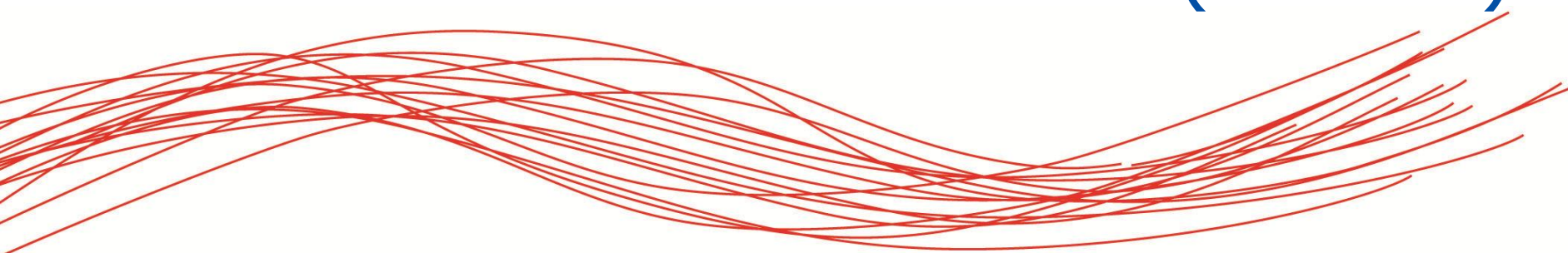


# **Orientations for Work Programme 2012 (6<sup>th</sup> call)**



**Nicola Bergonzi**  
***HEALTH National Contact Point***  
***APRE- Agenzia per la Promozione della Ricerca Europea***

## The 7th Framework programme (FP7)

- **Introduction**
- **Basic principles**
- **2012 Work programme**
  - **Key features / priorities**
- **Considerations for SMEs**
- **Information sources**
- **Annexes:**
  - list of topics
  - Health research in other themes

# EU research policy

## Why ?

- **to improve quality of life and**
- **to improve competitiveness of Europe**  
**through collaboration**

## How ?

- **by pooling resources** (funds for Framework Programme)
- **by coordinating national research programmes**

# 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)**

# Collaborative research across borders and other barriers

## ● **between countries:**

→ At least 3 partners from 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.

→ or 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.: Australia, Brazil, Canada, China, Egypt, India, Japan, Korea, Russia, South-Africa, USA, ...

and in many cases, can be funded.

# Drivers for FP7 from Innovation Union policy

- **Innovation-driven approach**
  - **Focus on SMEs** through genuine academia-industry collaborations
- **Challenge-driven approach**, focussed on key challenges
- **Support implementation of European Innovation Partnerships**, such as “**Active and healthy ageing**”
- Stronger **socio-economic impact** - innovation dimension
  - with more attention on **exploitation phase**
- **Balance** upstream research and activities closer to market in order to achieve short and medium-term impact

# Features of FP7 Health in 2012 & 2013

- fewer, more prominent priorities  
i.e. more focus on fewer areas
- fewer, broader topics, two-stage submission-evaluation
- greater emphasis on innovation
  - especially through SME-targeted topics
  - and continued support of clinical trials
- emphasis on flexibility for consortium, duration & budget
- international cooperation with more strategic focus

# Trends in Health Work programmes

	<b>2007</b>	<b>2008</b>	<b>2009</b>	<b>2010</b>	<b>2011</b>	<b>2012</b>
Budget for calls	641	577	593	628	657	650*
Topics	86	87	71	72	51	37*
Projects	153	172	108	131	125*	127**
Budget / topic	7.5m	6.6m	8.4m	8.7m	13.1m	17.5m*
Budget /project	4.2m	3.35m	5.5m	4.8m	5.3m*	5.1m**

\* tbc

\*\* est.

