Working paper

for 2012

research funding for the Health theme of FP7

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Objective: Improving the health of European citizens and increasing the competitiveness and boosting the innovative capacity of European health-related industries while businesses, and addressing global health issues including emerging epidemics. Emphasis will be put on translational research (translation of basic discoveries in clinical applications including scientific validation of experimental results), the development and validation of new therapies, methods for health promotion and prevention, including promotion of child health, healthy ageing, diagnostic tools and medical technologies, as well as sustainable and efficient healthcare systems.

I STRATEGY AND CONTEXT

Approach for 2012 and 2013

The Specific Programme for Theme Health and its work programmes are aligned with the fundamental objectives of EU research policies: improving the health of European citizen and increasing competitiveness of European health-related industries and services, as well as addressing the socio-economic dimension of health care and global health issues.

Major policy initiatives, including the European Research Area (ERA), and the state of play regarding scientific opportunities and healthcare needs played an important role in the development of the work programme. The work programmes for the last two years of FP7 will have strengthened priorities and thus will contribute to putting knowledge into practice and enhance the socio-economic impact of research following the Europe 2020 strategy[1] with more industry-driven applied research. These work programmes will also continue "to secure world excellence in basic research" (Barroso, 2009[2]) through large-scale collaborative research efforts. The 2012and 2013 work programmes for Theme Health will contribute to achieving the research and innovation goals inherent to establishing a European innovation economy.

Approach for 2012

Innovation dimension and responding to socio-economic and societal challenges

The 2012 work programme will place a strong emphasis on the participation of small and medium enterprises (SMEs) in most research areas with a major focus on the medical technologies sector. Thus, it will consolidate the major effort initiated in 2011 to stimulate innovative ideas for research and SME participation via broad, bottom-up topics to be implemented through two-stage submission and evaluation procedure. Such activities are also envisioned to complement the ongoing public-private partnership with the pharmaceutical industry, the Innovative Medicine Initiative (IMI[3]). Overall this work programme will continue to support top quality collaborative research that meets the stringent criteria of scientific excellence, professional management of public funding and high socio-economic impact.

[1] Europe 2020 A strategy for smart, sustainable and inclusive growth COM(2010) 2020

[2] Political Guidelines for the New Commission, J.M. Barroso, 2009

[3] IMI: the Innovative Medicines Initiative, a public-private partnership between the European Commission and the European Federation of Pharmaceutical Industries and Association (EFPIA)

On the basis of the current coverage of the specific programme, the priority setting for the last two work programmes of FP7 will be responding to the major health-related socio-economic and societal challenges in view of the new orientations given by the Europe 2020 Strategy, including the realisation of the Innovation Union flagship initiative[4] "active and healthy ageing". Throughout the work programmes, an integrated set of approaches will contribute to a healthier life in the latter years. For 2012 this will be specifically reflected through topics related to developing personalised medicines approaches, improving availability of organs for replacement; medical technologies; gaining a better understanding of ageing; tackling chronic diseases linked to ageing; adapting healthcare systems to meet specific needs.

Key Research Challenges 2012

With a budget of approximately €620 million, given the many health issues, prioritisation allows the mobilisation of a critical mass of resources and the implementation of a coherent set of actions, to ensure greater effectiveness, impact and visibility. A number of complementing areas will be open, although not as priorities, as most of them are mainly to support one of the challenges, either research or overarching challenges. **The research priorities for 2012 will be ageing, including health systems, medical technologies and rare diseases.**

The 2012 priorities are closely linked. For instance, medical technologies are expected to contribute substantially to facilitate active and healthy ageing and could thus form a contribution of Theme Health to the European Innovation Partnership initiative, as well as fulfilling the specific programme. Furthermore, such topics offer an excellent opportunity for the participation of SMEs, thereby addressing the socio-economic challenge of innovation.

- **Ageing will be the 1st priority across the theme in 2012 (see also below)**
- **Medical technologies will be the 2nd priority**, with a focus on organ transplantation and artificial organs, diagnostics for infectious diseases, management of diabetes, sensory impairment, chronic inflammatory disease and health technology assessments.
- **Rare diseases will be the 3rd priority,** including the development of new technology for diagnosis and treatment, as well as drug development. In this area a large-scale collaboration with the US National Institute of Health is foreseen. In this area, a major effort is envisaged, both in using "-omics" technologies to achieve better diagnosis and treatment. There will also be a major push for pre-clinical or clinical development of orphan drugs, as well as observational trials. Furthermore, research into rare diseases also offers insights into human physiology, which can serve as models for personalised medicine approaches, and thus yield potential gains for the health of all.

These are major European challenges, but also world-wide key challenges, which urgently need the attention, bringing together researchers and coordinating research in a structured manner with common efforts into holistic approaches, such as critical mass for rare diseases research, or new ideas for innovative healthcare for the elderly combined with better knowledge for healthy ageing.

[4] Communication from the commission to the European parliament, the council, the European economic and social committee and the committee of the regions, Europe 2020 Flagship Initiative, Innovation Union; SEC(2010) 1161

Key cross-cutting socio-economic and societal challenges 2012

- **SME targeted actions**

  Promoting innovation by strengthening the links between academia and industry will be the driving force of the work programmes over the final two years of FP7 for Theme Health, with an unprecedented effort to engage SMEs. In 2012, many broad, SME-targeted topics are set out in areas of great interest to SMEs, such as medical technologies, and where, for each project, a minimum of 15% or 30% of EU funding must go to SMEs. It is expected that 20-25% of the total budget for 2012 will be awarded to SMEs in collaborative projects. These efforts will increase the drive to development of new technologies, new drugs and new therapies into marketable products and thus contribute to *i-economy* goals in the health sector, while improving people's quality of life in Europe and around the world.

- **Active and healthy ageing**

  Theme Health will contribute to the realisation of the "active and healthy ageing innovation partnership" with the strategic aim of contributing to the Europe 2020 objectives of inclusion, sustainability and growth. More specifically it will promote and enable EU citizens to lead healthy, active and independent lives until old age; ensure the sustainability and efficiency of social and healthcare systems; and create a European and global market for innovative products and services related to healthy and active ageing.

  The area of human development and ageing will be open for ageing-related research to contribute to a longer healthy period at old age. In addition this will be supported by topics related to medical technologies for different purposes, large scale data gathering, chronic diseases, health care systems and various clinical trials.

- **Specific support for clinical trials**

  The initiative started in Theme Health in 2011 to fund investigator-driven clinical trials on a large scale will continue and will include other areas. In 2012, clinical trials will be foreseen for optimisation of treatment in the elderly, on paediatric/adolescent diabetes medicines, and on orphan drugs (treatments for rare diseases).

Dissemination

Theme Health will also address the "innovation lifecycle" by calling for technology transfer and dissemination actions for funded projects, but also in view of new initiatives for FP8.

International cooperation

The strategy for international cooperation in Theme Health is many fold: tackling global challenges, such as emerging epidemics; addressing diseases of poverty, including neglected diseases; improving the competitiveness of the European science base and industry through global cooperation; supporting external relations of the EU, noting that health issues, including health research are shared between all countries, rich and poor. Thus it is imperative to join forces, to avoid duplication and speed up developments in large scale initiatives, while keeping the administrative complexity of the procedure at a minimum.

All topics under Theme Health work programmes are open for the participation of international partners from third countries. In recognition of the opening of NIH[5] programmes to European researchers, participants established in the *United States of America* are eligible for funding and participation in all topics described in this work programme.

Over the next two years, Theme Health will concentrate on a few major efforts for international cooperation, such as in 2012 programme level collaboration in rare diseases with the US and in innovative therapies with Australia, as well as specific actions in the area of poverty related diseases with developing countries and public health in order to contribute to achieving the Millennium Development Goals.

[5] National Institutes of Health of the US Department of Health and Human Services

II PROPOSED CONTENT FOR CALLS 2012

1. BIOTECHNOLOGY, GENERIC TOOLS AND MEDICAL TECHNOLOGIES FOR HUMAN HEALTH

This activity aims at developing and validating the necessary tools and technologies that will enable the production of new knowledge and its translation into practical applications in the area of health and medicine.

1.1 HIGH-THROUGHPUT RESEARCH

Closed in 2012

1.2 DETECTION, DIAGNOSIS AND MONITORING

The objectives are to develop visualisation, imaging, detection and analytical tools and technologies for biomedical research, for prediction, diagnosis, monitoring and prognosis of diseases, and for support and guidance of therapeutic interventions. The focus will be on a multidisciplinary approach integrating areas such as: molecular and cellular biology, physiology, genetics, physics, chemistry, biomedical engineering, nanotechnologies, microsystems, devices and information technologies. Non- or minimally- invasive and quantitative methods and quality assurance aspects will be emphasised.

For this call for proposals, the focus will be on the development of detection diagnosis and monitoring technologies for personalised medicine applications.

Note: For the topic listed below, applicants will have to follow the rules for **two-stage submission procedure (see also respective call fiche in section III).**

2012-1.2-1. Development of technologies with a view to patient group stratification for personalised medicine applications. The aim of this topic is to support research and development and/or proof of principle of technologies for application in the area of personalised medicine, i.e. tailored medical interventions which are more effective and have fewer undesirable adverse effects in specifically defined patient groups. These technologies should be of use for research, screening, diagnostics and/or guidance of therapeutic interventions. The projects must include quality control aspects for data generated and where appropriate use statistical tools. Potential end-users should actively be included in the project, at least for proof of principle projects. **Note:** Limits on the EU financial contribution apply. These are implemented strictly as formal eligibility criteria.

Funding scheme: SME-targeted Collaborative Project

Requested EU contribution per project: Maximum EUR 6 000 000.

One or more proposals can be selected.

Expected impact: The development of new and improved tools and technologies will contribute to enabling the uptake of personalised medicine into clinical practice and support the competitiveness of Europe in this area. The applications are expected to advance research in personalised medicine and have an impact in the relevant industry (in particular for SMEs).

Specific feature: SME-targeted research is designed to encourage SME efforts towards research and innovation. Priority will be given to proposals demonstrating that research intensive SMEs play a leading role. The projects will be led by SMEs with R&D capacities but the coordinator does not need to be an SME. The expected project results should clearly be of interest and potential benefit to SME(s).

