Towards Health Work Programme 2013

Directorate Health

DG Research & Innovation
European Commission

EU research policy

Why ?

- to improve quality of life and
- to improve competiveness 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)**

Drivers for 2013 calls and the 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*
- *Guides for applicants will be adapted accordingly*

Collaborative research across borders

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 14 Associated Countries:**
  Albania, Bosnia-Herzegovina, Croatia, FYROM, Iceland, Israel, Liechtenstein, Montenegro, Norway, Serbia, Switzerland, Turkey, Faroe Islands & Moldova.
- **In addition, researchers from anywhere in the world can participate:**
  e.g.: Australia, Brazil, Canada, China, India, Japan, Korea, Russia, South-Africa, USA …
  and in many cases, can be funded.

Why should I apply?

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"**
- **Short proposal: max. 6 pages in the 1st stage**
- **The size of consortium (beyond min. 3)***
- **The EU contribution requested****
- **The duration of the project*****

is for the applicants to determine

* with the exception of 3-5 max. for the "INNOVATION-2" call
** within ceiling
*** with some exceptions

Outcome of the 2012 calls for proposals

FP7-HEALTH-2012-**Innovation-2** – results:

- stage 1 (deadline: 27/09/2011) – 112 proposals received
  evaluation: October. Notification: "yes" 28 Oct. ,"no" 8 Nov.

Outcome of 1st stage:

	received	above threshold	Success rate
Proposals	112	46	**41%**

- stage 2 (deadline: 13/12/2011) – 45 proposals received
  evaluation: 20/12/2011-20/01/2012 - Notification: 9 Feb. 2012

Outcome of 2nd stage:

	received	above threshold	funded	Success rate
Proposals	45	19	19	**42%**

- Many proposals poor on "Expected Impact"

FP7-HEALTH-2012-**Innovation-1** – results:

- stage 1 (deadline: 4/10/2011) – **1173 proposals received**
  evaluation: Oct-Nov. Notification: 7-8 December 2011

Outcome of 1st stage:

	eligible	above threshold	Success rate
Proposals	1136	322	**27.5%**

- stage 2 (deadline: 8/02/2012) – 321 proposals received
  evaluation: mid-February – end-March; notification 20 April.

Outcome of 2nd stage:

	eligible	above threshold	funded	Success rate
Proposals	319	151	121	**38%**

The 2013 Health work programme

Key features for 2013 work programme

- *Three research priorities:*
  - **Brain research**
  - **Antimicrobial drug resistance**
  - **Comparative effectiveness research**
- *2 calls: INNOVATION-1 (34 topics), INNOVATION-2 (2 topic)*
- *Topics overview:*
  - **Many SME/industry targeted topics:** minimum15% to 30% of EU contribution has to go to SMEs
  - **3 large projects:** EU contribution of €24 million or € 30 million
  - **2 pilot SME topics:** minimum 50% of EU contribution has to go to SMEs
  - **6 topics with clinical trials**

Key features for 2013 work programme

- *Indicative budget:*
  - **INNOVATION-1: €679 million**
  - **INNOVATION-2: €140 million**
- *Several projects funded for MOST topics*
- *Two-stage call for all topics,*
  with short proposals (5 pages) at 1st stage
- *Deadline for submission:*
  - **INNOVATION-1 (34 topics): 2 October 2012***
  - **INNOVATION-2 (2 pilot SME topic): 25 September 2012***

* To be confirmed in official call documents to be published in July 2012

General conditions 2013

- *Any research organisation can participate, including larger companies, as well as service-providers.*
- *However, the funding levels are different:*
  - **For academia & SMEs: 75% of research costs**
  - **For larger companies: 50% of research costs**
  - **For all: 100% management & training & eligible IP costs**

- *What is an SME ? (for the EC: 1 + 2 + 3)*

1. **less than 250 employees**
2. **annual turnover ≤€50 million OR balance sheet total ≤€43 million**
3. **must be autonomous***

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

Specific conditions for INNO-2 call

- *Pilot initiative to stimulate innovation via enhanced SME participation*
- *Special conditions:*
  - **3-5 partners, min. 50% of EU funding for SME(s)**
  - **SME participation restricted to EU and Associated Countries**
  - **Maximum 3 years**
  - The SME must have a leading role in the project
  - Higher threshold for "Impact" criterion
  - Simplified application process: short project description
  - Accelerated procedures for submission, evaluation & negotiation i.e.: earlier deadlines for 1st and 2nd stage submission.