Average size of consortia remains quite high: ~12

# Features of FP7 Health in 2012

- Indicative budget for 2012 calls: €650m (tbc)
- 2 “Health” calls:
  - FP7-HEALTH-2012-INNOVATION-1 (33 topics, €540m)
  - FP7-HEALTH-2012-INNOVATION-2 ( 3 topics, €108m)
  - FP7-2012-ERA-NET call (1 topic, €2m)
- ALL topics (but one) will have two-stage submission
- MOST topics (29/37) can have several projects funded (exceptions: 6 CSA, 1 IP, PLC with Australia)
- 15 SME-targeted topics (including special call)  
plus 2 Industry-targeted topics (including SMEs)
- A special action for the preparation of EDCTP-2

# Priorities of FP7 Health in 2012

## Main priorities:

- **Ageing** will be the 1st priority in 2012 – budget ~€220m (incl. med. tech, biomarkers, clinical trials, co-morbidity, health services)
  - **Medical technologies** – €160m
  - **Rare diseases** – ~€100m
  - **SME targeted actions:**
    - 3 topics:  $\geq 50\%$  EC contrib. to SMEs: €108m
    - 6 topics:  $\geq 30\%$  EC contrib. to SMEs: €180m
    - 6 topics:  $\geq 15\%$  EC contrib. to SMEs: €72m
- Total: 15 topics (out of 37 topics) – €360m (~55%)

NB: total budget: €650m (some overlap between priorities & budgets)

# New initiative “SMEs for Innovation” call (1)

Pilot initiative to stimulate innovation via enhanced SME participation

3 broad topics with a focus on medical technologies:

- 1.4-2 Medical technology for transplantation and bio-artificial organs
- 2.3.0-1 Diagnostics for infectious diseases (in humans)
- 2.4.5-1 Technological approaches to combating sensory impairment

# "SMEs for Innovation" call (2)

Pilot initiative to stimulate innovation via enhanced SME participation

## Special conditions:

- 3-5 partners, min. 50% of req. EU funding for SME(s)
- **Restricted to entities from EU and Associated Countries**
- max. 3 years
- The SME must have a leading role in the project
- 2-stage submission & evaluation
- Simplified application process: short project description
- Accelerated procedures for submission, evaluation & negotiation i.e.: earlier deadlines for 1<sup>st</sup> and 2<sup>nd</sup> stage submission.

- Any research organisation can participate, including larger companies, as well as service-providers.
- However, the funding levels are different:
  - For SMEs: 75% of research costs
    - (+ 100% management & training & eligible IP costs)
  - For larger companies: 50% of research costs
    - (+ 100% management & training & eligible IP costs)
- What is an SME ? (for the EC: 1 + 2 + 3)
  1. less than 250 employees
  2. annual turnover  $\leq$ €50 million OR balance sheet total  $\leq$ €43 million
  3. must be autonomous\*

\* check SME status: <http://ec.europa.eu/research/sme-techweb>

## Aim:

- Translating research into clinical practice
- Different types of clinical trials,  
e.g. investigator-driven, observational,

## Scope:

- specified in each topic, phases covered will depend on budget
- expected to be mostly phase II, but for details see specific topics and special instructions for clinical trials on page 9 of orientation paper.

For any project, such as CTs, epidemiological studies or whenever applicable an appropriate study design, data processing and statistical analysis of results are important for the quality and efficiency of the science and reliability of conclusions, and hence also ethically.

This may for example include:

- description of experimental plan and data gathering,
- method for uncertainty or measurement error estimation,
- statistical analysis of data
- methods of inference (e.g. statistical tests and p-values to be used, accounting for multiple comparisons or small sample size, dealing with missing or noisy data),
- statistical power analysis and estimate (justification) of the number of needed animals or human subjects\*.

\*If these are not applicable or not justified, the proposal should briefly explain it.

