



Ethics, Gender and funding of cardiovascular research within the EU 7th Framework Program

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Context of Research funding by EU (1)

- Ø 1967: Council of Ministers established committee on S&T research = legal basis for research activities at EEC level, including medicine & health
- Ø 1978: First Medical & Public Health Research Programme (ECU 1 million over 3 years, 3 concerted actions)
- Ø FP3: Biomed1, FP4: Biomed2, FP5: Quality of Life, FP6: Life Sciences, Genomics and Biotechnology for Health
- Ø 2007-2013: Seventh Framework Programme € 6.1 billion over 7 years for Health research

Context of Research funding by EU (2)

Key objective of EU Research policy

(Art. 163 & 178 of the Treaty on European Union):

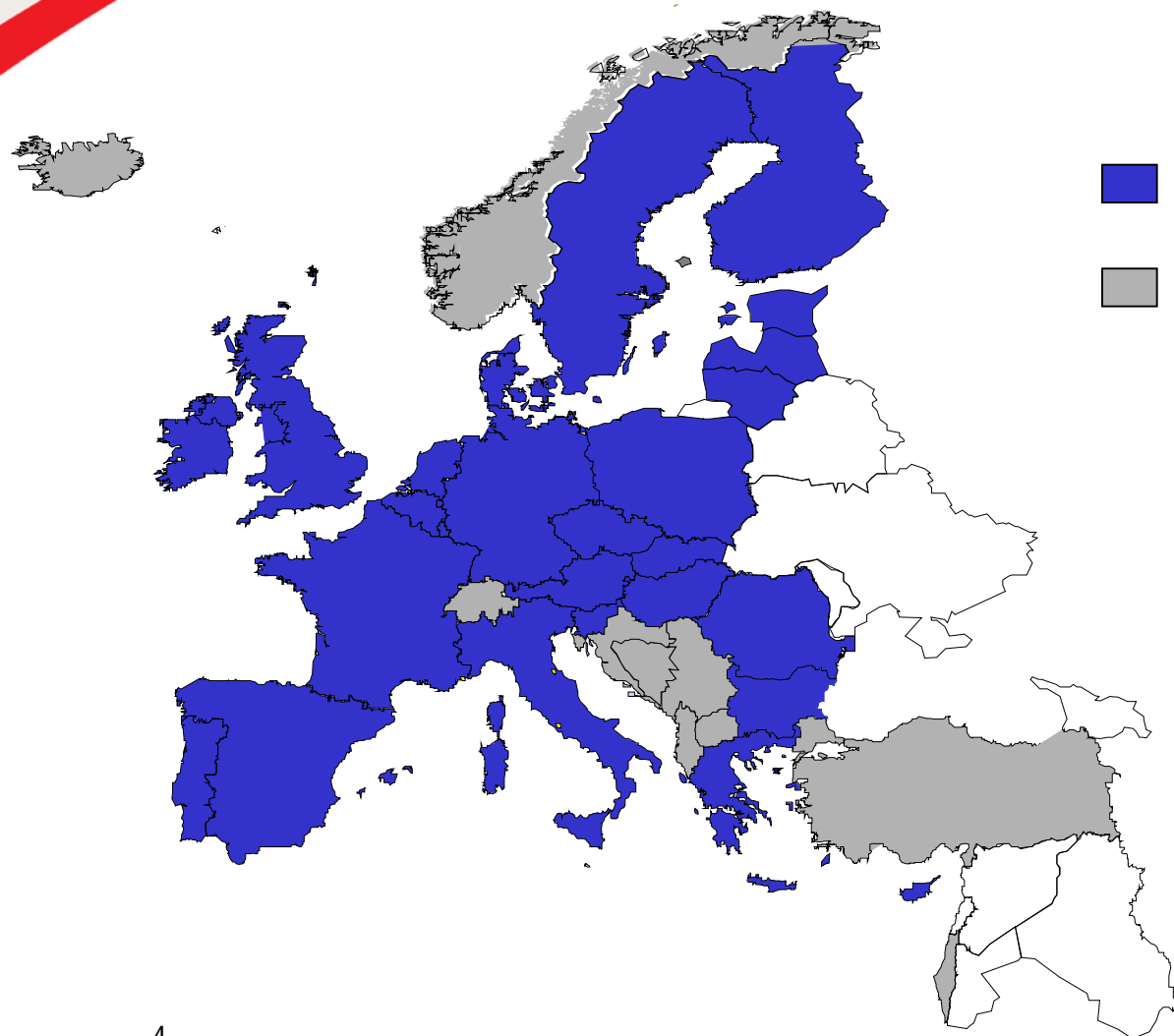
“the strengthening of the scientific and technological bases of Community industry” and “promoting all research activities deemed necessary for other policies”.