Clinical trial topics

Aim:

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

Scope:

- specified in each topic, phases covered are decided by the participants, and may be depend on the maximum possible allocated budget.
- expected to be mostly phase I, II, and IV - for details see specific topics and special instructions for clinical trials.

Note:

- Importance of ethics issues
- Patient involvement
- Statistics

Funding schemes

Type of instrument	Number of topics	maximum EU contribution
Large-scale integrating project (IP)	6	€12m, up to €30m
Small or medium-scale focused research project (FP)	24	€3m or €6m
Coordination and Support action (CSA)	6	100k€, up to €2,5m

Note: there are some exceptions to the ceilings

Advice for applicants

- *Analyse the work programme carefully*
- *Apply if you see a clear opportunity that fits your strategy*
- *Choose your partners carefully*
- *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 planned & resourced – but you have control.*
- *Use support structures:*

  National Contact Points (NCPs), Fit-for-Health, …

Thank you

Contacts & Information:

FP7 Health web 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/

FitForHealth: www.fitforhealth.eu

EC projects database: www.healthcompetence.eu

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Topics foreseen in 2013 Health work programme*

* To be confirmed in official call documents to be published in July 2012

Horizontal topic for collaborative projects relevant for the whole of theme health

50% SME

FP7-HEALTH-2013-INNOVATION-2:

HEALTH.2013.0-1 Boosting the translation of health research projects' results into innovative applications for health

- Allow SMEs to take up health research outcomes resulting from earlier FP funding under health FP7 or FP7.
- Prove the viability of methodologies, processes, prototypes, models, technologies, clinical trials etc. developed under these projects, with a potential for application.
- Demonstrate clear exploitation potential and socio-economic benefits for the patients.
- Applicants should have the freedom to exploit results for commercial use.

Activity 1: Biotechnologies, tools and medical technologies for Human health

Biotech, tools & technologies

1.1 - High-throughput research - *closed*

1.2 - Detection, diagnosis and monitoring

30% SME

1.2-1 Development of imaging technologies for therapeutic interventions in rare diseases

- Support development and/or proof of principle of new or improved combined imaging technologies for therapeutic interventions in rare diseases.
- Two or more techniques, at least one should be molecular imaging, should be integrated into a complete simultaneous system for application in one or more rare diseases in the frame of personalised medicine
- The technologies should be of use as biomarkers during the therapeutic interventions. Clinicians should actively be included in the project.

Biotech, tools & technologies

1.3 - Suitability, safety, efficacy of therapies

1.3-1 Modelling toxic responses in case studies for predictive human safety assessment.

15%
Ind/SME

- to exploit in case studies recent advances in computational chemistry and systems biology in order to provide the basis for innovative approaches to predictive human safety assessments.
- Integrated research should be undertaken (see topic for details)
- It should be built on current attempts around the world that model specific organs, and
- it should go beyond these to deliver an approach which is fit-for-purpose for predictive toxicology.

Biotech, tools & technologies

1.3 - Suitability, safety, efficacy of therapies

1.3-2 Innovative approaches to address adverse immune reactions to biomedical devices, implants and transplant tissues

30%
Ind/SME

- Holistic systems approach to adverse immune reactions
- Identification and validation of predictive biomarkers
- Integration of –omics data
- New *in silico* and *in vitro* models

Biotech, tools & technologies

1.3 - Suitability, safety, efficacy of therapies

30%
Ind/SME

1.3-3 Safety and efficacy of therapeutic vaccines

- to advance promising new therapeutic vaccines into clinical safety and efficacy testing
- Therapy should be based on an active vaccination effect triggering a human immune response as opposed to passive immunization
- Projects must demonstrate that a therapeutic vaccine in the envisaged application area is superior to existing or competing therapies under development, and
- that the expected cost-medical benefits ratio meets public health needs