# Funding schemes for FP7 Health in 2012

<b>Funding scheme</b>	<b>Ceiling for EU contribution</b>	<b>Number of topics</b>	<b>% budget</b>
Large-scale integrating project (CP-IP)	€12m	4	~ 16.5%
Small or medium scale focused project (CP-FP)	€3m / €6m	24	~ 78%
Coordinating or supporting action (CSA)	various	9	~ 2.5%
Other actions*	various	–	~ 2%
<b>Total</b>		<b>37</b>	<b>100%</b>

\* including HFSP0, EDCTP, study on emerging areas for research/innovation, study on impact of ethics review on health research, production of videos.

## Single-stage call:

- 33/166 proposals short-listed
- Success rate: 20%
- €166.5m awarded

## Two-stage call:

- 91/220 proposals short-listed
- Success rate: 41%
- €495.1m awarded

## Overall

Average grant: €5.33m

## Clinical trials (8 topics):

- 26 projects (including 3 from single-stage call); €152m awarded

## SME-targeted topics (10):

- 34 projects (including 2 from single-stage call); €221m awarded
- 15 projects led by SMEs

# Key messages for potentials applicants

## Opportunity & Flexibility

### Opportunity:

- for ambitious, well-funded R&D projects
- for genuine collaborations (esp. academia – industry), across borders

### Flexibility at submission stage:

- Broader topics: more “bottom-up”
  - The size of consortium (beyond min. 3)\*
  - The EU contribution requested\*\*
  - The duration of the project\*\*\*
- } is for applicants to decide

*(\* with the exception of 3-5 max. for the “SMEs for innovation” call,  
\*\* within ceiling, \*\*\*some exceptions)*

# Is applying for EC funding a waste of time?

## It depends...

**applicants need to be aware of the conditions.**

- Main condition: it must be **collaborative research** (min. 3), but this obligation should be seen as **an opportunity**.
- **Time to start**: the process is not quick.
- **No strings attached**: with grants, you own the IPR.
- **Support structures**: the National Contact Points (NCPs) the "FIT-for-Health" network
- **Consultants** can help... but **you** must stay in charge.

# Is applying for EC funding a waste of time?

## It depends...

**applicants need to examine cost/benefit ratio.**

- Apply only **if it fits your strategy** AND if you play a major role in the project and get significant funding. Don't get dragged into projects/consortia.
- Do not view EC grants only as a source of cash, but as a means to **access know-how & resources** from partners.
- Managing the project yourself is a major task – it needs to be properly resourced – but you have **control**.

# Challenges for SMEs

- Confirm SME status => size, turnover, autonomy
- Find partners => SMEs-go-Health / Fit-for-Health  
[www.fitforhealth.eu](http://www.fitforhealth.eu)
- Matching funds => foresee & demonstrate
- Financial viability => check may be needed
- Consortium agreement => address this early

# Basic principles for calls & evaluation

Peer review

Equality of treatment

Transparency

Aim: to fund the best R&D proposals

## FP7-HEALTH-2012-Innovation-1

## FP7-HEALTH-2012-Innovation-2

### Eligibility/Exclusion check (before evaluation)

#### Eligibility criteria:

#### For all proposals

- Date and time of receipt of the proposal
- Minimum of eligible, independent partners
- Completeness of the proposal (forms and descriptive part)

#### Topic related

- *Scope (for clear cut cases)*
- *Budget thresholds where appropriate*
- *Percentage of EU funding going to SMEs or industry*
- *Project duration*

# Submission & evaluation

## Basic principles:

- **Annual calls for proposals** (in two stages)
- **Evaluation by panels of independent experts** overseen by Independent Observers
- **3 criteria:**
  - Science & Technology excellence
  - Implementation & Management
  - Potential Impact
- **Feedback:** Evaluation Summary Reports (ESRs)

Experts wanted !