Additional eligibility criterion: Projects will only be selected for funding on the condition that the estimated EU contribution going to SME(s) is 30% or more of the total estimated EU contribution for the project as a whole. *This will be assessed at the end of the negotiation, before signature of the grant agreement. Proposals not fulfilling this criterion will not be funded.*

***Justification**: This topic is of interest to DG SANCO and DG ENTER. Personalised medicine is a newly emerging field that aims at tailoring medical interventions to be more effective and have fewer undesirable side effects in specifically defined patient groups. There are technical bottlenecks that need to be overcome for the rapid uptake of personalised medicine into clinical practice. This is an area that has been identified in the workshops on personalised medicine that were organised by the Commission in 2010.*

1.3 SUITABILITY, SAFETY, EFFICACY OF THERAPIES

Closed in 2012

1.4 INNOVATIVE THERAPEUTIC APPROACHES AND INTERVENTIONS

For this call for proposals, the main focus is on transplantation, with subsidiary topics on international cooperation in stem cell research and targeted nucleic acid delivery. In order to assess the impact of research, all topics have a requirement for clinical trials to be undertaken during the life-time of the project. In addition, in order to be of benefit to industry, all topics have a requirement for SME participation. Large industry may of course also participate. Another feature of the topics is that they are drafted in broad terms in order to encourage exploitation of original ideas.

Organ transplantation is the only available treatment for a variety of life-threatening diseases and conditions. The demand for organs is increasing while the supply becomes more and more critical. Research for improved transplantation techniques and for a better immune tolerance with less side effects and longer organ survival is urgently needed. To meet the challenges of solid organ transplantation the first topic focuses on clinical trials of promising recent research.

A second topic on transplantation takes a more technological approach and focuses on medical technology for the transplantation sector, considering both solid organs *and* cells and tissues. It also includes possibilities to work on bioartificial organs; these have the function of solid organs and can substitute them but exploit living, cultured cells as their active component.

The topic on international cooperation involves Australia and presents an opportunity for European stem cell researchers to interact with a wider scientific community.

An innovative therapeutic approach in this call concerns nucleic acid transfer. The use of nucleic acids provides the basis of powerful therapeutic or prophylactic applications in vaccination, gene transfer, immunomodulation or RNA interference.

Note: Depending on the topics listed below, applicants will have to follow the rules for **two-stage submission procedure depending on the topic (see also respective call fiche in section III).**

2012-1.4-1: Innovative approaches to solid organ transplantation. The aim of this topic is the practical exploitation of recent research findings to improve the outcome, increase efficiency or widen the scope of solid organ transplantation. Projects are required to include clinical work and the necessary regulatory work as appropriate. Full attention needs to be paid to safety and immunological aspects of the work. Research should be translational, and may include improvement of understanding of mode of action if needed. For projects on xenotransplantation, if the work is not yet ready for clinical application, proposals should include a reasoned plan indicating the main development and regulatory steps needed to move the technology to the clinic. Research should involve European industry, in particular the SME sector. **Note:** Limits on the EU financial contribution apply. These are implemented strictly as formal eligibility criteria.

Funding scheme: Collaborative Project (small or medium-sized focussed research project)

Requested EU contribution per project: Maximum EUR 6 000 000.

One or more proposals can be selected.

Expected impact: Results should lead to improved treatment outcome for transplantation patients, better understanding of mode of action of treatments or potential treatments and be of use to the industrial, especially SME, sector.

Additional eligibility criterion: Projects will only be selected for funding on the condition that the estimated EU contribution going to SME(s) is 15% or more of the total estimated EU contribution for the project as a whole. This will be assessed at the end of the negotiation, before signature of the grant agreement. Proposals not fulfilling this criterion will not be funded.

***Justification**: This topic is of interest to DG SANCO. Critical shortage of solid organs for transplantation calls for more effective approaches to improve organ survival, minimise adverse immune reactions, expand donor pool, etc. Recent scientific progress, e.g. biomarkers for tolerance, opportunities for personalised treatment, synergies with stem cell transplantation, some deriving from successful FP6 activities suggest opportunities to exploit. Organ transplantation has not been covered so far in FP7. Since it ties in with their new policy initiative on organ quality, safety and donation, it is supported by SANCO. It has also received full support in the AG and PC.*

2012-1.4-2: Medical technology for the transplantation sector and bioartificial organs. The aim of this topic is to develop and carry out clinical testing of novel tools, techniques and devices for use in transplantation and in bioartificial organs. Work on transplantation may involve the use of cells, tissues or organs. Work on bioartificial organs should take into account

the fact that these are composed of both biological and artificial components. Research should focus on preparation, delivery or follow-up of transplanted material. Projects are required to include safety and efficacy assessment and regulatory work, and the execution of clinical/in-patient trials should represent a central part of the project. Since bioartificial pancreas is covered under topic 2012-2.4.3-1: "Innovative approach to manage/cure diabetes", it is excluded here. **Note:** Limits on the EU financial contribution apply. These are implemented strictly as formal eligibility criteria.

Funding scheme: SME-targeted Collaborative project

Requested EU contribution per project: Maximum EUR 6 000 000.

One or more proposals can be selected.

Expected impact: Results should lead to development and clinical testing of new tools, technologies or devices for use in transplantation and for replacing essential organ function by bioartificial organs. Results should also be of benefit to SMEs.

Specific feature: SME-targeted research is designed to encourage SME efforts towards research and innovation. Priority will be given to proposals demonstrating that research intensive SMEs play a leading role. The projects will be led by SMEs with R&D capacities but the coordinator does not need to be an SME. The expected project results should clearly be of interest and potential benefit to SME(s).

Additional eligibility criterion: Projects will only be selected for funding on the condition that the estimated EU contribution going to SME(s) is 30% or more of the total estimated EU contribution for the project as a whole. This will be assessed at the end of the negotiation, before signature of the grant agreement. Proposals not fulfilling this criterion will not be funded.

Justification: *This topic is of interest to DG SANCO and DG INFSO. The topic includes cells, tissues, organs and bio-artificial organs because of common objectives and technologies, and this has been supported by AG and PC members. Transplantation practice uses much technology, often at the cutting edge, e.g. clinical apparatus, transportation, storage devices, etc. Bio-artificial organs are essentially an application of medical technology and are sometimes proposed as a stand-alone solution but also as a temporary solution until a donor organ is available. Since bio-artificial organs often use cultured cells, the topic would be open to technologies applicable to both cell and organ transplantation.*

2012-1.4-3: Innovative strategies for translation of stem cell based therapies in regenerative medicine. Projects should aim to develop innovative strategies to stem cell-based therapies based on various approaches including allogeneic and/or autologous sources, with an emphasis on understanding the mechanisms of action and nature of the host response. Proposals should include thorough characterisation, quality control of the product(s), efficacy and safety in relevant pre-clinical models and, if possible, early assessment in humans or relevant bridging studies. The selected project should capitalise on the strong expertise and synergistic opportunities available in Australia and Europe in the fields of stem cell biology, cell-host interactions, and bioengineering, bio-processing and clinical trial management. Therapeutic products and clinical protocols should be developed through collaboration with industry partners and in consultation with appropriate regulatory bodies and health economic advisors.

Cooperation between the EU funded projects and nationally funded projects in Australia should be ensured and part of the budgets should be set aside for this cooperation and for training activities. Industrial participation is required. **Note:** Limits on the EU financial contribution apply. These are implemented strictly as formal eligibility criteria.

Funding scheme: SME-targeted Collaborative Project.

Requested EU contribution per project: Maximum EUR 3 000 000.

Only up to one proposal can be selected.

Expected impact: The main impact of this work should be the extent to which new, innovative therapeutic approaches for these diseases can be tested in relevant preclinical models or humans. Projects are expected to lead to closer cooperation between the EU and Australia in the stem cell research field.

Special feature: Programme Level Cooperation with between the EU and Australia: It is suggested that the European Commission and the competent Australian authorities will issue complementary calls to finance Australian and European projects in this field and that the funded projects will cooperate closely with each other (common meetings and training, exchange of personnel, etc.).

This initiative should follow a two-phase process which would include a review at 3 years (out of 5). To continue into the second phase of the project success must be proven as defined by approval of a regulatory joint filing within the first 3 years of a Clinical Trial Exemption (CTX) with the Therapeutic Goods Administration (TGA) and of an Investigational Medicinal Product Dossier (IMPD) clinical trial authorisation with the European Medicines Agency (EMA)

Additional eligibility criterion: Projects will only be selected for funding on the condition that the estimated EU contribution going to SME(s) is 15% or more of the total estimated EU contribution for the project as a whole. This will be assessed at the end of the negotiation, before signature of the grant agreement. Proposals not fulfilling this criterion will not be funded.

Justification: *This topic is proposed by a workshop held in Melbourne in June 2010. Cellular therapies are an emerging area which offers unprecedented opportunities for clinical therapies in a wide range of diseases. However, clinical application of these technologies must overcome unique hurdles in scientific, manufacturing and regulatory areas. This initiative aims to bring together groups with varied skill sets encompassing these areas within Australia and Europe. This alignment will result in successful deliverables from this program and will establish a platform for sustainable Australia-Europe collaborations in regenerative medicine.*

2012-1.4-4: Targeted nucleic acid delivery as an innovative therapeutic or prophylactic approach. The aim of this research is to exploit newly-developed technology for nucleic acid delivery through testing in clinical trials carried out within the lifetime of the project. Recent innovative developments in DNA vaccination, immunotherapy, gene therapy or RNA interference are very encouraging but remain challenging and more proof-of-principle is needed. Any justified disease or disorder may be targeted. Detailed safety, immunogenicity, toxicity and feasibility studies in a preclinical setup (animal models) should preferably be already available or addressed before the beginning of the project. The necessary regulatory work should be included as appropriate. Proposals should develop multidisciplinary and translational research with potential for exploitation by the clinical and/or industrial sectors. Active participation by SMEs

(minimum 30% of the EC contribution to the budget) is required and this will be considered in the evaluation of the proposal. **Note:** Limits on the EU financial contribution apply. These are implemented strictly as formal eligibility criteria.