Biotech, tools & technologies

1.3 - Suitability, safety, efficacy of therapies

30%
Ind/SME

1.3-4 Development of alternative in vitro, analytical, immuno-chemical, and other test methods for quality control of vaccines

- Novel technological approaches are needed to ensure faster and more reliable testing of vaccine products
- Exploring to which extent animal-based safety and potency testing of experimental or licensed vaccines can be replaced (in totality or partially) by alternative tests or processes
- Support to studies aiming to develop and validate novel, rapid and reliable safety and potency assays that demonstrate correlation of safety of vaccine products with animal-tested batches

Biotech, tools & technologies

1.4 – Innovative therapeutic approaches and interventions

1.4-1 Controlling differentiation and proliferation in human stem cells intended for therapeutic use

15% SME

- Develop application of stem cells for new therapies
- Addressing identified and justified and therapeutic concept
- Focus on control of differentiation and proliferation
- Assessment of biological activity/potency
- Use of advanced research tools and in vivo investigations preferred
- Pre-clinical and clinical testing encouraged

Activity 2: Translating research for human health

Translating research for human health

2.1 – Integrating biological data and processes: Large-scale data gathering, systems biology

2.1.1 Large-scale data gathering

2.1.1-1 Functional validation in animal and cellular models of genetic determinants of diseases and ageing processes

30% SME

- Use models to discover functions of genes associated to human diseases and/or ageing processes.
- Aim at understanding disease and ageing processes in view of new therapeutic targets.
- Large-scale phenotyping of model organisms and *in vitro* systems.
- Envisage generating models to investigate diseases variations.
- Develop standardised and reliable tools, procedures and technologies for phenotyping.

Translating research for human health

2.1 – Integrating biological data and processes

2.1.1 Large-scale data gathering

2.1.1-2 High impact research initiative on metagenomics for personalised medicine approaches

30% **Ind/SME** **€30m**

- Contribute to International Human Microbiome Consortium (IHMC) and include
- Metagenome profiling in health, diseases & ageing (pop. studies).
- Investigations of the links: human microbiome – diets.
- Investigations of the role of the metagenome in drug response.
- New diagnostic and prognostic tools for personalised treatments.
- Bioinformatics; Training and exchange programmes

2.1.2 Systems biology closed

Translating research for human health

2.2 – Research on the brain and related diseases, human development and ageing

2.2.1 Brain and brain-related diseases

2.2.1-1 Prospective longitudinal data collection and Comparative Effectiveness Research (CER) for traumatic brain injury (TBI)

€30m

- Clinical study to collect a large set of harmonised data for subsequent analysis using CER.
- Aiming at identifying the most effective clinical interventions to treat TBI according to patient history and type of injury
- Consortia required to use the TBI Common Data Elements as data standards.
- Part of the International Initiative for Traumatic Brain Injury Research (InTBIR), a global international effort with the US and Canada.

Translating research for human health

2.2.1 Brain and brain-related diseases

30%
Ind/SME

2.2.1-2 Development of effective imaging tools for diagnosis, monitoring and management of mental disorders

- Develop new and/or optimise existing imaging technology for use in mental disorders.
- Imaging data to be correlated with e.g. genomics, biomarkers, bioinformatics and clinical data.
- Aiming at enabling diagnosis of mental disorders at the pre-symptomatic stage, a more accurate patient stratification and better monitoring of disease progression.

Translating research for human health

2.2.1 Brain and brain-related diseases

15% SME

2.2.1-3 Paediatric conduct disorders characterised by aggressive traits and/or social impairment: from preclinical research to treatment

- Aiming at gaining new insights into the mechanisms underlying pathological aggression as well as develop preventative and therapeutic strategies for conduct disorders.
- Targeted at the paediatric population (0-18 years).
- Consortia expected to apply a multidisciplinary approach to address pre-clinical and/or clinical research bottlenecks (eg: genes/environment interactions, neurobiology of aggression, predictive biomarkers, preventative and therapeutic strategies).

