



Paediatric Medicines and the Health theme in the Co-operation Programme of FP7

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The Health Theme in Framework Programme 7

- **Rationale for pan-European approach**
- **The Health Theme** (calls, ceilings, policy drivers)
- **The Health Theme** (structure and content)
 - Biotechnology, generic tools and technologies for Health
 - Translating research for human health
 - Optimising the delivery of healthcare to citizens
 - Other actions across the theme
- **Ethical issues in proposals**
- **Information & Contacts**



to promote collaborative research

EC programmes bring down barriers

- **between countries:**
 - multinational consortia (EU-27 + associated countries : IS, LI, NO, CH, IL, TR, HR, YU)
 - researchers from any country in the world can participate; and promotes coordination of national funding programmes (ERA)
- **between different types of organizations:**
universities, research centres, SMEs, large companies, etc.
- **between disciplines:** focus on translational research



FP7: main elements

- Budget to be increased: €50.5 billion over 7 years **+ 40 %**
- European Research Council (*Ideas programme*) **ERC**
- Collaborative research (*Cooperation*)
 - continuity in themes & instruments.
 - funding levels to be raised in some cases, **50 % → 75 %**
 - Joint Technology Initiatives,
eg: **the Innovative Medicines Initiative** **(IMI)**
- Infrastructures, SME, regions & potential (*Research Capacities*)
- Human potential and science careers (*People*)



Cooperation: Collaborative research in FP7

Thematic Priorities

1. Health	6.1
2. Food, agriculture, fisheries and biotechnology	1.9
3. Information and communication technologies	9.1
4. Nanosciences, nanotechnologies, materials and new production technologies	3.5
5. Energy	2.3
6. Environment (including climate change)	1.9
7. Transport (including aeronautics)	4.2
8. Socio-economic sciences and the humanities	0.6
9. Security & 10. Space	<u>2.8</u>
Total for collaborative research	€32.4 billion



Collaborative research in the Health theme

Main policy drivers:

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

- Budget:

- **€6.1 billion over 7 years (2007-2013)**



First calls for the Health theme

- Work programme published 22 Dec. 2006 for years 1 & 2
 - one-step proposals
 - first deadline: 19 April 2007 €637 million
 - **second deadline: 18 September 2007** **€532 million¹**
(+ JTI: €125 million)²
- [¹: pending approval of 2008 budget]
[²: pending approval by Council]
- not all areas will be open in each call
 - no Networks of Excellence
 - 1 ERA-NET (cancer registries), with deadline 30 July 2007



Funding schemes for research in FP7

- **Collaborative projects** to develop new knowledge, new technology, products, demonstration activities
 - **Small- or medium-scale focused research actions (FRP)**
 - **Large-scale integrating projects (IP)**
 - **Projects targeted at special groups (SMEs & SICA)**
- **Networks of Excellence (NoE)**
- **Coordination actions (CA) and support actions (SA)**
- **ERA-Nets**

- Support for investigator driven research by individual teams (**ERC**)
- Support for training and career development of researchers
- Research for the benefit of specific groups (in particular SMEs)



Funding levels in the Health theme

Warning: these will be an eligibility criteria !

	min.	max.*
➤ Small- or medium-scale focussed research project (FRP)		€3m
➤ Large-scale integrating project (IP)	€6m	€12m
➤ Projects targeted at (SMEs & SICA)		€3m
➤ Coordination action (CA)		
➤ Support action (SA)		
➤ ERA-Net (for cancer topic)		€2m

* except where otherwise stated in work programme.



Scope of research in the Health Theme

- In the Health theme, the Framework programme supports basic and applied collaborative research
- This includes discovery activities, translational research and early clinical trials (normally only phase I and II)



Collaborative research in the Health theme

Activities in 3 main areas:

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

Main features of transition from FP6 to FP7:

Continuity; broader scope; less focus on genomics; emphasis on translational research; health policy driven research strongly reinforced.

New: emerging epidemics, obesity, chronic diseases, biomedical technology & engineering.



Collaborative research in the Health theme

Two other issues will be addressed across all activities:

- **Child health**
 - The health of the ageing population
-
- Throughout all work programme topics, where appropriate.
 - Through specific topics



Cross-cutting aspects for the Health theme in FP7

Special emphasis and measures for:

➤ SMEs

- Participation encouraged in all areas
- Special topics for SMEs
- Support actions

➤ International Cooperation

- Participation possible in all areas
- Special International Cooperation Actions (SICA)
- Coordination or Support actions



Collaborative research in the Health theme

Activities in 3 main areas:

- Biotechnology, generic tools & technologies for health
 - Translating research for human health
 - Optimising the delivery of healthcare to citizens
- + Other actions across theme



Topics from first calls **responding to EU policy needs**

(Area 4.2)

Topics for second call (18 September 2007):

Paediatric medicinal products

- **Adapting off-patent medicines to the specific needs of paediatric populations** (FRP - Max. €6m).