Core objectives for Health research in FP7:

“improving the health of the European citizens and increasing the competitiveness of the European health related industries and businesses...” with emphasis on “translational research”.

N.B.: EU Member States currently invest about 1.9% of GDP in research

European Research Area - ERA - 39 countries participate in a « Single Market for Research »

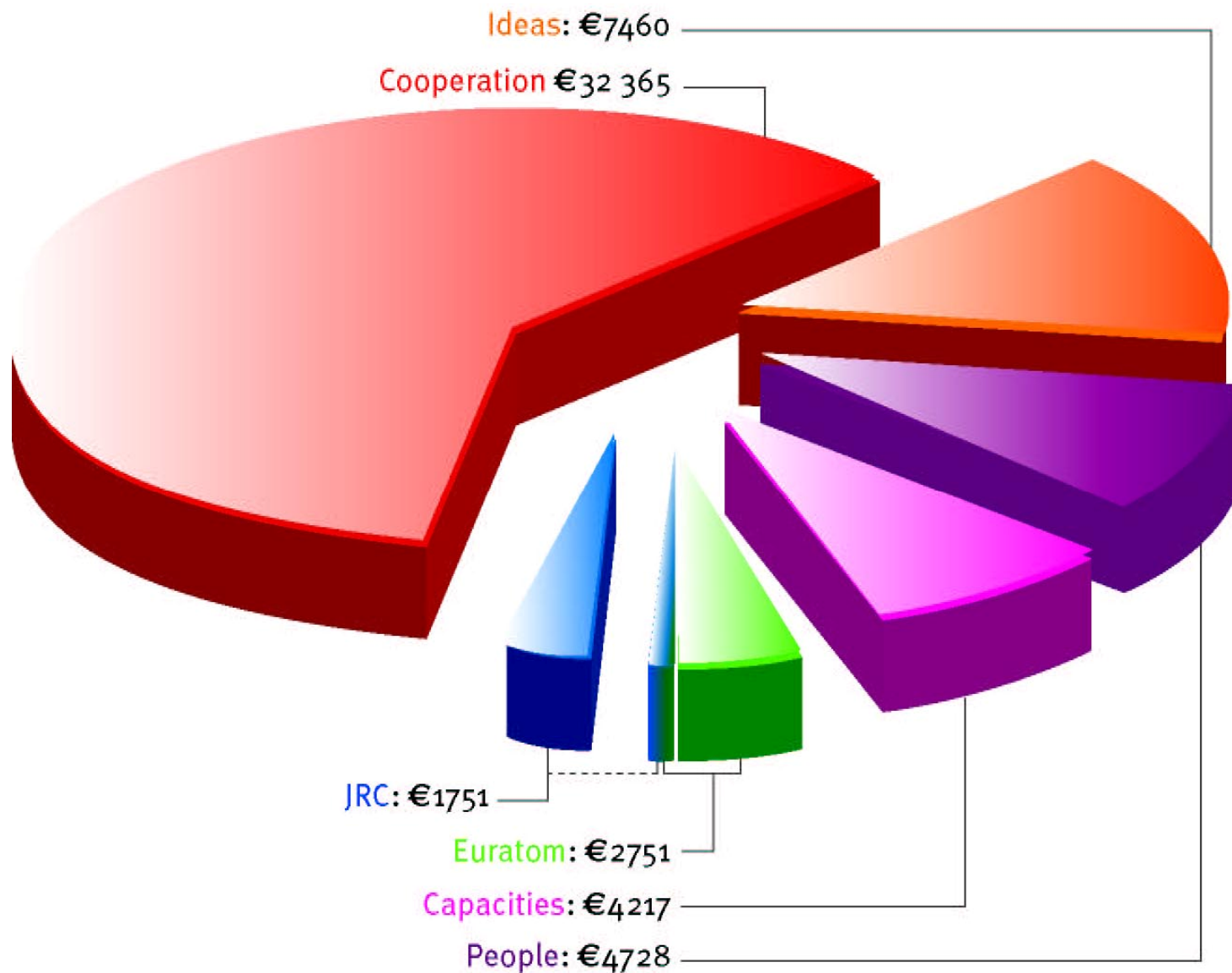


 **EU – Member States (n = 27)**

 **12 Countries associated with FP7**

- Albania
- Bosnia Herzegovina
- Croatia
- FYR of Macedonia
- Iceland
- Israel
- Liechtenstein
- Montenegro
- Norway
- Serbia
- Switzerland
- Turkey