Translating research for human health

2.2.1 Brain and brain-related diseases

15% SME

2.2.1-4 Patho-physiology and therapy of epilepsy and epileptiform disorders

- Consortia are expected to use multidisciplinary strategies to improve our understanding of the aetiology and mechanisms of epilepsy and epileptiform disorders.
- Both pre-clinical and clinical research can be addressed, e.g. (non-exhaustive): genetics of epilepsy, ictiogenesis, epilepsy prevention, refractory epilepsy, age- and aetiology-specific drug targets.

Translating research for human health

2.2 – Research on the brain and related diseases, human development and ageing

2.2.1 Brain and brain-related diseases

2.2.1-5 Understanding and controlling pain

- Targets pain syndromes such as headache and migraine, neurogenic and neuropathic pain.
- Consortia are expected to deepen our knowledge of how pain is generated, propagated and quenched, as well as work towards the identification of more effective diagnostic and/or treatment approaches.
- The goal is to identify and develop biomarkers for pain to enable better patient stratification, mechanism-based treatment selection and targeted prevention strategies for high-risk individuals.

2.2.2 Human development and ageing *closed*

Translating research for human health

2.3 – Translational research in major infectious diseases: to confront major threats to public health

2.3.0 Cross-cutting priorities

2.3.0-1 Innovation in vaccines

30% SME

- Development of new, safe and effective vaccines.
- Proposals are expected to address pre-clinical and clinical development.
- Proposals must focus either on:
  1. "Universal" Influenza vaccines with the ultimate aim to protect from seasonal and pandemic influenza
     or:
  2. Prophylactic vaccines for any of the neglected infectious diseases*. Research must be advance to initiate clinical testing during the early phases of the project

** as listed in the text of the topic*

Translating research for human health

2.3 – Translational research in major infectious diseases: to confront major threats to public health

2.3.1 Anti-microbial drug resistance

50% SME

FP7-HEALTH-2013-INNOVATION-2

2.3.1-1 Drugs and vaccines for infections that have developed or are at the risk of developing significant antimicrobial resistance

- Aim to develop novel, safe and efficacious antimicrobials, vaccines or alternative medical approaches to treat infections.
- Proposals may include different components of the drug development pipeline from discovery phase to clinical trials.
- Proposals are expected to be complementary to any potential upcoming activities undertaken in the context of IMI on antimicrobial resistance

Translating research for human health

2.3.1-2 Stratified approaches to antibacterial and/or antifungal treatment

- to improve the use of antibacterial and antifungal (dosage, duration, indication and combinations), antimicrobial administration need to be better tailored to the actual needs of individual patients.
- Proposals should aim to gain a better understanding of both pathogen and host factors as well as their interaction.
  The objective is to allow for more stratified treatment options & improved antimicrobial administration

Translating research for human health

2.3 – Translational research in major infectious diseases: to confront major threats to public health

2.3.2 HIV/AIDS, malaria and tuberculosis *closed*

Translating research for human health

2.3.3 Potentially new and re-emerging epidemics

€24m

2.3.3-1 Clinical management of patients in severe epidemics ***(1/2)***

- To set up a multidisciplinary consortium for a rapid, harmonized and optimised approach to clinical management of patients in relation to any severe infectious outbreak with pandemic potential or significant risk of major damage to health and socio-economics in the EU
- The consortium must address severe acute respiratory infections and other acute infections
- It should build a standardised methodological approach to ensure readiness to perform large-scale clinical studies in response to emerging an threat
- It must have a solid "inter-epidemic" research plan, to address issues such as multicenter clinical trials, studies on pathogenesis, immunity and determinants of severity