Funding scheme: SME-targeted Collaborative project

Requested EU contribution per project: Maximum EUR 6 000 000.

One or more proposals can be selected.

Expected impact: Building on recent results the project should link promising emerging technologies with clinical application in the area of nucleic acid delivery for prophylactic or therapeutic purposes. This would enhance European expertise and competitiveness in an important emerging market. Research will also support the European biotechnology industry, especially the SME sector.

Specific feature: SME-targeted research is designed to encourage SME efforts towards research and innovation. Priority will be given to proposals demonstrating that research intensive SMEs play a leading role. The projects will be led by SMEs with R&D capacities but the coordinator does not need to be an SME. The expected project results should clearly be of interest and potential benefit to SME(s).

Additional eligibility criterion: Projects will only be selected for funding on the condition that the estimated EU contribution going to SME(s) is 30% or more of the total estimated EU contribution for the project as a whole. This will be assessed at the end of the negotiation, before signature of the grant agreement. Proposals not fulfilling this criterion will not be funded.

Justification: *Recent innovative developments in DNA vaccination, immunotherapy, gene therapy or RNA interference reported in the literature are very encouraging but remain challenging and more proof-of-principle is needed. This area has been substantially supported through FP6 but the tools for nucleic acid delivery have received little attention so far in FP7. The topic has received support from AG and PC.*

2. TRANSLATING RESEARCH FOR HUMAN HEALTH

This activity aims at increasing knowledge of biological processes and mechanisms involved in normal health and in specific disease situations, to transpose this knowledge into clinical applications including disease control and treatment, and to ensure that clinical (including epidemiological) data guide further research.

2.1 INTEGRATING BIOLOGICAL DATA AND PROCESSES: LARGE-SCALE DATA GATHERING, SYSTEMS BIOLOGY

2.1.1 Large-scale data gathering

The objective is to use high-throughput technologies to generate data for elucidating the function of genes and gene products and their interactions and control by epigenetic and other mechanisms in complex networks in important biological processes.

In the post-genome era the "-omics" technologies are advancing to the bedside. Personalized medicine is taking advantage of the cutting edge "-omics" technologies (genomics, proteomics, structural biology, interactomics, metabolomics, pharmacogenomics) to enable new approaches in diagnosis, drug development, and individualized therapy. There is a need to streamline the research in order to understand and evaluate predisposition to diseases before onset. The selected projects will set up the necessary data resource and technological platforms for developing personalized medicine approaches.

For these calls for proposals, topics focus on clinical use of -omics approaches and the analysis of their outcomes. A first topic will explore the clinical utility of -omics for better diagnosis and treatment of rare diseases. A second topic will be dedicated to the validation of -omics-based biomarkers for diseases affecting the elderly. A third topic will address statistical methods for collection and analysis of -omics data.

Note: For the topic **2012-2.1.1-1**, applicants will have to follow the rules for single-stage submission procedure; for the topics **2012-2.1.1-2 and 2012-2.1.1-3**, applicants will have to follow the rules for two-stage submission procedure **(see also respective call fiche in section III)**.

2012-2.1.1-1: Clinical utility of -omics for better diagnosis and treatment of rare diseases. The project will in a systematic way apply -omics approaches and technologies for the molecular characterisation of a chosen group of rare diseases in view of developing new diagnostics and treatments. Existing databases and biobanks (biological resources) should be exploited towards clinical applications. The development of new databases/biobanks could be envisaged only in the absence of already existing resources. Ways for ensuring the sustainability of these resources should be effectively put in place. In addition, appropriate *in vitro* or *in vivo* models should also be used with the aim to support clinical trials. The project elements should be:

- deep phenotyping of models and patients, including use of -omics technologies for better understanding of disease allowing the development of novel diagnostic tools and treatments;
- development of the relevant technologies for utilisation in a clinical setting for diagnostic or screening purposes; appropriate quality control, standardisation and statistical treatment of data must be addressed; reference -omics profiles of diseases should be established, to set or confirm a diagnosis;
- establishment and/or harmonisation of databases and bio-resources including standardisation and quality control aspects;
- development of appropriate *in vitro* and *in vivo* models for development of appropriate preventive or therapeutic personalised interventions.

The project is expected to have appropriate plans to engage with relevant stakeholders, such as patient organisations and regulatory bodies. **Note:** Limits on the EU financial contribution apply. These are implemented strictly as formal eligibility criteria.

Funding scheme: Collaborative Project (large-scale integrating project)

Requested EU contribution per project: Maximum EUR 30 000 000.[6]

Only up to one proposal can be selected.

Expected impact: This project is expected to provide better means for the correct diagnosis and treatment of rare diseases for which there is no or unsatisfactory diagnosis and/or treatment available. It should also contribute to networking and harmonising patient registries for rare diseases in Europe. The project should contribute to the International Rare Disease Research Consortium goals.

Additional eligibility criterion: Projects will only be selected for funding on the condition that the estimated EU contribution going to industry, including SME(s) is 30% or more of the total estimated EU contribution for the project as a whole. *This will be assessed at the end of the negotiation, before signature of the grant agreement. Proposals not fulfilling this criterion will not be funded.*

***Justification**: This topic is of interest to DG SANCO, DG ENTER, DG JRC and DG INFSO. This initiative should contribute to the ambitious 2020 goals of the International Rare Diseases Research Consortium: 200 new therapies for rare diseases (orphan drugs). The consortium should develop the necessary measures and policies to facilitate the development of new therapies for rare diseases. Coordinate and network patient registries: common standard operating procedures (SOPs); common ontology, harmonised ethical approaches and access to patient data and samples. Enhance clinical trials: identify and validate biomarkers and surrogate end-point. Contribute to the improvement of the regulatory framework to facilitate the development of novel therapies. Diagnostics tests for all rare diseases. Use -omics and other approaches to identify biomarkers of rare diseases (such as coordination of genome sequencing of patients with rare and non-classified syndromes). Stimulate the development of efficient, multi-purposes diagnostic tests for rare diseases.*

[6] The Maximum EU contribution per project will be re-assessed after the 2011 HIP evaluation.

2012-2.1.1-2 Validation of -omics-based biomarkers for diseases affecting the elderly. The projects should aim at clinical validation of already identified -omics-based potential biomarkers for age-related diseases or disorders affecting the elderly. The biomarkers should be potentially usable indicators for at least one of the following: prediction, diagnosis, prognosis or response to therapy. The validity should be demonstrated with existing or new studies involving human subjects. The clinical validation should show the extent to which the biomarker correlates with the disease and should be measured by sensitivity, specificity, and predictive power. The projects must take into account the use of appropriate statistical models and well as include quality control aspects for data generated. **Note:** Limits on the EU financial contribution apply. These are implemented strictly as formal eligibility criteria.

Funding scheme: SME-targeted Collaborative Project (large-scale integrating project)

Requested EU contribution per project: Maximum EUR 12 000 000.

One or more proposals can be selected.

Expected impact: The research should lead to validated biomarkers in clinical settings allowing diagnosis, prognosis, patient stratification or treatment monitoring of diseases with relevance to the ageing population. The project should bring benefits to patients and support the competitiveness of the European industry (in particular SMEs).

Additional eligibility criterion: Projects will only be selected for funding on the condition that the estimated EU contribution going to SME(s) is 30% or more of the total estimated EU contribution for the project as a whole. *This will be assessed at the end of the negotiation, before signature of the grant agreement. Proposals not fulfilling this criterion will not be funded.*

Justification: *This topic is of interest to DG SANCO and DG INFSO. Biomarkers are powerful tools in clinical practice for prediction, diagnosis, prognosis and response to therapy. For age-related diseases, the number of proposed -omics-based biomarkers is large and is rapidly increasing; however, their utility is limited by the lack of validated biomarkers in clinical settings. The need for reliable biomarkers has also been identified in the reports of several workshops on personalised medicine that were organised by the Commission in April-June 2010 in Brussels.*

2012-2.1.1-3. Statistical methods for collection and analysis of -omics data. The objective is to improve or develop new statistical methods and tools for an appropriate and accurate analysis of -omics data to better understand the results and use them more efficiently. The project may focus on a specific data type, such as genomics or proteomics, or target a particular class of analyses. Planning of experiments (e.g. through -omics-specific optimal statistical testing approaches), data gathering (including how to deal with missing or "dirty" data) and the problem of meta-analyses (to exploit limited availability and individually insufficiently powered studies) should also be considered. Clinical trials per se are explicitly excluded. The project should also include appropriate training and dissemination activities to increase awareness of current best practices and facilitate the rapid uptake by the scientific community and the industry**. Note:** Limits on the EU financial contribution apply. These are implemented strictly as formal eligibility criteria.

Funding scheme: SME-targeted Collaborative Project

Requested EU contribution per project: Maximum EUR 6 000 000.

One or more proposals can be selected

Expected impact: New and improved statistical tools allowing better use, analysis and interpretation of large scale, multivariate and/or small-sample –omics data and better experimental design. The new methods should meet the scientific needs and have the potential for rapid uptake in practice.

Specific feature: SME-targeted research is designed to encourage SME efforts towards research and innovation. Priority will be given to proposals demonstrating that research intensive SMEs play a leading role. The projects will be led by SMEs with R&D capacities but the coordinator does not need to be an SME. The expected project results should clearly be of interest and potential benefit to SME(s).

Additional eligibility criterion: Projects will only be selected for funding on the condition that the estimated EU contribution going to SME(s) is 15% or more of the total estimated EU contribution for the project as a whole. This will be assessed at the end of the negotiation, before signature of the grant agreement. Proposals not fulfilling this criterion will not be funded.

***Justification**: This topic is of interest to DG SANCO and DG INFSO. The development of new and improved statistical methods are needed for the experimental design of –omics technologies and for a better use and interpretation of the large scale and multivariate data sets generated. The need for such methods for -omics research was identified as one of the research issues in several workshops on Personalised Medicine organised by the Commission in 2010. Training is also needed, to stimulate the use of the appropriate state-of-the-art statistical techniques.*

2.1.2 SYSTEMS BIOLOGY

The focus of this area is to apply multidisciplinary research that will integrate a wide variety of biological data and will develop and apply system approaches to understand and model biological processes in all relevant organisms and at all levels of organisation.

