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REMEDiE Project  
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# **“European Policies and Priorities for Stem Cell Research”**

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# Outline of presentation

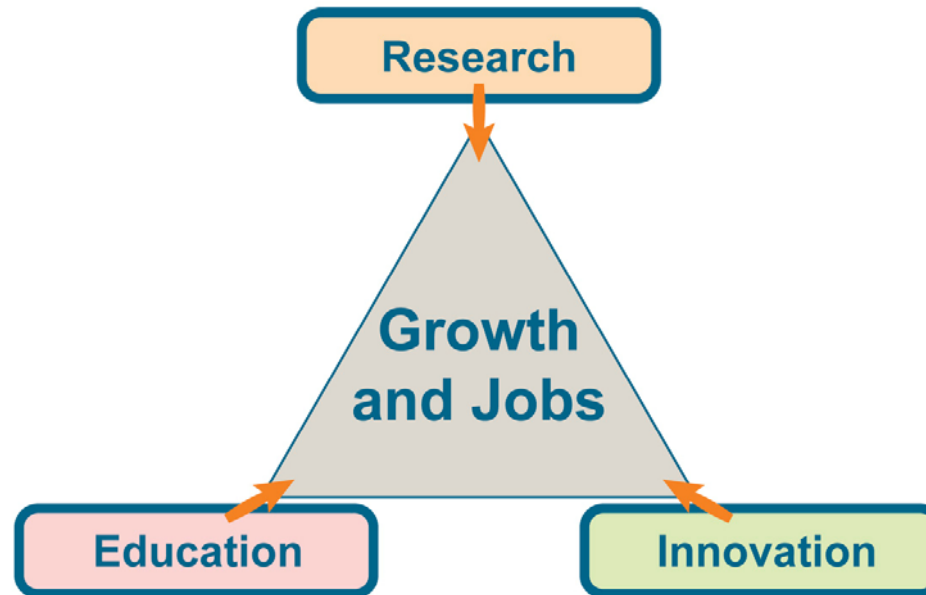
- **Main features of EU research programmes**
- **EU support for stem cell research**
  - Framework for support
  - hESC research
  - Examples of projects
- **New opportunities**



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# Lisbon strategy



S&T contributes to the **Lisbon** objectives: economic **growth**, **employment** creation, **environmental** protection, **social** challenges: fight **poverty**, improve human **health** and **quality** of life



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# Seventh FP: main elements

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



## *Cooperation - 9 Thematic Priorities*

Million Euro

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



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# Collaborative research in Health

## Three main areas:

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



# EU Research Projects

- **Networks (min 3 countries; average 7 partners)**
- **Multidisciplinary**
- **Competitive calls for proposals, peer review**
- **Scientific excellence**
- **Potential impact**
- **Industry/SMEs**
- **Up to 50% funding from EU (75% SMEs, public bodies)**
- **Special actions for mobility, SMEs, etc**
- **Third country participation**
- **Outreach/training/ethics/etc, esp in IPs**

# Stem cell research in EU

- **Active research area relevant to our priorities that cannot be ignored**
- **Uneven regulations governing hESC research in MS, eg:**
  - Cannot derive but can import hESC lines (DE, IT);
  - Allow procurement of hESC from supernumerary IVF embryos (CZ, DK, EL, FI, FR, NL, PT), and
  - Allow somatic cell nuclear transfer (BE, ES, SE, UK);
  - Embryo research legislation, not specifying hESC (HU, SI);
  - No specific hESC research regulation (BG, CY, EE, IE, LU, LV, PT, RO; AT, LT, MT, PL, SK).
- Moving field

*Source EGE Opinion 22*





# hESC research in FPs

- **EU has no legal competence to regulate this sector**
- **Respect of national rules is fundamental principle**
- **EU has responsibility to implement FP and to set up clear rules/conditions for Community funded research raising ethical issues**