Translating research for human health

2.3.3 Potentially new and re-emerging epidemics

€24m

2.3.3-1 Clinical management of patients in severe epidemics ***(2/2)***

- To explore ways to speed-up the identification and characterisation of pathogens
- It should include training activities to spread the new insights to clinical centres
- The consortium should give special attention to EU MSs and ACs with limited capacity
- To structure the European contribution towards the international initiatives
- The consortium should collaborate with ECDC in order to improve the European preparedness & response to any emerging threat

Translating research for human health

2.3.4 Neglected infectious diseases

*2.3.4-1 Neglected infectious diseases of Central and Eastern Europe (CEE)**

- To perform innovative, collaborative biomedical research focused on one or more of the neglected viral, bacterial and/or helminthic human diseases* affecting Central and Eastern Europe.
- Proposals must provide significant participation of partners from disease-endemic areas
- They should include plans for translating research results into innovation in the health systems or through product development activities

- ** as listed in the text of the topic*

Translating research for human health

2.3.4 Neglected infectious diseases

15% SME

2.3.4-2 Drug development for neglected parasitic diseases

- To bring together promising European and global attempts to discover and develop drugs for neglected parasitic diseases*. Proposals should focus either on:

1) establishing a common drug discovery platform by joining experts in the field from industry & the public sector in Europe & disease-endemic countries. The discovery platform should address a min of 3 parasitic diseases
or:

2) undertake advanced clinical testing of new or improved drug candidates, including new formulations of combinations of already approved drugs. The candidates must have undergone already first-in-man testing

** as listed in the text of the topic*

Translating research for human health

2.4 – Translational research in other major diseases

2.4.1 Cancer

2.4.1-1 Investigator-driven treatment trials to combat or prevent metastases in patients with solid cancer

- Assessing advanced therapeutic strategies for metastases in patients with solid cancers or for preventing their development.
- Consortia required to use state-of-the-art technologies to ensure proper patient staging and assessment of treatment efficacy. The primary endpoint should be overall survival.
- CTs need to be appropriately powered to produce statistically significant evidence. Also important: gender aspects, differences related to age groups; registration; involvement of patient advocacy groups if appropriate.

Translating research for human health

2.4 – Translational research in other major diseases

2.4.1 Cancer

2.4.1-2 Strengthening the cancer patient's immune system

30%
Ind/SME

- Reverse translate clinical observations concerning cancer immunotherapy into improving treatment efficacy of future immunotherapeutic strategies.
- It could address: (1) cell- or antibody-based immunotherapy; (2) therapeutic cancer vaccines directed against clinically relevant tumour and/or host antigens; (3) immune evasion impacting on clinically relevant tumour-host micro-environment interactions in localised or systemic disease.
- Where appropriate, tumour response criteria must be considered and existent or newly developed assays harmonised while validating cancer immunotherapeutic regimens in models or first-in-human trials.

Translating research for human health

2.4 – Translational research in other major diseases

2.4.1 Cancer

2.4.1-3 Investigator-driven supportive and palliative care clinical trials and observational studies

- Aiming at improving quality-of-life of cancer patients or cancer survivors.
- address management of symptoms caused by cancer, cancer treatment, long-term side-effects in cancer survivors or address end of life symptoms.
- The outcome should be relevant for patients and have a potential to lead to changes in clinical practice.
- CTs need to be appropriately powered to produce statistically significant evidence. Also important: gender aspects, differences related to age groups; involvement of patient advocacy groups.

Translating research for human health

2.4 – Translational research in other major diseases

2.4.2 Cardiovascular diseases

2.4.2-1 Discovery research to reveal novel targets for cardiovascular disease treatment

30% SME

- Explore available and emerging molecular, genomic and other omics data from large-scale population studies and lead to the identification, characterisation and validation of in vitro and in vivo models of novel therapeutically relevant targets.

- Achieving this aim should be ensured by multidisciplinary research consortia with advanced biotechnological tools available.

Translating research for human health

2.4 – Translational research in other major diseases

2.4.2 Cardiovascular diseases

2.4.2-2 Comparative effectiveness research of existing technologies for prevention, diagnosis and treatment of cardiovascular diseases

- Compare the use of currently available technical procedures and/or devices in selected broad populations.
- Asses a comprehensive array of clinical and safety, as well as socio-economic outcomes (e.g. quality of life, mortality, morbidity, costs) for chosen CVD patient populations.
- Randomised controlled trials, observational studies and meta-analysis can be considered. May include also prospective data collection, development of clinical data networks, databases or patient registries.