For this call for proposals, topics focus on multidisciplinary research that will integrate a wide variety of biological, medical and clinical data and will develop and apply systems biology approaches to understand and model common human diseases. A major goal of this call is to stimulate systems biology approaches for medical and clinical applications and therefore to establish the basis for systems medicine.

Note: For the topics listed below, applicants will have to follow the rules for **two-stage submission procedure (see respective call fiche in section III).**

2012-2.1.2-1. Systems medicine: Applying systems biology approaches to address clinical needs. Research should focus on the development, improvement and application of systems biology approaches to the following medical/clinical questions, such as:

- Re-design of clinical trials by shortening times and costs
- Re-definition of clinical phenotypes based on molecular and dynamic parameters
- Development of tools for *in vivo* dynamic and quantitative clinically-relevant measurements at the cellular/tissue/organ level

- Development of combinatorial therapies and/or chronotherapies for complex diseases
- Development of combinatorial biomarkers
- Development of new and/or improvement of existing computational models to meet the needs of bio-medical or clinical research and to present the proof-of-concept for clinical utility

Consortia should aim at the exploitation of the results in the clinical and/or industrial sectors (especially SMEs) as appropriate. **Note:** Limits on the EU financial contribution apply. These are implemented strictly as formal eligibility criteria.

Funding scheme: SME-targeted Collaborative Project

Requested EU contribution per project: Maximum EUR 3 000 000.

One or more proposals can be selected, project duration up to 2 years.

Expected impact: These SME-driven collaborative research projects are specifically designed to encourage SME efforts towards research and innovation. These projects should be centred on the reinforcement of SME's scientific and technological knowledge and on the development of innovative solutions in the area of systems biology for medical applications.

Specific feature: SME-targeted research is designed to encourage SME efforts towards research and innovation. Priority will be given to proposals demonstrating that research intensive SMEs play a leading role. The projects will be led by SMEs with R&D capacities but the coordinator does not need to be an SME. The expected project results should clearly be of interest and potential benefit to SME(s).

Additional eligibility criterion: Projects will only be selected for funding on the condition that the estimated EU contribution going to SME(s) is 30% or more of the total estimated EU contribution for the project as a whole. *This will be assessed at the end of the negotiation, before signature of the grant agreement. Proposals not fulfilling this criterion will not be funded.*

Justification: *In order to make systems medicine a reality, the relevant clinical needs should be the driving force for research and innovation activities. This topic specifically addresses focused medical needs where systems biology approaches would be beneficial. The SME sector in the field of systems biology is particularly interested in areas such as the development of computational and mathematical modelling tools, identification of novel biomarkers and drug development. This type of projects having a targeted approach with few partners and short duration (max 2 years) and which are focused on clinical/medical needs ought to be attractive to SMEs. The proposed topic reflects several of the recommendations of the EC workshop "From Systems Biology to Systems Medicine", 14-15 June 2010, Brussels, published at: http://ec.europa.eu/research/health/past-events_en.html*

2012-2.1.2-2. Systems medicine: Applying systems biology approaches for understanding common human diseases and their co-morbidities. Multidisciplinary research that crosses the borders of different disciplines including basic and clinical research, network analysis, and experimental and computational modelling should focus on improving understanding of the patho-physiological mechanisms, prognosis, and diagnosis of common human diseases and their co-morbidities. The research should be driven by clearly defined clinical need and provide new avenues for disease diagnosis and/or treatment. Active participation of SMEs and patient

organisations could lead to an increased impact of the research proposed and this will be considered in the evaluation of the proposal. **Note:** Limits on the EU financial contribution apply. These are implemented strictly as formal eligibility criteria.

Funding scheme: Collaborative Project (large-scale integrating project)

Requested EU contribution per project: Maximum EUR 12 000 000.

One or more proposals can be selected.

Expected impact: Recent advances in systems biology and network analysis have opened new ways of understanding the pathophysiology of common diseases. It is of equal importance to address also the clinical needs in cases where several diseases co-occur (co-morbid) in the same patient, and hence the pathology and subsequently the potential treatments become even more complex. These collaborative projects are expected to deliver new insights into common human diseases and their co-morbidities with potential clinical impacts and improved quality of life of patients.

Justification: *For many common diseases and disorders it has been demonstrated that many different factors are involved; in particular, there are cases where several diseases (co-morbidities) are presented in the same patient and the level of the disease complexity is increased. To better understand the complex networks of factors behind such diseases and their co-morbidities it would be beneficial to apply systems biology approaches. The proposed topic reflects several of the recommendations of the EC workshop "From Systems Biology to Systems Medicine", 14-15 June 2010, Brussels, published at: http://ec.europa.eu/research/health/past-events_en.html*

2012.2.1.2-3: Preparing for the future research and innovation activities in systems medicine. The project should aim to promote and support the networking and coordination of European research activities for systems biology applications to medicine. The focus should be on bringing together different national and European efforts with the aim: (i) to develop a road-map and set-up of research priorities for systems medicine in Europe; (ii) to establish a plan for addressing the educational needs and multidisciplinary training in systems approaches for the next generation of scientists and medical doctors; (iii) to share best practices, information/resources on successful methodological approaches, including innovation activities such as technology transfer and exploitation. The partnership should include the appropriate stakeholders, such as systems biology scientists, clinicians, policy makers, industry, SMEs, media, in order to have a major impact in the area. **Note:** Limits on the EU financial contribution apply. These are implemented strictly as formal eligibility criteria.
Funding scheme: Coordination and Support Action (coordinating action)

EC contribution per project: Maximum EUR 3 000 000.

Only up to one proposal can be selected.

Expected impact: Building a strategy at the European level and setting out a coordinated approach to promote and integrate research in systems medicine in Europe.

Justification: *Europe is already a world force in systems biology research, which would facilitate its future leading role in the area of systems medicine. In order for systems medicine to become a reality, the community must build a coordinated vision and a road-map, where all the relevant stakeholders are involved. The proposed topic reflects several of the recommendations*

of the EC workshop "From Systems Biology to Systems Medicine", 14-15 June 2010, Brussels, published at: http://ec.europa.eu/research/health/past-events_en.html

2.2 RESEARCH ON THE BRAIN AND RELATED DISEASES, HUMAN DEVELOPMENT AND AGEING

2.2.1 Brain and brain-related diseases

Closed in 2012

2.2.2 Human development and ageing

Europe currently has the highest proportion of older people in the world and is expected to maintain this leading position for the next 50 years.

Increase in longevity has not been accompanied by an increase in disease-free life expectancy and research into human development and ageing is indeed among the important cross-cutting issues for the Health programme in FP7. Research on the basic mechanisms of development and ageing is required to improve health and quality of life during the life course through the use of a wide variety of methodologies and tools aimed at better understanding the processes of life-long development and healthy ageing, preventing and curing a series of the most common age-related diseases

For this call the focus will be on the use and application of –omics knowledge and tools to gain a clear understanding of the fundamental mechanisms of human ageing and on the detection, monitoring and development of innovative therapeutic tools for age-related diseases as well as the optimisation of treatment for elderly patients.

Ageing research is characterized by large-scale, heterogeneous data sets that require strong expertise from molecular biology and medicine, as well as engineering, computer science, mathematics and statistics.

Note: For the topics listed below, applicants will have to follow the rules for **two-stage submission procedure (see also respective call fiche in section III).**

2012-2.2.2-1: Integrative systems biology and comparative genomics for studying human ageing and most common age-related conditions. This topic will address the basis of human ageing by studying genes, gene regulation and pathways involved in the process and defining the interactions through which the ageing phenotype evolves in physiological and pathological conditions. Research will encompass computational approaches and comparative genomics building on existing data and the use of appropriate models when needed. The role of known drug combinations, nutrients, lifestyle and environmental determinants on the whole body over a long period of time will also be considered. **Note:** Limits on the EU financial contribution apply. These are implemented strictly as formal eligibility criteria.

Funding scheme: SME-targeted Collaborative Project

Requested EU contribution per project: Maximum EUR 6 000 000.

One or more proposals can be selected.

Expected impact: This project is expected to translate knowledge to humans and contribute directly to bio-gerontology. By studying the interactions between genetic, epigenetic and environmental factors, and how these give rise to the ageing phenotype, the project(s) should improve the lives of older people.

Specific feature: SME-targeted research is designed to encourage SME efforts towards research and innovation. Priority will be given to proposals demonstrating that research intensive SMEs play a leading role. The project will be led by SMEs with R&D capacities but the coordinator does not need to be an SME. The expected project results should clearly be of interest and potential benefit to SME(s).

Additional eligibility criterion: Projects will only be selected for funding on the condition that the estimated EU contribution going to SME(s) is at least 30% of the total estimated EU contribution for the project as a whole. *This will be assessed at the end of the negotiation, before signature of the grant agreement. Proposals not fulfilling this criterion will not be funded*.

Justification: *This topic is of interest to DG SANCO and DG INFSO. A lot of data, especially on model organisms and humans has been generated by research supported at national and EU level in the area and is now available for further exploitation to the benefit of the whole scientific community and translation to the elderly population. Moreover, national funding is being activated right now for the same purpose of applying systems biology to ageing research. Ageing research is characterized by large-scale, heterogeneous data sets that require strong expertise from molecular biology and medicine, as well as engineering, computer science, mathematics and statistics.*

2012-2.2.2.-2: Investigator-driven clinical trials for optimisation of treatment for elderly patients with multiple diseases. The aim of the projects should be the comparison of outcomes of various treatment regimens for those diseases that are most common in elderly populations. Research will focus on drug therapy and other therapeutic interventions for patients affected by and treated for multiple diseases. Studies should include the evaluation of efficacy and adverse events. Applicants must demonstrate that clinical trials are appropriately powered to produce statistically significant evidence. *Gender aspects and differences related to age groups should be appropriately considered.* The clinical trials to be supported must be registered in a publicly accessible clinical trials registry. The applications must consider the relevant governance issues for clinical trials such as good clinical practice and respect of the appropriate international, European and national legislation and guidelines. Patient advocacy groups, which can contribute to the quality, feasibility and impact of clinical trials, should be involved where appropriate. **Note:** Limits on the EU financial contribution apply. These are implemented strictly as formal eligibility criteria.