## FP7-HEALTH-2012-Innovation-1

## FP7-HEALTH-2012-Innovation-2

### Proposal scoring:

- Each criterion is scored 0-5
- half-scores allowed
- Scores must pass *thresholds* if a proposal is to be considered for funding
- Thresholds apply to individual criteria...

	stage 1			stage2			
	S&T	Impact	total	S&T	<b>Implementation</b>	<b>Impact</b>	total
Innovation -1	4/5	3/5	8/10	4/5	3/5	3/5	12/15
Innovation -2	4/5	<b>4/5</b>	8/10	4/5	3/5	<b>4/5</b>	12/15

FP7-HEALTH-2012-Innovation-1  
Stage 1 proposals: 04 October 2011

FP7-HEALTH-2012-Innovation-2  
Stage 1 proposals: 27 September 2011

\*: to be confirmed  
see in calls published on CORDIS in July 2011.



## Health Research


- Home
- About Health Research
- Newsroom
- Find a call
- Get support
- International cooperation
- SMEs in Health Research
- Events
- Library
- Useful links



Previous Programmes



### Health Research homepage



#### Highlights

- **New: FP7 Health - 2012 orientation paper** [here](#)

The 2012 calls are expected to be published in July 2011.

- The European and Developing Countries Clinical Trials Partnership ([EDCTP](#)) has launched new calls for proposals (deadline: 14 June 2011).
- [Publication on "International Cooperation in EU-funded Health Research"](#)
- **News alert:** [www.healthcompetence.eu](http://www.healthcompetence.eu), a new interactive platform on European health research

[More highlights ...](#)

### Health is our priority

The objective of health research under FP7 is to improve the health of European citizens

#### Latest News

- [Scientists discover three human gut types; what's yours?](#)

In the same way humans can be divided into blood groups, EU-funded scientists have now discovered that we can categorise ourselves by gut type too. [read more](#) [Date: 2011-04-26]

[more news](#)

#### Events

- **Register now European Perspectives in Personalised Medicine Conference**, 12 - 13 May 2011, Brussels. Find more information [here](#).
- **Register now FP7 Health - Open Information Day & Partnering event**, 9 June 2011, Brussels. Find more information [here](#).

