



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Public funding of research – EU perspective

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An agency of the European Union








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Funding research into health/medicines in Europe

- **EC public funding** - current programming period: 2007-2013
 - 7th Framework Programme (FP7)  **55 bn**
 - European Regional Development Fund (ERDF) ⇒ Regional support in line with National Strategic Reference Frameworks  **86 bn**
- **Public Private Partnerships:** FP7 Joint Technology Initiatives
 - Innovative Medicines Initiative Joint Undertaking (IMI JU)  **2 bn**
- **National funding schemes**
 - Example UK: Medical Research Council, National Institute for Health Research, etc



EC 7th Framework Programme (FP7)



- ➔ Set up by Decision of the European Parliament and the Council (1982/2006/EC) ⇒ 2007-2013
- ➔ Directorate-General for Research & Innovation (Directorate F – Health)

Strategic Objectives:

- strengthen the scientific and technological base of European industry;
- encourage Europe's international competitiveness, while promoting research that supports EU policies.



EC 7th Framework Programme (FP7)



- Co-finances research & technological development in the main areas of the EU research policy
- 5 building blocks

Initial training
Lifelong training
Industry-academia pathways
International dimension
Specific actions

€ 4.7 bn

Cooperation

Ideas

People

Capacities

**Nuclear
Research**

Health

Food, agriculture and fisheries, and biotechnology

Information and communication technologies

Nanosciences, nanotechnologies, materials and new production technologies

Energy

Environment (including climate change)

Transport (including aeronautics)

Socio-economic sciences and the humanities

Space

Security

€ 6.1 bn overall € 600-800 m per year



FP7 – Health Theme



- **Priority areas:**



EUROPEAN COMMISSION / European Research Area / Health & life sciences

Activity 1:

Biotechnology,
generic tools
& technologies
for health

Activity 2:

Translating
research for
human health

Activity 3:

Optimising
the delivery
of health care

Activity 4: Support actions & response to EU policy needs

cross-cutting issues:

- **international cooperation, SMEs**
- **child** health, **ageing** populations, **gender**-related health issues

(Special attention will also be given to communicating research outcomes and engaging in dialogue with civil society, in particular with patient groups.)



FP7 – Health Theme



- **Features in 2012 and 2013**



EUROPEAN COMMISSION / European Research Area / Health & life sciences

2012 thematic priorities:	2013 thematic priorities:
<ul style="list-style-type: none">➔ Ageing➔ Medical technologies➔ Rare diseases / Personalised Medicines➔ Healthcare systems	<ul style="list-style-type: none">➔ The brain➔ Anti-microbial Resistance



EMA & EC's DG Research – funding safety studies

- **List of priorities in drug safety research provided by EMA**
 - Scope: class issues or off-patent substances
 - Characterisation of safety profile(s)
 - Consider public health impact of research:
 - ✓ Usage of the drug class
 - ✓ Seriousness of the safety issue
 - ✓ Possibility of obtaining comparative safety data
- **Draft list discussed at PhVWP plenary; adopted by CHMP**



Safety Research Topics proposed by EMA & included in FP7

Call:	Consortium	Title	Co-ordinator	Drugs studied
2 nd 2007	SOS	Cardiovascular and gastrointestinal safety of NSAIDs	Miriam CJM Sturkenboom, Erasmus Medical Centre	Traditional nonaspirin, nonsteroidal anti-inflammatory drugs *tNSAIDs) and cyclo-oxygenase II inhibitors (coxibs)
3 rd 2008	ARITMO	Arrhythmogenic potential of drugs	Miriam CJM Sturkenboom, Erasmus Medical Centre	Antipsychotics (ATC N05A), anti-infectives (antibacterials (J01), antimicrotics (J02) and antivirals (J05) and H1-antihistamines
4 th 2009	ADDUCE	Attention Deficit Hyperactivity Disorder Drugs Use Chronic Effects	Ian Wong, School of Pharmacy, University of London	Methylphenidate
4 th	EURO-medicAT	EUROmedicAT: Safety of Medication use in Pregnancy in Relation to Risk of Congenital Malformations	Helen Dolk, University of Ulster	New antiepileptics, insulin analogs, SSRI antidepressants, and antiasthmatics
4 th	PHARMA-CHILD	Long-term PHARMacovigilance for Adverse effects in childhood arthritis	Nico Wulffraat, University Medical Centre Utrecht	Immune modulatory drugs
4 th	STOP	Suicidality: Treatment Occurring in Paediatrics	Paramala J Santosh, University College London, Institute of Child Health	Risperidone in conduct disorder, fluoxetine in depression, and montelukast in bronchial asthma
Total funding volume so far: € 18 m; € 3 m each				
Under negotiation				
5 th 2010				Cancer risk and insulin analogues
5 th				Safety of anti-diabetes drugs (cardio/cerebrovascular and pancreatitis/pancreatic cancer) such as iguanids, Sulfonamides, urea, Alpha_glucosidase inhibitors, Thiazolidinones, DPP-4, others
5 th				Safety of asthma treatments (long acting β -agonists)
5 th				Long term risks (tumour progression and thromboembolic events) of Epoetins