FP7 budget (2007-2013): €55 billion



FP7 (2007 – 2013)

4 Specific Programmes

Cooperation € 32.3bn - Consortia of research projects from research groups, institutions or programmes

- Innovative Medicines Initiative (IMI)
- Article 169 initiatives (e.g. EDCTP)



People € 4.7bn



- Marie Curie activities
- Human potential, science careers and exchange of staff

http://cordis.europa.eu/fp7/people/home_en.html

Ideas € 4.5bn



- European Research Council (ERC)
- Funding of “frontier research” (individual teams)

<http://erc.europa.eu/>

Capacities € 4.2bn



- Research infrastructures
- SMEs
- Regional funds

http://cordis.europa.eu/fp7/capacities/research-infrastructures_en.html

Cooperation: Collaborative research in FP7

Ten Themes

1. Health
2. Food, agriculture, fisheries and biotechnology
3. Information and communication technologies
4. Nanosciences, nanotechnologies, materials and new production technologies
5. Energy
6. Environment (including climate change)
7. Transport (including aeronautics)
8. Socio-economic sciences and the humanities
9. Security
10. Space

Across borders and other barriers

∅ Between countries:

- ∅ multinational consortia, with at least 3 partners from 27 EU Member States (MS) + 12 Associated Countries (AC)

AC: Albania, Bosnia-Herzegovina, Croatia, FYROM, Iceland, Israel, Liechtenstein, Montenegro, Norway, Serbia, Switzerland, Turkey.

- ∅ researchers from any country in the world can participate, from industrialised countries and from developing countries.

Recent participation: Argentina, Australia, Brazil, Canada, China, India, Japan, Korea, New-Zealand, Russia, South-Africa, USA, ...

∅ Between different types of organizations

Public & private sector: universities, research centres, large companies, small and medium-sized enterprises (SMEs), etc.

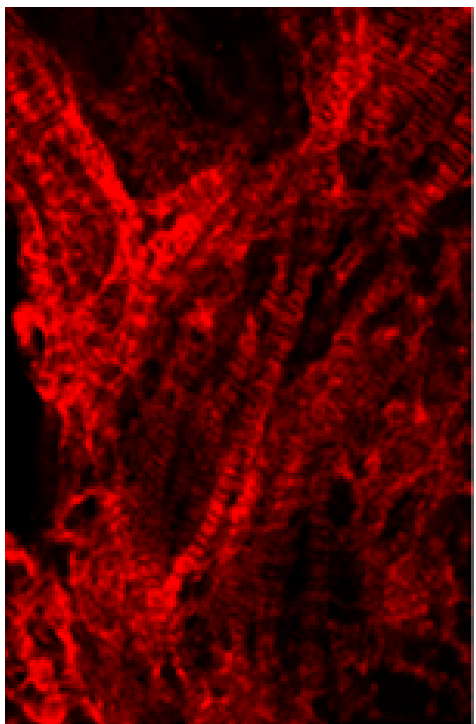
∅ Between disciplines: multidisciplinary, translational research



Scientific excellence at European level

- Ø The policy for Health research is described in the FP7 specific programme (available on CORDIS web-site)
- Ø Each year, a work programme is prepared by the EC, with the Advisory Group and in consultation with the Programme Committee
- Ø Through calls for proposals on specific topics the EC invites researchers from all Europe and beyond to submit their proposals
- Ø The very best projects are selected on the basis of evaluation by independent experts (peer review)
- Ø After negotiation of a grant agreement, a project is funded for 2-5 y.

Cardiovascular Research Support



- Recognising the importance of stimulating cardiovascular disease research activities at the European level, the EU provides direct financial support for research projects through the Framework Programmes

Cardiovascular Research Support in the past

- FP5
- 1998-2002
- 33 projects devoted to CVD research and carried out under various sections of the **Quality of Life Programme**
- more than **€50 million** from the EU



- FP6
- 2002 - 2006
- 23 projects - nine large-scale and fourteen smaller-scale research projects in CVD research
- almost **€124 million**



Cardiovascular Disease Projects in FP6

Vascular biology

EVGN (NoE)

Molecular Physiology

EICOSANOX (IP; overarching topic)

Drug development

**CARDIOWORKBENCH
(STREP; biotech)**

VASOPLUS (SME-STREP)

Stem Cells

MYOCARDIAL REPAIR (SSA)

HeartRepair (IP)

SC & CR (STRP; biotech)

STROKEMAP (STREP; biotech)