Ref.: priority list of paediatric working party of EMEA (www.emea.europa.eu)

Drug safety research

- **Relative safety of non-steroidal anti-inflammatory drugs (NSAIDs)** (FRP).



Important definitions in FP7

- **Public body** means any legal entity established as such by national law, and international organisations.
- **Research organisation** means a legal entity established as a non profit organisation which carries out research or technological development as one of its main objectives.
- **Higher and secondary education establishments** = Term used by Financial Regulation / Implementing Rules, includes universities, schools for applied sciences and similar.
- **SMEs** mean micro, small and medium-sized enterprises within the meaning of Recommendation 2003/361/EC in the version of 6 May 2003 (OJ L 124, 20.5.2003, p. 36).
- **International cooperation partner countries** = FP6 INCO countries – three categories according to income per capita (low-income, lower-middle-income, or upper-middle-income); will be identified as such in the work programmes.



Minimum conditions for participation in FP7

General:

- 3 independent participants from 3 different Member States (MS) or Associated countries (Ac)
- Natural persons may participate
- JRC may participate and is deemed to be from a different MS or Ac (same principles for international European interest organisations and entities established under Community law)
- Additional conditions can be established by the work programme (WP) or specific programme (SP) (e.g. number or type of participant, place of establishment)



SMEs : Commission Regulation (EC) No 2049 / 2005

- Administrative and procedural assistance from the SME Office at EMEA;
- Fee reductions for scientific advice, inspections and (for veterinary medicines) establishment of maximum residue limits;
- Fee exemptions for certain administrative services of the EMEA;
- Deferral of the fee payable for an application for marketing authorisation or related inspection;
- Conditional fee exemption where scientific advice is followed and a marketing authorisation application is not successful;
- Assistance with translations of the product information documents submitted in the application for marketing authorisation.



SMEs

To determine which companies are eligible for SME incentives, the EMEA will apply the definition of micro, small and medium-sized enterprises provided in ***Commission Recommendation 2003/361/EC***



***EMEA : <http://www.emea.eu.int>
E-mail : smeoffice@emea.eu.int***



Ethical framework in FP7

Same as for FP6

with a revision foreseen for 2nd phase of FP7 (2010-2013)

3 areas are excluded from funding

- Human reproductive cloning
- Intentional germ line modification*
(* Research relating to cancer of the gonads can be financed)
- Creation of human embryos for research or stem cell procurement
(including by means of somatic cell nuclear transfer)



Application Procedures

- Electronic submission (on line) via Electronic Proposal Submission Service (EPSS)
- Administrative forms (Part A)
- Technical Content (Part B) (.pdf format only - 3rd version or higher),
- Exclusion criteria :
 - Incomplete
 - Illegible
 - Infected
 - In other ways (e-mail, fax, CD-ROM, etc)

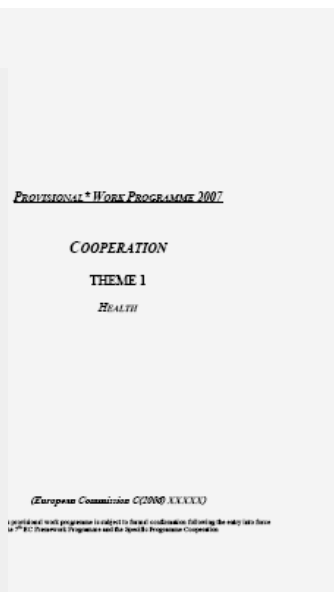
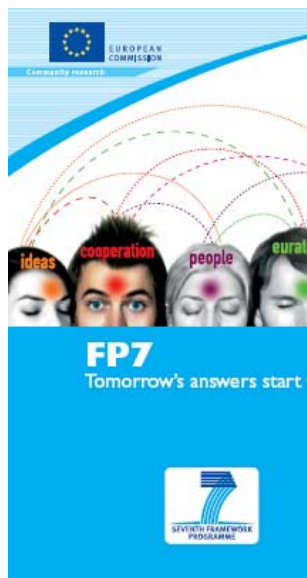
http://cordis.europa.eu/fp7/epss_en.html



EUROPEAN
COMMISSION

Community research

Application Procedures





Application Procedures

*PROVISIONAL * WORK PROGRAMME 2007*

COOPERATION

THEME 1

HEALTH

(European Commission C(2006)XXXXX)

* This provisional work programme is subject to formal coordination following the entry into force of the 7th EC Framework Programme and the Special Programme Cooperation.

HEALTH-2007-4.2-1:

“Adapting off-patent medicines to the specific needs of paediatric populations.”