Funding scheme: SME-targeted Collaborative project.

Requested EU contribution per project: Maximum EUR 6 000 000.

One or more proposals can be selected.

Expected impact: the impact will be threefold: on treatments better suited to the needs of older people, on lowering healthcare costs and on engaging in the pre-normative setting of geriatric medicines.

Specific feature: SME-targeted research is designed to encourage SME efforts towards research and innovation. Priority will be given to proposals demonstrating that research intensive SMEs play a leading role. The projects will be led by SMEs with R&D capacities but the coordinator does not need to be an SME. The expected project results should clearly be of interest and potential benefit to SME(s).

Additional eligibility criterion: Projects will only be selected for funding on the condition that the estimated EU contribution going to SME(s) is at least 15% of the total estimated EU contribution for the project as a whole. *This will be assessed at the end of the negotiation, before signature of the grant agreement. Proposals not fulfilling this criterion will not be funded.*

Justification: *This topic is of interest to DG SANCO and DG INFSO. In a growing elderly population there is a high potential for medication-related problems and adverse drug reactions as both increase with the age of the patient and with the number of medications prescribed. Elderly patients are also exposed to an increased risk for harmful adverse effects linked to the medication and drug-drug interactions. The topic will contribute to the optimization of therapy in geriatrics; reduce medication errors while at the same time optimizing guidelines of therapeutic interventions.*

2.3 TRANSLATIONAL RESEARCH IN MAJOR INFECTIOUS DISEASES: TO CONFRONT MAJOR THREATS TO PUBLIC HEALTH

2.3.0 Cross-cutting

The aim of this area is to confront major threats to public health with emphasis on HIV/AIDS, malaria and tuberculosis, neglected infectious diseases and emerging epidemics, as well as on anti-microbial drug resistance including fungal pathogens. For this call for proposals, topics focus on diagnostics across the major infectious diseases area.

Note: For the topic listed below, applicants will have to follow the rules for **two-stage submission procedure (see also respective call fiche in section III).**

2012-2.3.0-1: Diagnostics for infectious diseases. This topic covers diagnostic tests for major infectious diseases, with the aim of meeting real clinical needs. The selected projects can be of short duration (1-2 years) or longer. They are expected to address either a specific disease problem in diagnostics or focus on innovative approaches with a broad aim of distinguishing several diseases. Priority will be given to projects addressing diseases with a major lack of suitable diagnostic tests, or diseases where improved diagnostic tests would have a significant impact on disease control and management. For the disease of applicant's choice, research will aim at the development and/or improvement of one or more of the following: 1) Rapid, robust and cost-effective point of care tests for various clinical or field settings. 2) Tests that can

differentiate individuals with latent infection. The test should distinguish between individuals who remain infected from those who have eliminated the pathogen. 3) Tests to be used to monitor treatment outcome. 4) Tests that provide prognostic information 5) Tests for disease surveillance. **Note:** Limits on the EU financial contribution apply. These are implemented strictly as formal eligibility criteria.

Funding scheme: SME-targeted Collaborative Project

Requested EU contribution per project: Maximum EUR 6 000 000.

One or more proposals can be selected.

Expected impact: The projects are expected to deliver improved diagnostic tools for high priority disease, and to pave the way for early treatments of conditions which, if not early diagnosed and treated, might become very costly to the society. The main purpose is to reduce the price of diagnostic tests, interrupt transmission of the diseases and to reduce the spread of infections of global importance.

Specific feature: SME-targeted research is designed to encourage SME efforts towards research and innovation. Priority will be given to proposals demonstrating that research intensive SMEs play a leading role. The projects will be led by SMEs with R&D capacities but the coordinator does not need to be an SME. The expected project results should clearly be of interest and potential benefit to SME(s).

Additional eligibility criterion: Projects will only be selected for funding on the condition that the estimated EU contribution going to SME(s) is 30% or more of the total estimated EU contribution for the project as a whole. *This will be assessed at the end of the negotiation, before signature of the grant agreement. Proposals not fulfilling this criterion will not be funded.*

Justification: *This topic is of interest to DG SANCO and DG DEVCO. It is a broad topic with the aim that the tests should meet a real clinical need and go all the way to clinical validation. In many infectious diseases the diagnostic tests in use are antiquated and inadequate. Rapid and reliable tests are needed for reporting purposes, infection-control interventions and for treatment monitoring. Several small projects have been funded from FP before, but no substantial effort has been made to integrate European knowledge in diagnostics. Several meetings and workshops have highlighted the need of better diagnostic tools, e.g. Meeting on Moving Forward in the Diagnosis of Infectious Diseases in Developing countries: a Focus on Malaria, Forum organized by Merieux & RollBack Malaria Partnership in Annecy, France, June 22-24, 2009.*

2.3.1 Anti-microbial drug resistance

Closed in 2012

2.3.2 HIV/AIDS, malaria and tuberculosis

The focus will be on promoting translational research aiming at bringing basic knowledge through to clinical application in developing new therapies, diagnostic tools and vaccines. Research efforts will confront the three diseases at global level, but will also address specific

European aspects. The objective is to create a European research environment, where highly innovative ideas are conceived and new approaches to prevention, treatment, diagnosis and management of the diseases can be developed.

For this call for proposals, topics focus on co-infection and co-morbidity, as well as on prevention and treatment for HIV/AIDS, malaria and tuberculosis.

Note: For the topics listed below, applicants will have to follow the rules for **two-stage submission procedure (see also respective call fiche in section III).**

HIV/AIDS, malaria and tuberculosis cross-cutting 2012

2012-2.3.2-1: Co-infection and co-morbidity in HIV/AIDS, malaria, tuberculosis and hepatitis. Increasing evidence suggests that pathologies of infectious diseases are strongly influenced by concurrent presence in the same individual of other infections or non-infectious diseases. The objective of this topic is to support basic, translational and/or clinical research with the aim of improving basic knowledge therapeutic management and prognosis of patients with more than one disease. The proposals are expected to address key research questions, such as immunological mechanisms and responses to co-infection, rapid diagnosis, or investigator driven clinical trials for treatment combinations. In the present call, priority will be given to applications addressing either or both of the following areas of research:

1) Co-infections between two or more of the following diseases: HIV/AIDS, malaria, tuberculosis and hepatitis.

2) Co-morbidity between infectious and non-communicable disease. The proposals could address combination(s) of any of the major poverty-related diseases (HIV/AIDS, malaria or tuberculosis) or any of the neglected infectious diseases with non-infectious diseases, such as rheumatic or cardiovascular diseases, cancer or diabetes, with priority given to co-morbidity of particular relevance for developing countries. **Note:** Limits on the EU financial contribution apply. These are implemented strictly as formal eligibility criteria.

Funding scheme: Collaborative Project (small or medium scale focussed research project).

Requested EU contribution per project: Maximum EUR 6 00 000.

One or more proposals can be selected.

Expected impact: The successful projects will increase knowledge of co-infection and co-morbidity and contribute to better prevention, treatment and management of them. The expected impact includes optimized treatment, reduced mortality and ameliorated quality of life of the patients. Selected projects need to demonstrate how innovative approaches that foster collaboration between different disease areas can significantly strengthen and integrate the health systems.

Justification: *This topic is of interest to DG SANCO and DG DEVCO. Co-infection and co-morbidity has been recognised as an important issue for poverty related diseases and many non-communicable diseases connected to them. In the case of HIV/TB co-infection, TB is a leading cause of death in people with HIV infection, and HIV has exacerbated the TB epidemic globally. The need to support research for the development of new and improved prevention technologies*

and treatments for HIV and associated infections is highlighted in the policy document: EU Communication "Combating HIV/AIDS in the European Union and neighbouring countries" with its annexed action plan 2009-2013(Com(2009)569). Several rapid actions are needed to address these issues; in FP7 we have not had any topics yet in this area.

2012-2.3.2-2: Prevention and treatment for HIV/AIDS, malaria and tuberculosis. The supported projects should aim at developing innovative strategies for the prevention or treatment of poverty-related diseases (HIV/AIDS, malaria or tuberculosis). Priority will be given to projects addressing key research areas such as combinatorial strategies for prevention, novel therapeutic approaches, development of models for progression of the disease, and host-pathogen interaction in the human host. Projects may contain elements of both basic and translational research. A detailed plan for development and exploitation of the end results will be an important aspect to be considered during the evaluation of the proposal. The intention is to provide the individual members of the consortium with sufficient resources to deliver results in the short term. Therefore, applications from small consortia (typically 3-5 partners) are encouraged. Typical duration of the projects should be 1-3 years, and projects with expected EC contribution of €1-6 millions are sought. Potential links and synergies with existing EC-funded initiatives such as the EDCTP could be an added value. **Note:** Limits on the EU financial contribution apply. These are implemented strictly as formal eligibility criteria.

Funding scheme: SME-targeted Collaborative Project

Requested EU contribution per project: Maximum EUR 6 000 000.

One or more proposals can be selected.

Expected impact: The projects should contribute significantly to prevention and treatment of poverty related diseases by providing innovative strategies for integrating the inputs of individual research teams of the area. Progress should be translated into improving the lives of patients with PRD, and reducing their future incidence. Projects are expected to develop links and explore synergies with relevant ongoing EC initiatives, such as the EDCTP.

Specific feature: SME-targeted research is designed to encourage SME efforts towards research and innovation. Priority will be given to proposals demonstrating that research intensive SMEs play a leading role. The projects will be led by SMEs with R&D capacities but the coordinator does not need to be an SME. The expected project results should clearly be of interest and potential benefit to SME(s).

Additional eligibility criterion: Projects will only be selected for funding on the condition that the estimated EU contribution going to SME(s) is 15% or more of the total estimated EU contribution for the project as a whole. *This will be assessed at the end of the negotiation, before signature of the grant agreement. Proposals not fulfilling this criterion will not be funded.*

Justification: *This topic is of interest to DG SANCO and DG DEVCO. Innovative strategies are needed to fill the gaps in development and use of novel tools for prevention and treatment of PRD. The disease promoting interactions of the pathogens and human host needs to be better understood in order to be able to effectively intervene with the disease. This implies new drugs and vaccines, delivery systems, epidemiological studies, alternative drug application regimes and development of marketing of efficacious treatment and prevention plans. The need to support research for the development of better prevention and treatment has been highlighted in workshops and policy documents, e.g. EU communication "Combating HIV/AIDS in the*

European Union and neighbouring countries" with its annexed action plan 2009-2013 (COM(2009)569).