Atherosclerosis

CVDImmune (SME-STREP)

IMMUNATH (SME-STREP)

HDLomics (STREP)

SOUTH (STREP)

CVD genetics

BLOODOMICS (IP)

Cardiogenics (IP)

PROCARDIS (IP)

Stroke

MOLSTROKE (STREP)

EuroClot (STREP)

Heart Failure

EuGeneHeart (IP)

Renal disease

GENECURE (STREP)

Hypertension

**InGenious HyperCare
(NoE)**

Pulmonary Hypertension

Pulmotension (IP)

Arrhythmias

CONTICA (STREP)

NORMACOR (STREP)



Cardiovascular disease research

- ∅ The overall objective is to generate knowledge to improve diagnosis, prevention, treatment and monitoring of heart and blood vessel diseases (including vascular aspects of stroke) using broad multidisciplinary approaches
- ∅ Emphasis is placed on translational CVD research.

CVD research Projects in 2007-2008

- Ø 15 EU-funded CVD projects
- Ø These are Collaborative Projects receiving an EU financial contribution of between EUR 3 million and EUR 12 million
- Ø A total of EUR 79 million

CVD research areas addressed in 2007-2008

- Ø Atherosclerosis (AtheroRemo)
- Ø Aneurysmal disease (FAD)
- Ø Stroke (EUSTROKE, ARISE and EIS)
- Ø Genetics of hypertension (HYPERGENES)
- Ø Cell therapies for heart ischemia (Infarct Cell Therapy and CardioCell)
- Ø Organ imaging (EVINCI and Doppler-CIP)
- Ø Pharmacogenomics (PHASE and EU-PACT)
- Ø Congenital heart disease (CHearTED, CardioGeNet and CHD PLATFORM)

CVD research areas addressed in 2009

- Ø Clinical management of Heart Failure
- Ø Arrhythmias causing sudden cardiac death
- Ø Hypertrophic and dilated cardiomyopathies
- Ø Heart failure aggravated by type 2 diabetes, obesity and cachexia

5 projects will start in late 2009 – early 2010
> EUR 32 million

4th call for proposals - 2010 for the Health theme

Publication 30 July 2009

∅ Two main calls:

- ∅ FP7-HEALTH-2010-single-stage (40 topics) deadline: 19 Nov.'09
- ∅ FP7-HEALTH-2010-two-stage (13 topics) deadline: 29 Oct. 2009

∅ plus special calls:

- ∅ Coordinated call for AFRI CA (with Food and Environment themes)
6 topics, deadline: 14 Jan. 2010
- ∅ Coordinated call for Influenza (coordinated with Food theme)
1 topic, deadline: 29 Oct. 2009
- ∅ FP7-ERANET-2010-RTD
3 topics, deadline: 19 Jan. 2010
- ∅ FP7-HEALTH-2010-Alternative-testing-strategies
7 topics, deadline: 3 Feb. 2010

2.4.2 – Cardiovascular disease 4th call topics

Ø HEALTH.2010.2.4.2-1: Reducing in-stent thrombosis. EC contribution: max. EUR 6 000 000

Ø HEALTH.2010.2.4.2-2: New approaches to reduce ischemic damage to the heart. EC contribution: max. EUR 6 000 000

Ø HEALTH.2010.2.4.2-3: Identifying new therapeutic targets in atrial fibrillation. EC contribution: min. EUR 6 000 000 – max. EUR 12 000 000

Ø HEALTH.2010.2.4.2-4: Diastolic heart failure. EC contribution: min. EUR 6 000 000 – max. EUR 12 000 000

Only up to one proposal for each topic can be selected!



Compliance with Ethical Rules: Legal obligation

- FP7 Grant Agreement - Special Clauses applicable to the FP7 Model Grant
- Agreement for the implementation of the Seventh Framework Programmes of the European Communities (EC-EURATOM) See more on:

http://ftp.cordis.europa.eu/pub/fp7/docs/fp7-ga-clauses-v3_en.pdf

Clause 10

- 'A proposal [...] which contravenes fundamental ethical principles [...] shall not be selected. Such a proposal may be excluded from the evaluation and selection procedures at any time.'

Clause 13

- 'The beneficiaries shall comply with the ethical framework of FP7, all applicable legislation, any relevant future legislation and FP7 specific programmes on Cooperation", "Ideas", "People", "Capacities" (2007-2013) and "Euratom" (2007-2011).'



