Nuclear Transfer
- **hESC research can receive EU funds provided the cells are derived from supernumerary embryos**
 - In line with many countries in EU and world-wide



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hESC research in FP6/7 (2)

Implementation:

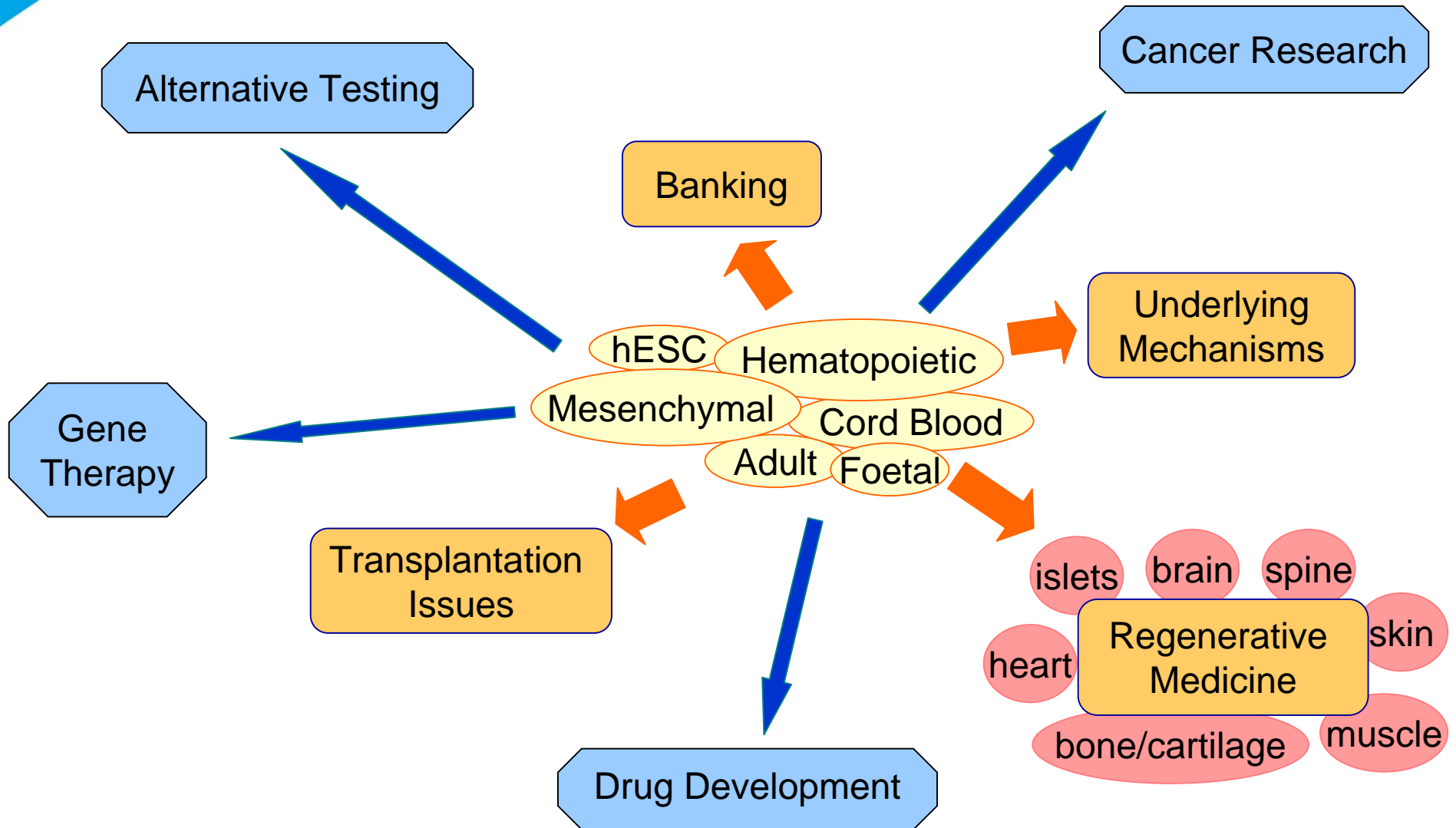
- **Case-by-case evaluation**
 - Must be scientific justification (ie non-trivial)
- **Approval by relevant national or local ethics committee**
- **Ethical review at EU level to assess:**
 - Respect of national laws
 - Informed consent
 - Source of lines
 - Protection of personal data
 - Nature of financial inducements, if any
- **Approval by regulatory committee (ie Member States)**



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Stem Cell Research in FP6





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Examples of EU Stem Cell Projects

European Consortium for Stem Cell Research

www.eurostemcell.org

Adult mesenchymal stem cell engineering for connective tissue disorders www.genostem.org

Immunotherapeutic strategies to treat haematological and neoplastic diseases with optimised allogeneic stem cell transplantation

www.allostem.org

Functional Genomics in Embryonic Stem Cells

www.fungenes.org

Novel approach in hazard and risk assessment or reproductive toxicity by in vitro, tissue and sensor technologies

www.reprotect.eu



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Examples of EU Tissue Engineering Projects

Soft tissue engineering for congenital birth defects in children www.eurostec.eu

A systems approach to tissue engineering processes and products www.stepsproject.com

Osteocord – osteogenic induction of MSCs from umbilical cord blood www.bonefromblood.org

Beta cell programme for treatment of diabetes www.betacelltherapy.org

Three-dimensional reconstruction of human corneas by tissue engineering www.cornea-engineering.org