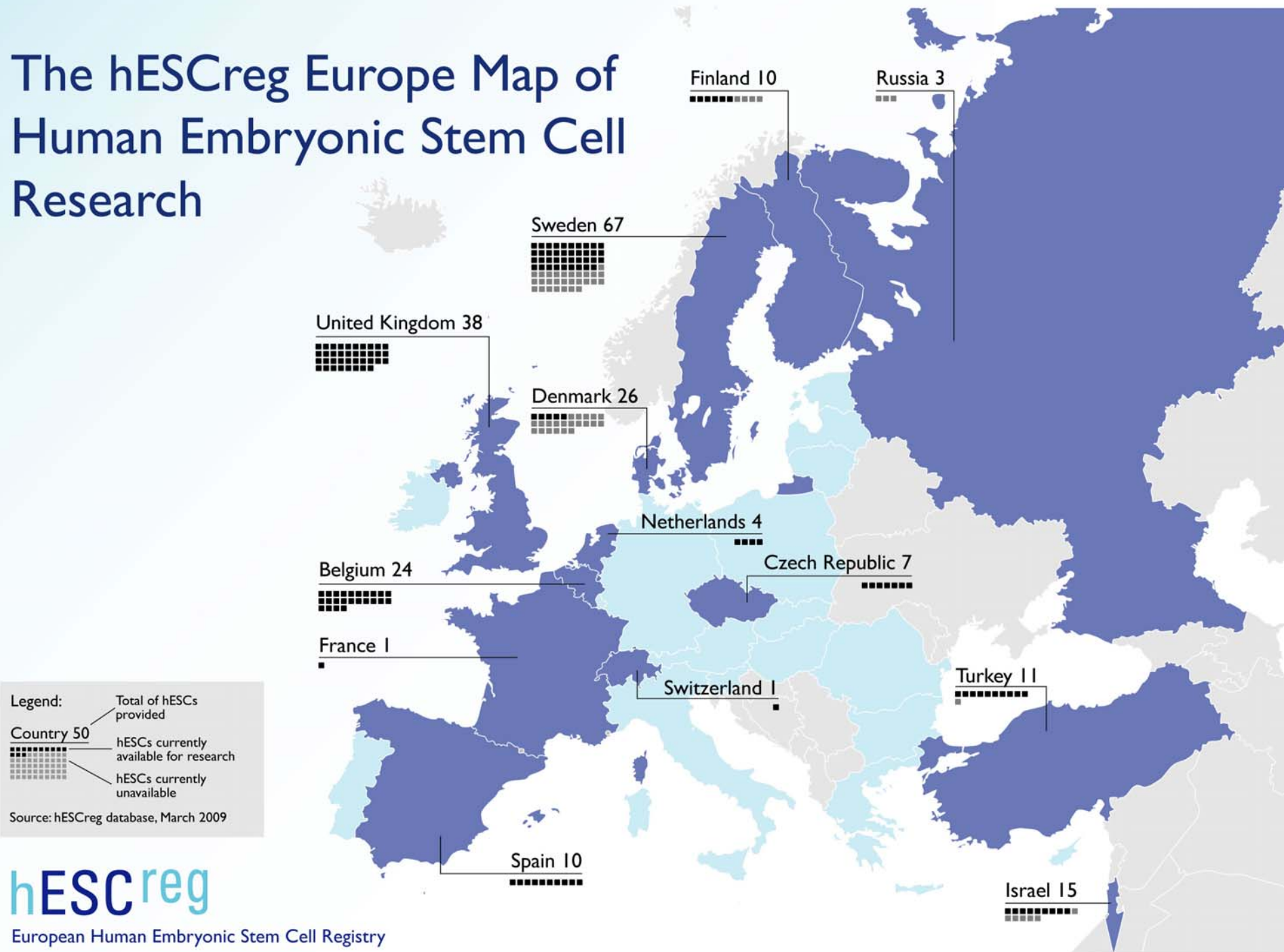
# hESC research in FP7 Implementation (1)

- **3 areas excluded from 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 in FP7 Implementation (2)

- **Case-by-case evaluation**
  - Must be scientific justification (ie non-trivial)
- **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)**
- **Approval by relevant national or local ethics committee (double ethical review)**

# The hESCreg Europe Map of Human Embryonic Stem Cell Research



**hESCreg**

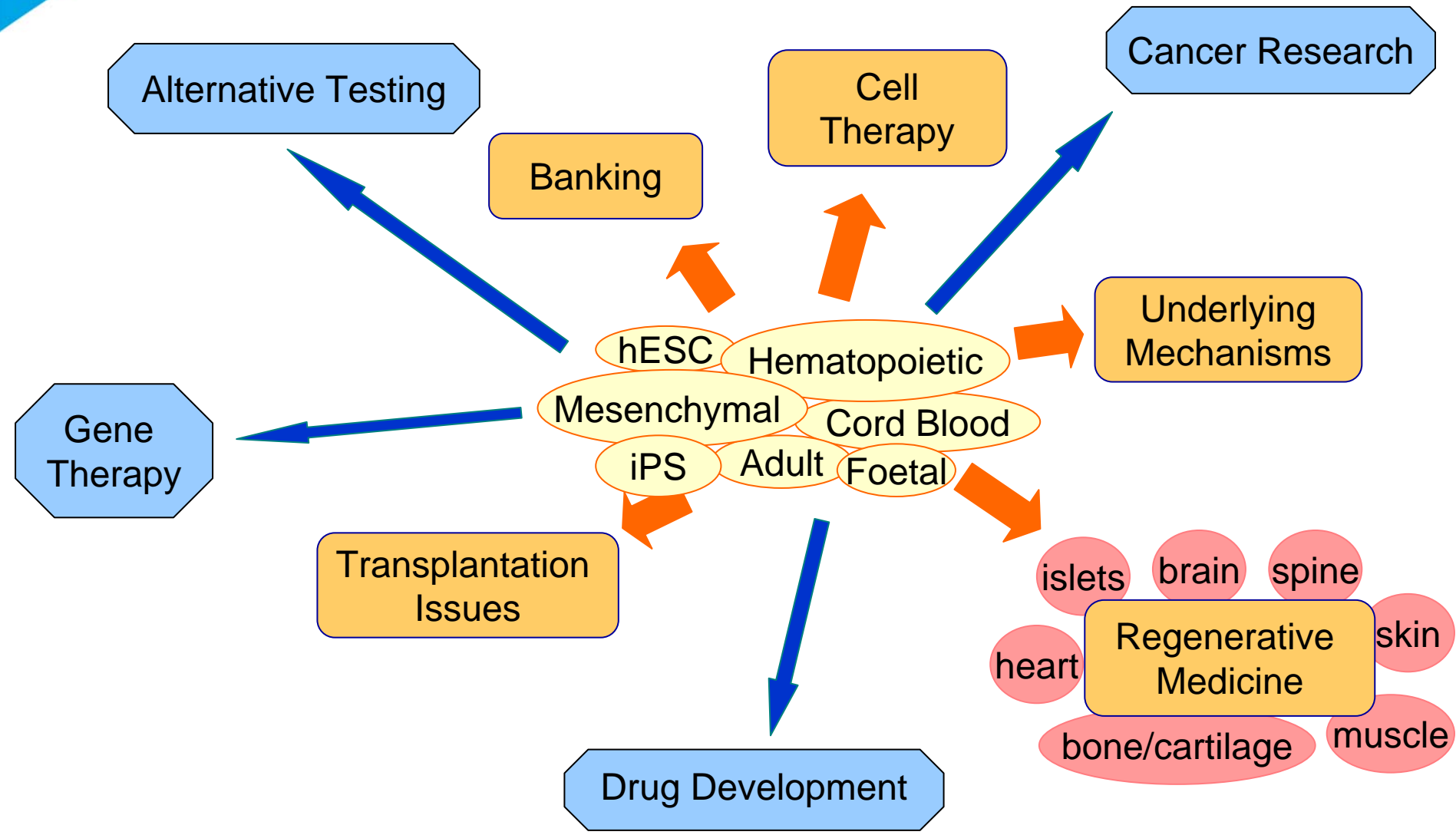
European Human Embryonic Stem Cell Registry