EMA priority safety topics (Dec 2010)

- **Drug-induced Progressive Multifocal Leukoencephalopathy (PML).**
- Long term safety of antipsychotic medication in patients with dementia
- Long term adverse skeletal effects of bisphosphonates.
- DNA collection and studies on the genetic causes of adverse drug reactions: angiotensin-converting enzyme inhibitors and angioedema, and statin-induced myopathy.
- Proton Pump Inhibitors and risk of myocardial infarction

However, no funding into Activity 4.2 'Responding to EU policy needs' foreseen in 2012 Work Programme!



How to learn about appropriate openings



- Go to FP7 health website at:
http://cordis.europa.eu/fp7/health/home_en.html
- Consult the Health Work Programme (currently 2012, 6th Call)
- Consult the open Health Calls (via EC' Research Participants Portal):
 - FP7-HEALTH-2012-INNOVATION-1 (34 topics, €546m)
 - FP7-HEALTH-2012-INNOVATION-2 (3 topics, €108m)
- Automatic notification through CORDIS e-mail alert system
(http://cordis.europa.eu/guidance/e-mail-notification_en.html)
 - All calls of interest.
 - Advance notice of calls that are imminent.



Application & evaluation & selection



Basic principles:

- Annual calls for proposals
- 2-stage application process: 1) short proposal; 2) full proposal
- Evaluation
 - by independent experts (overseen by independent observers)
 - 3 criteria:
 - Science & Technology excellence
 - Implementation & Management
 - Potential Impact
- Feedback: Evaluation Summary Reports (ESRs)



General conditions for participation



- Any research organisation can participate, including larger companies, as well as service-providers.
- Different funding levels:
 - For academia & SMEs: 75% of research costs
 - For larger companies: 50% of research costs
 - all 100% management & training & eligible IP costs
- FP7 is fully open to international cooperation



General conditions for participation



MUST: 3 partners from 3 EU or associated countries + ...

- **the 27 EU Member States:**
Austria, Belgium, Bulgaria, Czech Rep., Cyprus, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, the United Kingdom.
- **the 13 Associated Countries:**
Albania, Bosnia-Herzegovina, Croatia, FYROM, Iceland, Israel, Liechtenstein, Montenegro, Norway, Serbia, Switzerland, Turkey and the Faroe Islands.
- In addition, researchers from anywhere in the world can participate:
e.g.: USA, India, Russia, China, South-Africa, Canada, Tanzania, Australia, Brazil, Ghana, Uganda, Kenya, Korea, Japan, Mexico...
and in many cases, they can receive EU funding.



US participants in FP7 Health



Institution	Number of projects	Total EC contribution (~€ M)
Penn State	3	1.6
Johns Hopkins	2	1.3
Stanford	2	1.1
Duke	3	1.0
Jackson Laboratory	2	0.9
University of California	3	0.7
Brigham and Women's Hosp.	2	0.7
Harvard College	3	0.7
Other*	71	15.5
Total	91	23.5

* including: Dana Faber, Yale, Tufts, Sloan-Kettering, ISB, Soma Logic, Mayo Clinic, Novocell, Repligen, Parmatrope...



Now and beyond 2013

- Multiannual Financial Framework 2014-2020
- Future funding programmes to focus on *Europe 2020* priorities (already impacting on remaining FP7 calls)
 - Increase investment into R&D and innovation up to 3% GDP by 2020
 - *Innovation Union* (cross-portfolio initiative) ⇒ recent funding boost of 7 bn EUR under FP7 to tackle 'innovation deficit'



Future priorities - push for innovation

- **Europe 2020/Innovation Union**

- address societal key challenges (e.g. ageing population);
- further strengthen scientific excellence/performance in Europe;
- reduce time to market; and
- bringing together public and private actors
 - bridging the gap between research and the market & ensure short and medium-term impact;

- **EU Budget Review**

- ➡ Common Strategic Framework
 - Projects with a proven European added value
 - More results-driven
 - Leverage other public and private funding sources



Useful links

- Official FP7 webpage (CORDIS): <http://cordis.europa.eu/fp7/health/>
- Dedicated Health Site: <http://cordis.europa.eu/fp7/health>
- Participant portal: <http://ec.europa.eu/research/participants/portal>
- To register as an Expert: <https://cordis.europa.eu/emmfp7/>

Get support:

- General: http://cordis.europa.eu/fp7/health/support_en.html
- National Contact Points: http://cordis.europa.eu/fp7/ncp_en.html