2012-2.3.2-3: Low-cost interventions for disease control in resource poor settings. Projects should focus on innovative ways to confront and control neglected infectious diseases, including malaria in resource-poor settings. Projects should focus on novel applications of current tools and combining dispersed and fragmented knowledge to provide new and cost-effective solutions. Projects may address and combine knowledge from areas such as combination therapy, treatment strategies, epidemiology, operational- and implementation research including quality control. Projects are expected to deliver low cost medical solutions that can be implemented within the project period. The involvement of partners from disease-endemic countries is expected, and potential links and synergies with existing multilateral initiatives such as the EDCTP could be an added value. **Note:** Limits on the EU financial contribution apply. These are implemented strictly as formal eligibility criteria.

Funding scheme: Collaborative Project (small or medium scale focussed research project).

Requested EU contribution per project: Maximum EUR 3 000 000.

One or more proposals can be selected.

Expected impact: The supported projects are expected to develop low-cost interventions that can be implemented by the end of the project period and thereby have an immediate impact of improving control of malaria and neglected infectious diseases with a major disease burden. Projects are expected to develop links and explore synergies with relevant ongoing EC initiatives, most notably the EDCTP, and – if relevant – with other multilateral initiatives such as ANDI.

Justification: *Low-cost interventions are a priority for DG SANCO and DG DEVCO. In addition, workshops and consultations, organised by DG RI as well as other organisations (e.g. WHO), researchers from developing countries have repeatedly expressed the need to undertake research with a focus on short-term applicability in disease-endemic areas of the world and with benefits to the local population. In parallel with concentrating on pure basic research and scientific impact factors, more research efforts should be dedicated to operational research and better application of existing tools in the health system. In this way, a greater and more genuine involvement of scientists in disease-endemic areas of the world can be achieved. The need for low-cost intervention tools has been highlighted in several conferences and workshops, e.g. Workshop on optimizing control of infectious diseases in resource-poor countries: Malaria diagnosis, Fever home-based management and new tools, organized by European Commission – Red Cross- Roll Back Malaria Workshop in Brussels, Aug 31-Sep 01, 2010.*

2.3.3 Potentially new and re-emerging epidemics

Closed in 2012

2.3.4 Neglected infectious diseases

Closed in 2012

2.4 TRANSLATIONAL RESEARCH IN OTHER MAJOR DISEASES

2.4.1 Cancer

Closed in 2012

2.4.2 Cardiovascular diseases

Closed in 2012

2.4.3 Diabetes and obesity

For both diabetes and obesity, special attention will be given to juvenile diseases and factors operating in childhood. It is expected that the following topics will contribute not only to research breakthroughs in diabetes/obesity treatments but also in prevention and treatment of complications. Considering the reduction in life expectancy resulting from these diseases, particular attention should be given to *paediatric aspects*, whenever possible. As a healthy life-style is a pre-requisite for any containment of the steadily increasing costs of diabetes/obesity, projects should consider such aspects in their proposals whenever possible.

For this call for proposals, topics will focus on developing and testing innovation in the field of diabetes management, as well as on investigator-driven clinical trials addressing informed clinical management for type 1diabetes, particularly in childhood and adolescence.

Note: For the topics listed below, applicants will have to follow the rules for **two-stage submission procedure (see also respective call fiche in section III).**

2012-2.4.3-1: Innovative approach to manage diabetes. Taking into account state-of-the-art innovative research and technologies, the aim of this topic is to validate, in the preclinical and/or clinical setting, the performance and applicability of therapeutic devices or biological therapies aimed at improving diabetes management. This could include for instance glucose sensors, insulin delivery systems, devices that respond on low glucose levels to release glucagon or other insulin-counteracting therapies and surgical, cellular and bio-artificial therapy approaches. Full attention needs to be paid to safety, bio-compatibility, interoperability and regulatory aspects as appropriate. **Note:** Limits on the EU financial contribution apply. These are implemented strictly as formal eligibility criteria.

Funding scheme: SME-targeted Collaborative project

Requested EU contribution per project: Maximum EUR 6 000 000.

One or more proposals can be selected.

Expected impact: Large prospective clinical trials have established the long-term benefits of restoring blood glucose to near-normal levels in people with type 1 or type 2 diabetes and its key role in reducing microvascular and macrovascular complications. However, glycemic control remains suboptimal in many patients with diabetes, even with widespread use of self-monitoring of blood glucose, insulin pumps, and the introduction of insulin analogs. Results should lead to the development of more accurate detection, delivery and monitoring methods as well as strategies for the improved management of glycemia or contribute to solving current bottlenecks of restorative and regenerative approaches.

Specific feature: SME-targeted research is designed to encourage SME efforts towards research and innovation. Priority will be given to proposals demonstrating that research intensive SMEs play a leading role. The projects will be led by SMEs with R&D capacities but the coordinator does not need to be an SME. The expected project results should clearly be of interest and potential benefit to SME(s).

Additional eligibility criterion: Projects will only be selected for funding on the condition that the estimated EU contribution going to SME(s) is at least 30 % of the total estimated EU contribution for the project as a whole. *This will be assessed at the end of the negotiation, before signature of the grant agreement. Proposals not fulfilling this criterion will not be funded.*

***Justification**: This topic is of interest to the NMP programme and DG SANCO. Innovative approaches to manage diabetes are getting ready for translational processes to happen. The topic is highly prone to produce breakthroughs coming to the patients, but some technologies and as well clinical trials are still missing. Supported by a number of PC delegations (particularly bariatric surgery and artificial pancreas - also specifically mentioned in the DIAMAP roadmap), such an area has the potential to reveal new potential pathways for the management/cure of diabetes. SMEs involved in medical surgery, brain and gut imaging, in hormone tracing, etc would be concerned.*

2012-2.4.3-2: Investigator-driven clinical trials for type 1 diabetes research. The main aim is to launch major clinical trials in type 1 diabetes patients with a particular focus on children and adolescents, who are predominantly and severely affected. These trials should be designed to improve glycolic control and/or treat or reduce diabetes complications. The results of such trials should be of practical importance to clinical management. The outcomes must be relevant for patients and change clinical practice. Pilot studies and systematic reviews will not be funded. Applicants must demonstrate that clinical trials are appropriately powered to produce statistically significant evidence. *Gender aspects and differences related to age subgroups should be appropriately considered.* The clinical trials to be supported must be registered in a publicly accessible clinical trials registry. The applications must consider the relevant governance issues for clinical trials such as good clinical practice and respect of the appropriate international, European and national legislation and guidelines. Patient advocacy groups, which can contribute to the quality, feasibility and impact of clinical trials, should be involved where appropriate. **Note:** Limits on the EU financial contribution apply. These are implemented strictly as formal eligibility criteria.

Funding scheme: Collaborative project (small or medium scale focussed research project).

EU contribution per project: Maximum EUR 6 000 000.

One or more proposals can be selected.

Expected impact: New types of insulin, along with improved management and monitoring technologies, have the potential to improve outcomes. However, diabetes management requires complex balancing of medication dosing, diet and exercise in order to achieve good glucose control while avoiding hypoglycemia. It is expected that these clinical trials will inform clinical management of type 1 diabetes across the lifespan.

***Justification**: This topic is of interest to DG SANCO. Type 1 diabetes trials are required to allow translational research in type 1 diabetes, where Europe has the advantage of excellent research teams and a diversity of genetic and socio-economic conditions. Type 1 diabetes strikes mainly children at a very early age, with the prospect of severe complications. The DIAMAP report also pointed not only to the need for large clinical trials, but also that the prime roadblock to overcome in Europe is the lack of resource sharing in the field of clinical trials for paediatric and adolescent diabetic patients, contrary to what prevails in the United States. The need for research impacting children health as well as for clinical trials in this area has been a recurrent request by many PC delegations.*

2.4.4 Rare diseases

The focus will be on EU-wide studies of natural history, pathophysiology and on development of preventive, diagnostic and therapeutic interventions, including rare Mendelian phenotypes of common diseases. This area should help identifying and mobilising the critical mass of expertise in order (i) to shed light on the course and/or mechanisms of rare diseases, or (ii) to test diagnostic, preventive and/or therapeutic approaches, to alleviate the negative impact of the disease on the quality of life of the patients and their families, as appropriate depending on the level of knowledge concerning the specific (group of) disease(s) under study.

For this call for proposals the topics will focus on the preclinical and clinical development of orphan drugs, and on the conduction of observational trials for those rare diseases treated off-label, aiming to improve clinical practices in the management of these diseases. These efforts will be complemented with coordination action activities aimed at identifying and exchanging best practices in the clinical management of rare diseases.

Note: Depending on the topics listed below, applicants will have to follow the rules for **two-stage or single-stage submission procedure (see also respective call fiche in section III).**

2012-2.4.4-1: Preclinical and/or clinical development of substances with a clear potential as orphan drugs. Support will be provided to preclinical studies in models (pharmacological, pharmacokinetics and toxicological) and/or clinical studies (including phase III clinical trials) of EU designated orphan medicinal products. Clinical studies should focus on biopharmaceutical studies (including bioavailability, bioequivalence, *in vitro- in vivo* correlation), human pharmacokinetic and pharmaco-dynamic studies, human efficacy and safety studies. Clinical trials must be appropriately powered to produce statistically significant evidence. Involvement of industry, in particular SMEs, is strongly recommended. Diagnostics and therapies for cancer and nervous system diseases will not be considered. The orphan medicinal product will need to be granted the EU orphan designation at the latest on the date of the call closure. It is expected that the project will have appropriate plans to engage with relevant stakeholders such as patient

organisations and the European Medicines Agency. **Note:** Limits on the EU financial contribution apply. These are implemented strictly as formal eligibility criteria.