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EU Stem Cell Projects

General features

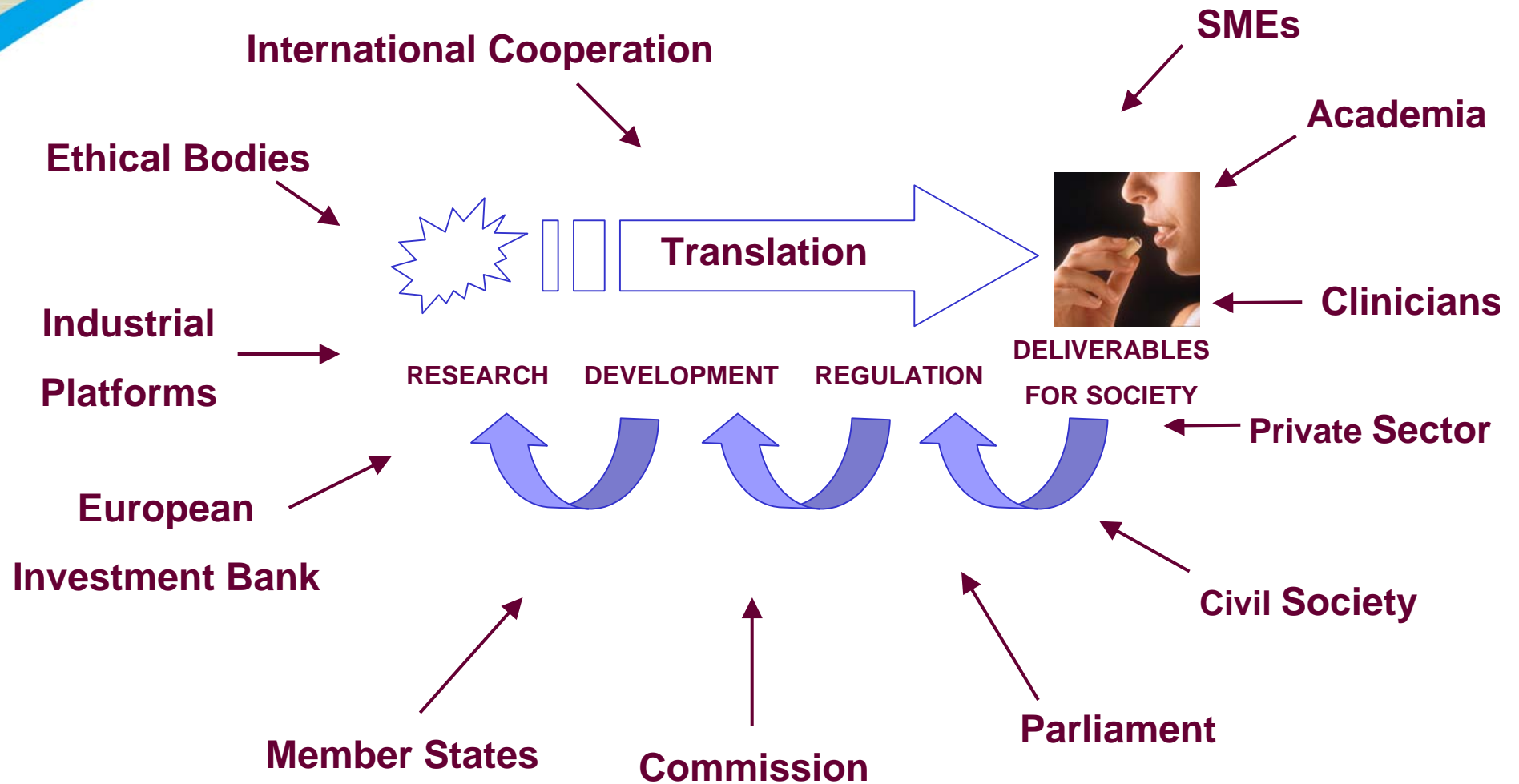
- **Project approaches**
 - Disease driven
 - Generic approach/tool development
 - Underlying biology
- **Comparison of SC sources**
- **Some research involving hESC**
- **Knowledge needed to illuminate debate**
- **Area in which EU added value is clear**



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Success will depend on mobilisation of all actors





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Tissue engineering and stem cell research topics in current calls for proposals

Deadline 4 May 2007:

- **NMP-2007-2.3-1 Highly porous bioactive scaffolds controlling angiogenesis for tissue engineering**

Deadline 18 September 2007:

- **Health-2007-1.4-6 Stem cell lines for cell-based therapies**
- **Health-2007-1.4-7 Development of stem cell culture conditions**
- **Health-2007-1.4-8 Stem cells for kidney regeneration**
- **Health-2007-2.4.2-5 Cell therapies for the treatment of heart ischemia**



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Advanced therapies regulation

Proposes

- **EU-wide rules for:**
 - Gene,
 - Cell, and
 - Tissue-based therapies
- **Centralised marketing authorisation procedure**
- **Currently in discussion in European Parliament**
- **<http://ec.europa.eu/enterprise/pharmaceuticals/advtherapies/index.htm>**



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Further information

- **FP7**

<http://cordis.europa.eu/fp7/>

- **Stem cells**

http://ec.europa.eu/research/fp6/index_en.cfm?p=1_stem_home

- **Become an evaluator**

<https://cordis.europa.eu/emmfp6/index.cfm?fuseaction=wel.welcome>



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Thank you for your attention!

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