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# EU Stem Cell Research



# Examples of stem cell projects UK-led, FP6

1. **EUROSTEMCELL** European Consortium for Stem Cell Research  
[www.eurostemcell.org](http://www.eurostemcell.org)
2. **ESTOOLS** Platforms for Biomedical Discoveries with Human ES Cells  
[www.estools.eu](http://www.estools.eu)
3. **ALLOSTEM** Immunotherapeutic strategies to treat haematological and neoplastic diseases with optimised allogeneic stem cell transplantation  
[www.allostem.org](http://www.allostem.org)
4. **STEMDIAGNOSTICS** Diagnosis and monitoring in haematopoietic stem cell transplantation
5. **NEUROscreen** Discovery of future neuro-therapeutic molecules
6. **OSTEOCORD** Bone From Blood, Optimised isolation, characterisation and osteogenic induction of mesenchymal stem cells from umbilical cord blood  
[www.bonefromblood.org](http://www.bonefromblood.org)
7. **KIDSTEM** and 8. **TRANSNET** (research training networks)

## Examples of stem cell projects (FP7)

### Translation to the clinic:

- **OptiStem:** Optimization of stem cell therapy for clinical trials of degenerative skin and muscle diseases
- **NeuroStemCell:** European consortium for Stem Cell Therapy for neurodegenerative diseases

### Tool development:

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

EuroStemCell portal: [www.eurostemcell.org](http://www.eurostemcell.org)

# European market

## Advanced Therapies Regulation

1394/2007 (EC)

- **Cell therapy, gene therapy, tissue engineering products**
- **Direct access to the Community market**
- **Scientific assessment by European Medicines Agency (new scientific Committee)**
- **Hospital exemption/incentives for SMEs**
- **Applies from 30 December 2008 to all Member States**





## Regenerative medicine 3<sup>rd</sup> call deadline December 2008

### Strategy:

- Support in-patient work, paving the way for new interventions/therapeutic products
- Remove bottlenecks and expand knowledge of mode of action
- Boost European biotech industry
- 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



## Regenerative medicine 3<sup>rd</sup> call deadline December 2008

### Application area:

● <i>Bone and cartilage</i>	<b>26</b>
● <i>Neuro (Parkinson, Alzheimer,...)</i>	<b>13</b>
● <i>Heart/Muscle</i>	<b>11</b>
● <i>Vascular</i>	<b>7</b>
● <i>Eye</i>	<b>3</b>
● <i>Kidney/liver</i>	<b>3</b>
● <i>Skin</i>	<b>2</b>
● <i>Diabetes</i>	<b>2</b>
● <i>Several conditions</i> (i.e. renal injury, cardiac infarction, gastro-intestinal disease)	<b>3</b>
● <i>Other (i.e. obesity)</i>	<b>4</b>

**TOTAL:**

**74**



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# 4th call, expected June 2009

## Topic:

### **Cell-based immunotherapy**

- **Including clinical work, scale-up and GMP**
- **Mechanism of action**
- **Large-scale integrated projects (€6-12 million)**



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# Information

## Health Research:

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



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# Thank you for your attention!

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