Translating research for human health

2.4 – Translational research in other major diseases

2.4.2 Cardiovascular diseases

2.4.2-3 Optimising lifestyle interactions in the prevention and treatment of cardiovascular disease across the lifespan

- Examine the effects of primary and secondary prevention of CVD using lifestyle intervention strategies.
- Research may include understanding the relationship between physical activity and cardiovascular health and the interactions between physical activity, other lifestyle factors and pharmacotherapy.
- Should also combine in vitro and in vivo studies on the cellular and molecular mechanisms underpinning physical activity-dependent changes in cardiovascular health.

Translating research for human health

2.4 – Translational research in other major diseases

2.4.3 Diabetes and obesity Closed

2.4.4 Rare diseases Closed

2.4.5 Other chronic diseases Closed

Activity 3: Optimizing the delivery of healthcare

Optimizing the delivery of healthcare

3.1 – Translating the results of clinical research outcome into clinical practice

3.1-1 Comparative effectiveness research (CER) in health systems and health services interventions 1/2:

- Objective: to evaluate the impact of **two or more** alternative **health system and health services interventions** in terms of **health benefit, patient needs, patient safety, effectiveness and quality of care**
- Research should
  - address the structural and policy components; cost effectiveness
  - use a multidisciplinary approach
  - take into account different organisation of care models within Europe
  - where relevant, take different population groups into account

Optimizing the delivery of healthcare

3.1 – Translating the results of clinical research outcome into clinical practice

3.1-1 Comparative effectiveness research (CER) in health systems and health services interventions 2/2

- Topic covers a broad array of interventions and approaches to be studied

- Expected impact:
  - **Provide evidence for informed decision making** in health system and health services interventions, in view of improving patient outcomes, quality of life and increase the cost/effectiveness of interventions

Optimizing the delivery of healthcare

3.2 – Quality, efficiency and solidarity of healthcare systems including transitional health systems *closed*

Optimizing the delivery of healthcare

3.3 – Health promotion and prevention

15% SME

3.3-1 Social innovation for health promotion 1/2

"Social innovations are new ideas (products, services and models) that simultaneously meet social needs (more effectively than alternatives) and create new social relationships or collaborations. In other words they are innovations that are not only good for society but also enhance society's capacity to act" .

- Objective: to identify, develop and better understand innovative approaches to reduce sedentary behaviour and enhance the level of physical activity
- Research should
  - include the identification of "good practices", the analysis of economic and social benefits and impact
  - address the role of diverse public and private entities and their interaction
  - integrate the views of potential end-users in design and M&E
  - have a strong communication strategy

Optimizing the delivery of healthcare

3.3 – Health promotion and prevention

15% SME

3.3-1 Social innovation for health promotion 2/2

- Research may cover *various areas affecting lifestyle* (e.g. sports, health, education, transport, urban planning, working environment, leisure) as well as *different intervention levels* (local, national, European).
- Expected impact:
  - identify more effective and efficient evidence-based strategies for reducing sedentary behaviour and increasing physical activity
  - provide the basis to empower society to reduce sedentary behaviour, increase physical activity in everyday life, thus preventing major lifestyle related diseases.

Optimizing the delivery of healthcare

3.4 – International public health & health systems

closed

Activity 4:
Other actions across the health theme

Other actions across the health theme

4.1 – Coordination and support actions across the theme

4.1-1 Supporting industrial participation in EU-funded research in the Health sector

- Promote participation of SMEs
- Assist SMEs in participating in EU-funded research proposals
- Encourage cooperation between SMEs and academia;
- To provide advice/information/training on valorisation of project results and knowledge transfer in view of future commercialisation.
- Max. 1 proposal to be funded; max. €2.5m.