Charter of Fundamental Rights - Article 3:

Everyone has the right

- to respect for his or her physical and mental integrity

In the field of medicine and biology:

- the free & informed consent of the person concerned
- the prohibition of eugenic Practices
- the prohibition on making the human body and its part as such a source of financial gain
- the prohibition of the reproductive cloning of human beings



Gender in Cardio Vascular Research:

- Clinical research must take into account (in the research protocols, methodologies and analysis of results) the differences in relation to gender and age.
- For clinical trials, EC contribution will be limited to phases I and II and only exceptionally to further studies, so Gender is only prospective...



Gender considerations are Twofold:

- Is there Gender balance/Gender Action Plan (similar to Ethics Issues)
- Is there Gender impact on scientific result (a question of Scientific greatness/innovation/awareness)
- How to show Gender sensitiveness?



Gender? What is checked? Is it evaluated with Ethics?

What is seen for ethics?

- Whether the researchers respect the FP7 ethical standards;
- Whether the relevant EU legislation is taken into account in the design of the proposed research frame;
- Whether the applicants have sought/ are planning to seek the approval of relevant local/national (ethics) committees;
- The awareness of the applicants on the ethical aspects and the social impact of the research they propose;
- Whether the relevant International Conventions, Treaties and Declarations are followed;
- The balance between the research objectives and the means to be used;



Ethics Review – What is expected of the applicant?

Proposals include a section:
("Ethical issues table") which Describes :

- Potential ethical aspects of the proposed research regarding its objectives;
- Methodology and the possible implications of the results;
- How the ethical requirements set out in the Work programme will be fulfilled;
- How the proposal meets the national legal and ethical requirements of the country where the research is performed;



What are we looking for?

- Awareness of the Ethical/social impact of research
- Conformity with EU Directives/Regulations, international conventions/declarations and codes of conduct
- Respect of FP7 ethical standards
- Approval of relevant local/national (ethics) committees
- Benefit/burden of research project

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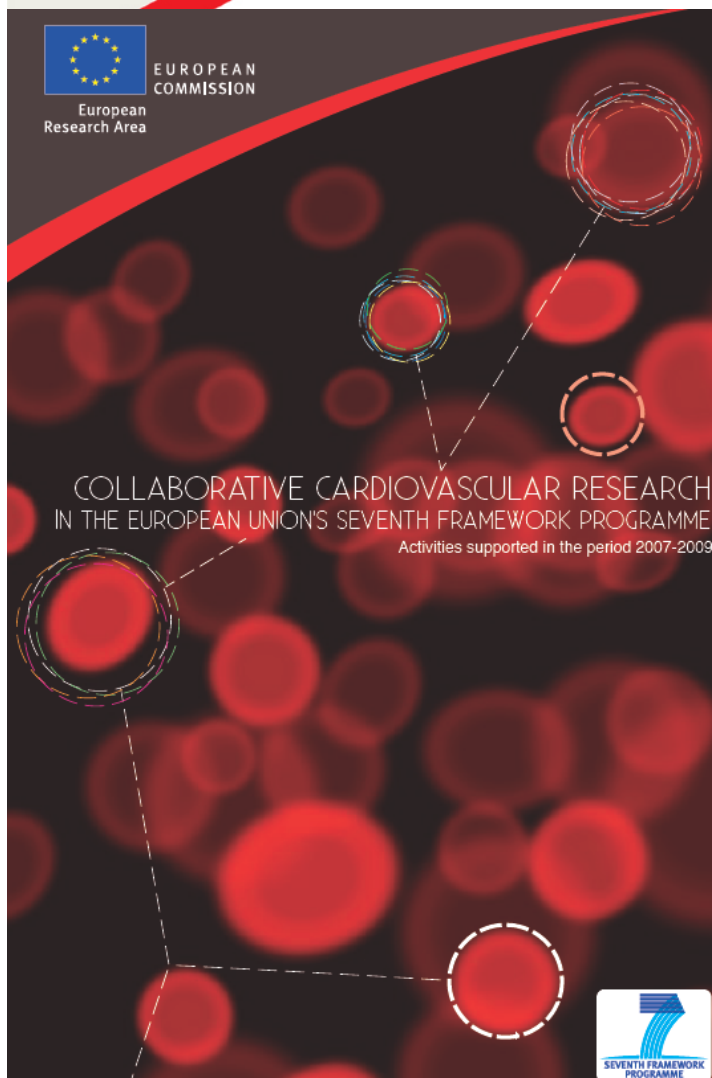
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EU Strategy Workshop on Translational CVD research



Cardiovascular Research
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Viewpoint Editorial

Identifying needs and opportunities for advancing translational research in cardiovascular disease[†]

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