Funding scheme: Collaborative project (small or medium scale focussed research project).

Requested EU contribution per project: Maximum EUR 6 000 000.

One or more proposals can be selected.

Expected impact: The project(s) should deliver appropriate information to i) start clinical development of orphan drugs (if the project includes preclinical development) and/or ii) improve care of rare diseases patients (if the project includes clinical development). Collected data should be of sufficient quality to be further exploited in marketing authorisation requests.

Additional eligibility criterion: Projects will only be selected for funding on the condition that the estimated EU contribution going to *industry is 30%* or more of the total estimated EU contribution for the project as a whole. This will be assessed at the end of the negotiation, before signature of the grant agreement. Proposals not fulfilling this criterion will not be funded.

Justification: *This topic is of interest to DG SANCO. 10 years after the EU orphan drug regulation, 62 orphan medicines have been approved for use in the EU, giving treatment options for 53 different rare diseases. 720 orphan designations were granted (success rate of 65 %). This means that a lot of designated products do not make it to the market, and there is a need to support the clinical development of the designated OD (repeated message from COMP/EMA). The clinical development topic of 4th call has clearly stimulated new applications for OD designation (as mentioned by COMP chair and EMA staff). An important fraction of sponsors for orphan-designated products are SMEs which need incentives to bridge the gap from designation to clinical studies. In addition, orphan drugs being often based on innovative technologies, this would contribute to boost innovation in Europe. Such a topic could offer a link with US initiatives (NIH), and could also attract SME participants.*

2012-2.4.4-2: Observational trials in rare diseases. The aim is to improve clinical practice in the management of rare diseases patients, and research should include the comparison of outcome of various treatment regimens for those rare diseases for which no orphan drug is available and that are being treated off-label. Studies should include the evaluation of effectiveness and adverse events. Particular attention should be given to the definition of appropriate outcome measures. Therapies for cancer and nervous system diseases will not be considered. Project should include appropriate plans to engage with relevant stakeholders such as patient organisations and dissemination plans to ensure the wide and rapid uptake of developed guidelines. **Note:** Limits on the EU financial contribution apply. These are implemented strictly as formal eligibility criteria.

Funding scheme: Collaborative project (small or medium scale focussed research project).

Requested EU contribution per project: Maximum EUR 3 000 000.

One or more proposals can be selected.

Expected impact: The project(s) should lead to accepted evidence-based clinical guidelines for a better care of patients afflicted by rare disease(s) for which no dedicated treatment is currently available.

***Justification**: This topic is of interest to DG SANCO. It is estimated that up to 90% of drug use for rare diseases is off-label (Science 2010, 327, 273-274). Given that orphan drugs are currently available for a minority of rare diseases only, it is important to collect, analyse and compare treatment data in order to capitalize on existing practice, to benefit patients until orphan drugs are marketed.*

2012-2.4.4-3: Best practice and knowledge sharing in the clinical management of rare diseases. This action is dedicated to the development of a networking platform supporting the collection of standardised and validated data and the exchange of information providing evidence for best clinical management of rare diseases. It should also help identifying additional research needs to further improve clinical practice. The platform should not be restricted to particular (groups of) rare diseases and the platform sustainability after the EC financing period must be established during the project. **Note:** Limits on the EU financial contribution apply. These are implemented strictly as formal eligibility criteria.

Funding scheme: Coordination and Support Action (coordinating action)

Requested EU contribution per project: Maximum EUR 2 000 000.

Only up to one proposal can be selected.

Expected impact: A recognised, sustainable networking platform facilitating the exchange of information, identifying and spreading best clinical practice for the management of rare diseases should be delivered.

***Justification:** This topic is of interest to DG SANCO and DG ENTER. Such a coordination action would complement the observational trials projects, and offer an EU platform for dissemination of best practices. It would be of high value for patients in a field that crucially lacks therapeutic options.*

2.4.5 Other chronic diseases

The focus will be on non-lethal diseases with a high impact on the quality of life at old age such as functional and sensory impairment, chronic inflammatory diseases (e.g. arthritis, celiac disease) and thyroid disorders. It is expected that collaborative research in this area will lead to improved diagnostics of the chronic conditions, develop tools and/or intervention strategies, which may contribute to delaying the onset of chronic diseases, their efficient treatment, and improving quality of life.

Note: For the topics listed below, applicants will have to follow the rules for **two-stage submission procedure (see also respective call fiche in section III).**

2012-2.4.5-1: Technological approaches to combating sensory impairments. The aim of this topic is to carry out preclinical and clinical testing of novel tools or devices for overcoming sensory disabilities. Impairment or loss of vision and hearing will be the main targets but other sensory systems may be addressed as well. Examples of eligible research are: strategies aiming at prevention of damage and rejuvenation of auditory cells and systems, treatment of auditory diseases, implantable devices, cell based approaches, including stem cells, and development of

artificial organs or their parts. Full attention needs to be paid to safety, bio-compatibility, interoperability and regulatory aspects as appropriate. **Note:** Limits on the EU financial contribution apply. These are implemented strictly as formal eligibility criteria.

Funding scheme: SME-targeted Collaborative project.

Requested EU contribution per project: Maximum EUR 6 000 000.

One or more proposals can be selected.

Expected impact: The project(s) should led to refined tools, technologies and procedures aimed at helping patients with sensory impairments to improve their quality of life by providing useful accessories or developing procedures to regeneration/rejuvenation or recreation of the affected organs or their parts.

Specific feature: SME-targeted research is designed to encourage SME efforts towards research and innovation. Priority will be given to proposals demonstrating that research intensive SMEs play a leading role. The projects will be led by SMEs with R&D capacities but the coordinator does not need to be an SME. The expected project results should clearly be of interest and potential benefit to SME(s).

Additional eligibility criterion: Projects will only be selected for funding on the condition that the estimated EU contribution going to SME(s) is at least 30 % of the total estimated EU contribution for the project as a whole. *This will be assessed at the end of the negotiation, before signature of the grant agreement. Proposals not fulfilling this criterion will not be funded.*

Justification: *This topic is of interest to the NMP programme, DG SANCO and DG INFSO. Impairments in sensory function due to age-related conditions and diseases are prevalent and can have significant consequences for everyday functioning and quality of life among older people. This area will be attractive for SMEs specialising in e-Health accessories for sensory handicapped persons, or in manufacturing of prostheses compensating sensory impairments as well as for biotech SMEs involved in stem cell research for regeneration of auditory cells or retinal regeneration.*

2012-2.4.5-2: Biomarkers and diagnostics for chronic inflammatory diseases of the joints and digestive system. Early diagnosis of chronic inflammatory diseases, establishment of the mechanisms of initiation, identification of genes involved, biochemical markers of diagnostic value, as well as identification of targets for therapeutic action of pharmaceutical agents and other treatments. **Note:** Limits on the EU financial contribution apply. These are implemented strictly as formal eligibility criteria.

Funding scheme: SME-targeted Collaborative Project.

Requested EU contribution per project: Maximum EUR 6 000 000.

One or more proposals can be selected.

Expected impact: The projects should deliver improved/novel methodology to enable early diagnosis of chronic inflammatory diseases, to identify genes involved in initiation of the diseases, which will allow for prediction of potential development of the disease in yet healthy population. A list of biochemical markers indicating onset of inflammation should be established and potential strategies for therapeutic intervention developed including identification of cellular and molecular targets for treatment of the disease.

Specific feature: SME-targeted research is designed to encourage SME efforts towards research and innovation. Priority will be given to proposals demonstrating that research intensive SMEs play a leading role. The projects will be led by SMEs with R&D capacities but the coordinator does not need to be an SME. The expected project results should clearly be of interest and potential benefit to SME(s).

Additional eligibility criterion: Projects will only be selected for funding on the condition that the estimated EU contribution going to SME(s) is at least 15 % of the total estimated EU contribution for the project as a whole. *This will be assessed at the end of the negotiation, before signature of the grant agreement. Proposals not fulfilling this criterion will not be funded.*

Justification: *This topic is of interest to DG SANCO. Chronic inflammatory diseases take their toll by seriously debilitating patients' ability to work, diminishing their ability to move, withdrawing them from the productive process and significantly decreasing quality of life. As these diseases represent lifelong conditions, their economic detrimental impact is immense both in direct costs of therapy, medical care and healthcare services, as well as due to a loos of working ability. The theme offers broad opportunity for the participation of SMEs, especially those involved in the identification of biomarkers of chronic inflammation and development of targeted therapies to address and suppress inflammatory burst (processes). The projects will enable SMEs to proceed in drug development and evaluation of intervention therapies as well as to offer a platform for use of animal models for drug evaluation including gene expression and analysis techniques.*

3. OPTIMISING THE DELIVERY OF HEALTHCARE TO EUROPEAN CITIZENS

This activity aims at improving the necessary basis both for informed policy decisions on health systems and for more effective and efficient evidence–based strategies of health promotion, disease prevention, diagnosis and therapy. The activity takes forward the principles of the EU Health Strategy: "Together for Health: A Strategic Approach for the EU 2008-2013"[7] and aims to anticipate future priority needs. In this call topics focus on improving the organisation of health service delivery and new methodologies for health technology assessment. Specific international cooperation actions to support the implementation of the Millennium Development Goals (MDGs), will address health systems/services research including research capacity building in terms of human resources.

3.1 TRANSLATING THE RESULTS OF CLINICAL RESEARCH OUTCOME INTO CLINICAL PRACTICE INCLUDING BETTER USE OF MEDICINES, AND APPROPRIATE USE OF BEHAVIOURAL AND ORGANISATIONAL INTERVENTIONS AND NEW HEALTH THERAPIES AND TECHNOLOGIES

Closed in 2012

3.2 QUALITY, EFFICIENCY AND SOLIDARITY OF HEALTHCARE SYSTEMS INCLUDING TRANSITIONAL HEALTH SYSTEMS

In Europe's health care landscape, service providers differ considerably in size and structure, varying from large structures, like general or specialised hospitals to small primary care units or health centres. Empirical evidence is a vital element in supporting informed policy decisions that can improve health care in European countries in particular in those Member States from the enlarged European Union and candidate countries. There is a clear need for a more systematic mapping of variations in health care practice, for understanding their causes and assessing their consequences for individual health improvement[8]. These issues have been highlighted both by Member States' and the Commission for example in the context of the discussions on the draft directive on the application of patients' rights in cross-border healthcare and in the Commission's initiative regarding the innovation partnership pilot on active and healthy ageing.