# Orientations for 2012 WP

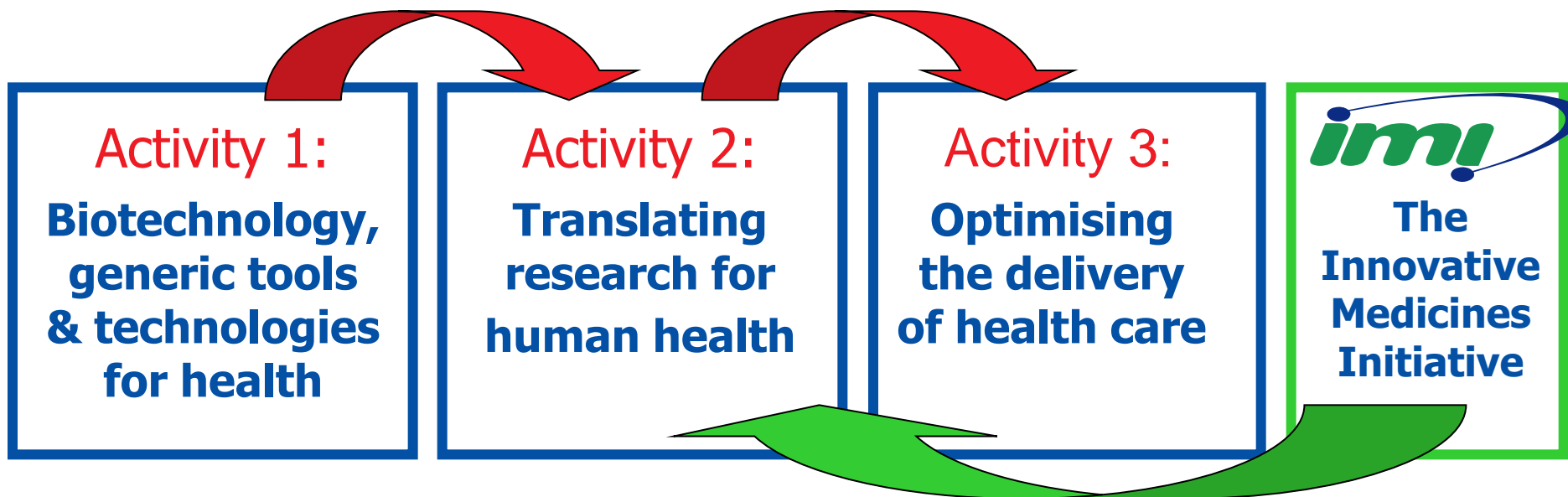
## Activity 1

### Biotechnology, generic tools and medical technologies for human health

**YOU MUST REFER TO THE FINAL PUBLISHED CALL FOR PROPOSALS  
for confirmation of deadlines, conditions & final topic descriptions.**

# The Health Theme

## Three main activities (“pillars”)



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

Activity 4: Support actions & response to policy needs

### 1.2 - Detection, diagnosis and monitoring

**1.2-1** Development of technologies with a view to patient group stratification for personalised medicine applications.

Funding scheme: CP-FP, SME-topic (min. 30% for SMEs)  
max. €6m/project. >10 projects to be funded

### 1.4 - Innovative therapeutic approaches & interventions

#### 1.4-1 Innovative approaches to solid organ transplantation.

Funding scheme: CP-FP, SME-topic (min. 15% for SMEs)  
max. €6m/project, ~3 projects to be funded

#### 1.4-2 Medical technology for transplantation and bioartificial organs. [ **"SMEs for Innovation" call** ]

Funding scheme: CP-FP, SME-topic (min. 50% for SMEs)  
3-5 partners, max. €6m/project. 5-7 projects to be funded

### 1.4 - Innovative therapeutic approaches & interventions

**1.4-3** Innovative strategies for translation of stem cell based therapies in regenerative medicine (EU-Australia cooperation)

Funding scheme: CP-FP, SME-topic (min. 15% for SMEs)  
max €6m/project, max 1 project to be funded

**1.4-4** Targeted nucleic acid delivery as an innovative therapeutic or prophylactic approach.

Funding scheme: CP-FP, Industry-topic (min. 30% for industry, including SMEs); max €6m/project, ~3 projects to be funded

# Orientations for 2012 WP

## Activity 2 Translating research for human health

## 2.1.1 – Large-scale data gathering

**2.1.1.1-A** Support for international rare diseases research.

Funding scheme: SA, max. €2m/project, max. 1 project

**2.1.1.1-B** Clinical utility of -omics for better diagnosis of rare diseases.

Funding scheme: CP-IP, SME-topic (min. 30% for SMEs); max. €12m/project, max. 2 projects

**2.1.1.1-C** Databases, biobanks rare diseases research.

Funding scheme: CP-IP, max. €12m/project, max. 1 project

## 2.1.1 – Large-scale data gathering

**2.1.1-2** Validation of -omics based biomarkers for diseases affecting the elderly.

Funding scheme: CP-IP, SME-topic (min. 30% for SMEs)  
max. €12m/project, up to ~2-3 projects

**2.1.1-3** Statistical methods for collection and analysis of -omics data.

Funding scheme: CP-FP, SME-topic (min. 15% for SMEs)  
max. €6m/project, ~1 project to be funded

## 2.1.2 – Systems Biology

**2.1.2-1** Systems medicine: SME-driven research applying systems biology approaches to address medical & clinical needs

Funding scheme: CP-FP, SME-topic (min. 30% for SMEs)  
max. €3m/project, up to 6-8 projects

**2.1.2-2** Systems medicine: applying systems biology approaches for understanding multifactorial human diseases and their co-morbidities.

Funding scheme: IP, max. €12m/project, up to ~3-4 projects

**2.1.2-3** Preparing for the future research and innovation activities in systems medicine.

Funding scheme: CA, max. €3m/project, max. 1 project funded

### 2.2.2 – Human development and ageing

**2.2.2-1** Integrative systems biology and comparative genomics for studying human ageing and/or most common age-related diseases.