- **Second Call**
(Deadline : 18.9.2007)
- pp. 51 (Word version) or 52 (.pdf version)



Application Procedures



- EPSS (Electronic Proposal Submission Service) :
http://cordis.europa.eu/fp7/epss_en.html
- English only!
- Part A (administrative, forms)
- Part B (Technical, .pdf only)
- Strict deadlines!!
- Corrections, withdrawals



Application Procedures

Part A (Administrative)

- A1 : Project Summary (Acronym, Title, Call Identifier, Activity Code(s), Keyword(s), Abstract (≤ 2000 characters)).**
- A2 : Participants : Name(s), Address(es), contact details, etc.**
- A3 : Budget : methods of calculation (see Annex 3)**



Application Procedures

Part B (Technical) - I

Cover Page

Title, Acronym, Type of Funding Scheme, Topic,
Participant list

Table of Contents :

1. Scientific / Technical Quality (20p. max.)

- i. Concepts & Objectives,
- ii. Progress beyond the state-of-the-art,
- iii. S/T methodology and associated work plan

Tables

- a. Work Package list,
- b. Deliverables list,
- c. Work Package Description,
- d. Staff efforts,
- e. Milestones



Application Procedures

Part B (Technical) - II

2. Implementation

- i. Management Structure & procedures (5p.)
- ii. Individual participants (1p. per participant)
- iii. Consortium as a whole (4p.)
- iv. Resources to be committed (2p.)

3. Impact (10p.)

- i. Expected impact listed to the Work Programme,
- ii. Results dissemination / exploitation & IPR management

4. Ethical Issues (length dep. on issues)

5. Gender Aspects (1 page)



Evaluation Procedures - I

General

- ✓ Independent Experts
- ✓ Acting on their own behalf
- ✓ Confidentiality
- ✓ NO Conflicts of Interest

Before individual Evaluation Eligibility check :

- ✓ On time
- ✓ Minimum no. of Participants (≤ 3)
- ✓ Complete (Parts A and B)
- ✓ Relevance to the topic
- ✓ Level of Funding (€3m EU requested contribution)



Evaluation Procedures - II

Individual Evaluation Criteria

1. S / T Quality

- i. Concepts & Objectives,
- ii. Progress beyond the state-of-the-art,
- iii. S/T methodology and associated work plan

2. Implementation

- i. Management Structure & procedures
- ii. Individual participants
- iii. Consortium as a whole
- iv. Resources to be committed

3. Impact

- i. Expected impact listed to the Work Programme,
- ii. Results dissemination / exploitation & IPR management



Evaluation Procedures - III

Individual Evaluation Criteria - Scores

0	Fails to address the criterion
1	Very poor
2	Poor
3	Fair
4	Good
5	Excellent

- Individual threshold = 3, overall = 10
- No weightings
- Half marks may be given



Evaluation Procedures - IV

- **Consensus Meeting**
- **Panel review**
- **Panel Report containing :**
 - i. Evaluation Summary Report for each proposal evaluated
 - ii. List of successful proposals
 - iii. List of unsuccessful proposals
 - iv. List of ineligible proposals
 - v. Summary of panel deliberations
 - vi. Ethical review (if necessary)
- **Contract negotiations**



Independent Experts

- to assist in the evaluation of proposals
- to assist in the monitoring of ongoing projects
- for other purposes where specific expertise might be required (assess RTD programmes, etc.)



Evaluation Procedures - V

Experienced in :

- **research in the relevant scientific and technological fields,**
- **administration, management or evaluation of RTD projects, programmes or policies,**
- **use of the results of RTD projects, technology transfer, innovation, and business cooperation, particularly with regard to SMEs.**
- **issues at the interface of science and society (e.g. education, communication, expertise, risk, ethics, etc.),**
- **international cooperation in science and technology,**
- **development of human resources.**



Evaluation Procedures – V

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Seventh Research Framework Programme (FP7) Important Legal Notice

CORDIS 2007 - 2013

CORDIS: FP7: EMM

Registration of Experts for Research Activities

The call for experts for the seventh framework programme has been launched. Please see the EC Official Journal [2006/C 305/16](#) (for individuals) and [2006/C 305/17](#) (for organisations) for further information.

The personal data collected in the context of the present call will be processed in accordance with the Regulation (EC) n° 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies on the free movement of such data.

Click [here](#) to view the privacy statement.

For further information and help, please look at our Frequently Asked Questions ([FAQ](#) Last Update: 2007-01-30).

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Click here to register as an organisation

Existing Expert / Organisation / Member State

If you are already registered as an FP6 / FP7 / Non-FP expert, organisation or member state please log in here. Existing FP6 experts wishing to register for FP7 activities also log in here.

Entering a wrong password three times will block your account; hence please use the password reminder facility if you are unsure of your password.

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Useful contact details

- **Community Research & Development Information Service :**
<http://cordis.europa.eu/en/home.html>
- **Calls for Proposals :**
<http://cordis.europa.eu/fp7/dc/index.cfm>
- **Health :**
http://cordis.europa.eu/fp7/dc/index.cfm?fuseaction=UserSite.CooperationCallsPage&id_activity=1
- **Work Programme, incl. Paediatric Medicines :**
http://cordis.europa.eu/fp7/dc/index.cfm?fuseaction=UserSite.CooperationDetailsCallPage&call_id=10
- **Independet Expert registration**
<https://cordis.europa.eu/emmfp7/index.cfm?fuseaction=welcome>



**“Eighty percent of
success is showing up.”**

Woody Allen