Other actions across the health theme

4.1 – Coordination and support actions across the theme

4.1-2 Interactions between EU legislation and health research and/or innovation and the effects of its application and implementation on health research and/or innovation

- Analyse & evaluate the interactions between relevant EU legislation with related guidelines and health research and/or innovation.
- This should include the way the specific application and implementation of this legislation at national level in this field, developments in the application and implementation.
- Each action is expected to address a specific issue relating to an EU legislation of major importance for the research and outcome performed within the health area.
- One or more proposal to be funded; max. €0.5m.

Other actions across the health theme

4.1 – Coordination and support actions across the theme

4.1-3 Support for Presidency events

- Organisation of supporting actions & events of a strategic nature
- Must be explicitly linked to the Presidency of the EU
- Specifically for Presidencies between mid-2013 and end 2014
- Can be in any area of the Health theme, but should address topics that are of high relevance at that time
- One or more proposal to be funded; max. €0.1m.

Other actions across the health theme

4.1 – Coordination and support actions across the theme

4.1-4 Preparing the future for health research and innovation

- Aimed at important and/or emerging areas, where there is a need to step up efforts between European players through coordination.
- To develop a strategic plan for the further development of the targeted health research area with high impact on competitiveness, healthcare systems and benefit for European citizens' health.
- European added value must clearly be discernible.
- Aim to assess profoundly the research and/or innovation resources, gaps and needs of the thematic target area, and to evaluate its potential as a focal area for a future innovative partnership.
- Should exclude research activities.
- One or more proposal to be funded; max. €0.5m.

Other actions across the health theme

4.1 – Coordination and support actions across the theme

4.1-5 Global initiative on gene-environment interactions in diabetes/obesity in specific populations

- Coordination of research activities in the field of population research into diabetes & obesity currently funded by the EC, Member States and Associated Countries, together with other national funding agencies, as well as charities.
- To foster a global initiative on gene-environment interactions in diabetes/obesity in specific populations.
- To address the fragmentation of research activities, develop synergies and possibly common research agenda.
- Max. 1 proposal to be funded; max. €2.0m.

Other actions across the health theme

4.1 – Coordination and support actions across the theme

4.1-6 Mapping chronic non-communicable diseases research activities

- To identify and analyse current EU-funded, as well as national and regional research programmes and initiatives in the field of non-communicable diseases.
- Aim to map the scale and scope of research activities with a view to identify potential overlaps, synergies, gaps and opportunities for collaboration.
- Max. 1 proposal to be funded; max. €1.0m.

Other actions across the health theme

4.2 – Responding to EU policy needs

4.2-1 Investigator-driven clinical trials for off-patent medicines using innovative, age-appropriate formulations and/or delivery systems

30%
Ind/SME

addressing one of the options below:

a) for use in children (Regulation (EC) No1901/2006)
(based on EMA "Priority list" already published on EMA website)

b) for use in the elderly

Other actions across the health theme

4.2 – Responding to EU policy needs

4.2-2 Adverse drug reaction research

15% SME

- Generate new knowledge on severe drug reactions and provide scientific evidence for post-authorisation risk assessment of medicinal products.
- Should be based on pharmaco-epidemiological approaches focusing on adverse drug reaction research in one of the areas indicated below.
  - Long term safety of antipsychotic medication in patients with dementia
  - Genetic causes of adverse drug reactions: angiotensin-converting enzyme inhibitors and angioedema, and statin-induced myopathy
  - Long-term adverse skeletal effects of bisphosphonates

Other actions across the health theme

4.2 – Responding to EU policy needs

4.2-3 New methodologies for clinical trials for small population groups

- Research should aim to develop new or improved methodologies for clinical trials in small populations for rare diseases or stratified, personalised or individualised medicine approaches.
- These new methodologies should allow the efficient assessment of the safety and/or efficacy of the treatment in small patient groups.
- Research should be multidisciplinary and should involve all relevant stakeholders incl. industry and patient advocacy groups as appropriate.
- Should also address regulatory issues. Clinical trials will not be funded.
- Collaboration with relevant organisations outside Europe is welcome.