Funding scheme: CP-FP, SME-topic (min. 30% for SMEs)  
max. €6m/project. Up to ~3 projects

**2.2.2-2** Investigator-driven clinical trials for optimisation of management of elderly patients with multiple diseases.

Funding scheme: CP-FP, SME-topic (min. 15% for SMEs)  
max. €6m/project. Up to ~3 projects

### 2.3 – Translational research in **major infectious diseases**

Covers major HIV/AIDS, malaria, tuberculosis, hepatitis, neglected infectious diseases, emerging epidemics, fungal pathogens, as well as anti-microbial drug resistance.

#### 2.3.0-1 Diagnostics for infectious diseases in humans [ **“SMEs for Innovation” call** ]

Funding scheme: CP-FP, SME-topic (min. 50% for SMEs)  
3-5 partners, max. €6m/project. Up to ~6 projects

#### 2.3.0-2 ERA-NET on infectious diseases [ **ERA-NET call** ]

Funding scheme: CA, max. €2m/project, max. 1 project

### 2.3.2 – HIV/AIDS, malaria and tuberculosis

**2.3.2-1** Co-infection of HIV/AIDS, malaria, tuberculosis and/or hepatitis.

Funding scheme: CP-FP, max. €6m/project, up to 2-3 projects

**2.3.2-2** Co-morbidity between infectious diseases and non-communicable diseases.

Funding scheme: CP-FP, max. €6m/project, up to 2-3 projects

### 2.3.2 – HIV/AIDS, malaria and tuberculosis

#### 2.3.2-3 Prevention and treatment for HIV/AIDS, malaria and tuberculosis.

Small consortia encouraged (3-5 partners), duration 1-3 years.

Funding scheme: CP-FP, SME-topic (min. 15% for SMEs)  
max. €6m/project, up to 2-3 projects

#### 2.3.2-4 Low-cost interventions for disease control in resource poor settings.

Funding scheme: CP-FP, max. €3m/project, up to 3-4 projects

#### **Action** to support preparation of 2<sup>nd</sup> phase of EDCTP

Funding scheme: CSA, max. €10m. (named beneficiary)

### 2.4.3 – Diabetes and obesity

#### 2.4.3-1 Innovative approaches to manage diabetes.

Funding scheme: CP-FP, SME-topic (min. 30% for SMEs)  
max. €6m/project. Up to 3-4 projects

#### 2.4.3-2 Investigator-driven clinical trials for type 1 diabetes research.

Funding scheme: CP-FP, max. €6m/project, up to 2-3 projects

## 2.4.4 – Rare diseases

**2.4.4-1** Preclinical and/or clinical development of substances with a clear potential as orphan drugs.

Funding scheme: CP-FP, Industry-topic (min. 30% for industry, including SMEs); max €6m/project, up to ~10 projects

**2.4.4-2** Observational trials in rare diseases.

Funding scheme: CP-FP, max. €3m/project, ~3-4 projects

**2.4.4-3** Best practice and knowledge sharing in the clinical management of rare diseases.

Funding scheme: CA, max. €2m/project, max. 1 project

## 2.4.5 – Chronic diseases

**2.4.5-1** Technological approaches to combating sensory impairments. [ **“SMEs for Innovation” call** ]

Funding scheme: CP-FP, SME-topic (min. 50% for SMEs)  
3-5 partners, max. €6m/project. Up to ~5-6 projects

**2.4.5-2** Biomarkers and diagnostics for chronic inflammatory diseases of the joints and/or digestive system.

Funding scheme: CP-FP, SME-topic (min. 15% for SME)  
max. €6m/project. Up to ~2 projects

# Orientations for 2012 WP

## Activity 3 Optimising the delivery of healthcare

## 3.2 – Quality, efficiency and solidarity of healthcare systems

### 3.2-1 Improving the organisation of health service delivery.

Funding scheme: CP-FP, max. €3m/project, up to ~7-8 projects

### 3.2-2 New methodologies for health technology assessment

Funding scheme: CP-FP, max. €3m/project, up to ~2-3 projects

### 3.2-3 Social innovation for ageing research

Funding scheme: CP-FP, max. €3m/project, up to ~1-2 projects



## 3.4 – International public health & health systems

### 3.4-1 Research on Health systems and services in low/middle income countries.

- Projects should generally be 5 years in duration.
- Min. 6 different ICPC partners & 2 EU/AC partners from different countries.

Funding scheme: CP-FP (SICA), max. €6m/project, ~3 projects

# Orientations for 2012 WP

## Activity 4 Other actions across the theme

## Actions across the Health theme

### 4.1 – CSAs across the theme

**4.1-1** Network to encourage knowledge transfer activity in FP-funded health research (especially in academic and governmental organisations).

Funding scheme: CA, max. €2m/project, up to 1 project.

**4.1-2** Training actions linked to intellectual property rights management and knowledge transfer.

Funding scheme: CA, max. €2m/project, up to 1 project

## Actions across the Health theme

### 4.1 – CSAs across the theme

**4.1-3** Support for presidency events. Organisation of supporting actions and events related to the EU Presidency.

Funding scheme: SA, max. €0.1m/project, up to 2-3 projects

**4.1-4** Communicating the benefits of European research to the general public.

Funding scheme: CA, max. €1m/project, up to 1-2 projects

**4.1-5** Preparing the future for health research and innovation

Funding scheme: CSA, max. €0.5m/project, up to 1-2 projects

## Opportunities in other Themes

# Opportunities in other Themes

## KBBE: complementary to Theme Health

- KBBE.2012.2.1-01: Role of health-related symbols and claims in consumer behaviour
- KBBE.2012.2.2-01: Beneficial effects of bioactive compounds in humans
- KBBE.2012.2.2-02: Study on the needs for food and health research infrastructures
- KBBE.2012.2.2-03: Impact of lifestyle on well-being and diet-related disease

## NMP: complementary to Theme Health

- NMP.2012.1.2-2: Development and phase-I clinical trials of novel therapeutic nanotechnology-enabled systems for the diagnosis and treatment of atherosclerosis
- NMP.2012.1.2-3: ERA-NET on nanomedicine
- NMP.2012.1.3-1: Systematic investigations of the mechanisms and effects of engineered nanomaterial interactions with living systems and/or the environment
- NMP.2012.1.3-2 : Modelling toxicity behaviour of engineered nanoparticles
- NMP.2012.2.2-1: Biomaterials for improved performance of medical implants

# Opportunities in other Themes

## SSH: complementary to Theme Health

- ERA-net Coordinating research economic agendas
- Making longevity an asset for economic and social development
- A European childhood and youth survey
- Forward looking tools and methods for answering major societal challenges

# Opportunities in other Themes

ICT: complementary to Theme Health

## **ICT-2011.5.2 Virtual Physiological Human (call 9)**

- a) Patient-specific predictive computer-based models and simulation
- b) Development of ICT tools, services and infrastructure to obtain more elaborate and reusable multi-scale model
- d) Early demonstrators and proof of concept of digital representations of health status

All other areas of challenge 5: 'ICT for Health, Ageing Well, Inclusion and Governance' are closed in 2012

# Thank you

## Contacts & Information:

**FP7 Health web site:** <http://cordis.europa.eu/fp7/health>

**Support:** [http://cordis.europa.eu/fp7/health/support\\_en.html](http://cordis.europa.eu/fp7/health/support_en.html)

Registration as an **Expert:** <https://cordis.europa.eu/emmfp7/>

**FitForHealth:** [www.fitforhealth.eu](http://www.fitforhealth.eu)

**EC projects database:** [www.healthcompetence.eu](http://www.healthcompetence.eu)

National Contact Points (NCP):

[http://cordis.europa.eu/fp7/health/ncp\\_en.html](http://cordis.europa.eu/fp7/health/ncp_en.html)