Fr this call the focus will be on health service delivery and health technology assessments.

Note: For the topics listed below, applicants will have to follow the rules for **two-stage submission procedure (see also respective call fiche in section III).**

2012-3.2-1: Improving the organisation of health service delivery. The aim of this topic is to seek empirical evidence about the structuring, care processes and performance on health care

[7] White Paper: "Together for Health: A Strategic Approach for the EU 2008-2013", 23.10.2007 COM 630 FINAL
[8] As highlighted by the FP7 projects *HSREPP* – a roadmap project on health services research (http://www.nivel.nl/oc2/page.asp?PageID=11023&path=/Startpunt/NIVEL%20international/HSREPP/Home) and *FUTURAGE* – a roadmap project on ageing research (http://futurage.group.shef.ac.uk/) also highlighted this need.

organisations in Europe. Priority will be given to proposals addressing either one or more of the following areas of research:

- **The integration of care across organisations** and how collaboration between different health care providers can integrate primary and secondary care in pathways. Such research should focus on the effect of integration on patient experiences, outcomes, and efficiency; what are the best forms of integration, under what conditions/context, for which patients groups is the integration of care suitable; and the evaluation of new organisational approaches to of integration.
- **Patient-centred care and patient involvement** and how organisations and patients can be empowered in this direction. Such research should focus on the evaluation of strategies, interventions, and incentives; under which conditions do new health technologies lead to more patient-centred care; and guideline adherence.
- **Skill mix and management of human resources**. Such research should focus on the impact of changing skill mix of health professionals across Europe on quality of care and future health needs, organisation of care processes and professional roles and competencies; identification and comparison of successful health workforce planning strategies addressing the ageing health workforce and increasing mobility of health professionals across Europe.
- **The transfer of knowledge into practice** using results and outcomes of relevant EU FP projects with regards to health systems and health services research[9], taking into account best practice and the factors that determine the transferability of these mechanisms[10], applying relevant tools, to better ensure that research findings and results are indeed applicable and used for a better organisation of health service delivery in Europe.

Proposals that include participation from Member States from the enlarged European Union and candidate countries will be considered. Proposals should generally be 4 years in duration; however a proposal addressing the issue of knowledge into practice should span 5 years. **Note:** Limits on the EU financial contribution apply. These are implemented strictly as formal eligibility criteria.

Funding scheme: Collaborative Project (small or medium scale focused research project).

Requested EU contribution per project: Maximum EUR 3 000 000.

One or more proposals can be selected.

Expected impact: This research should contribute to the scientific evidence base that supports Member States to better organise their health systems within the relevant policy context. Projects should address the varieties in health care practice across Europe's health care landscape including critically an understanding of the relationship between organisations and how patients move through them. Projects should advance the state of the art in the field of health services research, stimulate social innovation and enhance cooperation between researchers in Europe and other regions to promote integration and excellence of European research in the field.

Justification *This topic is of interest to DG SANCO and DG EMPL. The organisation of health care delivery is of major importance to Member States, the European Parliament and the European Commission within the current policy contexts. The knowledge generated should*

[9] See relevant FP7 projects (reference booklet public health research web pages)
[10] See relevant FP7 projects such as *BRIDGE, FIRE & SURE (reference public health project booklet)*

empower the policy and decision maker better to manage and reform healthcare systems at both (primary and hospital care levels) in view of common challenges and within the common framework of the European Union, making health service provision more effective, more patients centred and more sustainable.

2012-3.2-2: New methodologies for health technology assessment. Health Technology Assessment (HTA) is intended to provide a bridge between the world of research and the world of decision-making by providing relevant information about the medical, social, economic, legal and ethical issues related to the use of health technology. This should be achieved in a systematic, transparent, unbiased and robust manner, also highlighted by the European network for Health Technology Assessment[11]. Research under this call should develop new and /or improved methodologies for HTA that address the present challenges affecting the current methodological framework regarding complexity, efficacy and effectiveness. Proposals should address either one or more of the following areas:

- HTA methodologies should be broadened to expand further the spectrum and complexity of technologies assessed. Complex interventions consisting of a wide spectrum of technologies and multidisciplinary delivery modes should be addressed, such as personalised medicines, public health interventions, organisational interventions and information and communication technologies related to health. Other challenges to be addressed include the need for the continuous assessment of health technologies throughout their life cycles, the integration of social, organisational, ethical and legal aspects, assessment of relative effectiveness and to evaluate their implementation into health service provision.
- Research should address the real need to complement those efforts already undertaken by the Member States' network of HTA organisations (EUnetHTA JA) as regards the development of HTA methodologies to assess, for example, the efficacy and effectiveness of technologies. The applicability of these technologies into broader clinical contexts requires a better understanding of their use. In addition, there is a need to strengthen HTAs so that they may be used in very specific and particular circumstances, such as in hospital settings - mini-HTAs, where very local contextual organisational considerations have to be taken into account. Non-exhaustive examples would include: advanced therapies[12], diagnostic medical devices, personalised medicines and health-related information and communication technologies.

Targeted projects with short duration (2-3 years) will be prioritised. Collaboration between the selected projects should be foreseen in the proposals in view of exchanging information and promoting the development of best practice. **Note:** Limits on the EU financial contribution apply. These are implemented strictly as formal eligibility criteria.

Funding scheme: Collaborative Project (small or medium scale focused research project).

Requested EU contribution per project: Maximum EUR 3 000 000.

[11] EUnetHTA JA is a joint action funded under the EC's 2nd Community Programme of public health in response to the 2009 call - http://www.eunethta.net/Public/Home/.

[12] Gene therapy medicinal products, somatic cell therapy medicinal products and tissue engineered products, as defined by Regulation (EC) no 1394/2007 of the European Parliament and of the Council of 13 November 2007 on Advanced Therapy Medicinal Products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004

One or more proposals can be selected.

Expected impact: This research should improve the scope, validity and applicability of HTA as a tool to determine the potential impact of innovative technologies on individual and population health gains. It should complement work undertaken by the European Network for Health Technology Assessment and broaden the HTA methodological framework to develop it into a truly meaningful tool that provides structured, evidence-based input into health policies that are patient-focused and promoting good quality care, equity in access and best value for money[13].

Justification: *This topic is of interest to a range of other Commission services such as DG SANCO, DG INFSO and DG ENTER. It is a priority for the Commission as it will contribute to the implementation of the Innovation Union's Pilot Partnership on active and healthy ageing as well as emerging new fields such as personalised and individualised approaches. There is a need for a research based development of HTA as a policy instrument to include assessment of more complex interventions to foster the robust development of health services in Europe and realise the potential to improve the health of populations through more effective care. Such research offers a European solution to a fundamental problem that health (and finance) ministers are currently grappling with without calling into question the principle that Member States are solely responsible for the organisation of the health services in their countries.*

3.3 HEALTH PROMOTION AND PREVENTION

Closed in 2012

3.4 INTERNATIONAL PUBLIC HEALTH & HEALTH SYSTEMS

The specific cooperation actions in this area focus on the priorities agreed through bi-regional dialogues in third countries/regions and international fora, as well as within the context of Millennium Development Goals (MDGs). It has been long recognised at the global level that research is needed to address the weakness of the health systems in many low and middle income countries[14].

This call will focus on health systems/services research while at the same time strengthening research capacity building in terms of human resources.

Note: For the topic described below, applicants will have to follow the rules for **two-stage submission procedure (see also respective call fiche in section III).**

2012-3.4-1: Health systems/services research in low and middle income countries. A major obstacle to achieving the health-related MDGs is the weakness of the health systems in many

[13] FP7 HSREPP project– a roadmap project on health services research: http://www.nivel.nl/oc2/page.asp?PageID=11023&path=/Startpunt/NIVEL%20international/HSREPP/Home
[14] 1st Global Symposium on Health Systems Research, Montreux November 2010 http://www.hsr.symposium.org/ & relevant public health web pages

low and middle income countries and the requirement to provide effective healthcare to populations in need[11]. Research therefore has an important part to play in strengthening national health systems. National or regional decision makers should be empowered to allow the collection, analysis and translation of data into effective health services/systems policies and planning. Operational/implementation research taking an interdisciplinary, problem-oriented approach including investigating the process of turning evidence into policy and practice is required, as well as implementing measures to strengthen scientific capacity in health systems/health policy in **ONE** of the following domains:

- **Develop methods to investigate country comparisons** using mixed methods and qualitative approaches; working with national or regional decision makers in low and middle income countries, to identify approaches to contribute towards more effective health systems strengthening thus increase universal health coverage. Furthermore proposals must, by means of a training needs assessment adjusted to the contexts of low and middle income partner countries, implement measures for the strengthening and sustainable development of scientific capacity for such research. Measures may include interdisciplinary courses, training programmes - joint qualifications/degrees with consideration given to the next generation of researchers.
- **Better human resources for health** to effectively manage the health workforce in a low-resource setting, for example retention strategies against internal/outward migration of health personnel or interventions to attract and retain competence profiles for common health cadres, or addressing the feasibility and effectiveness of task-shifting. Furthermore proposals must, by means of a training needs assessment adjusted to the contexts of low and middle income partner countries, implement measures for the strengthening and sustainable development of scientific capacity for such research. Measures may include interdisciplinary courses, training programmes - joint qualifications/degrees with consideration given to the next generation of researchers.
- **Strengthening knowledge transfer and scientific capacity** using results and outcomes of FP international cooperation projects[15], taking into account best practice[16] and the factors that determine the transferability of these mechanisms, to better ensure that research findings and results become applicable to and be useful for a better organisation of health care in low and middle income countries. Furthermore proposals, by means of a training needs assessment adjusted to the contexts of low and middle income partner countries, implement measures for the strengthening and sustainable development of scientific capacity for health systems/health policy research, incorporating a substantial element of South-South cooperation. Measures may include interdisciplinary courses, training programmes - joint qualifications/degrees with consideration given to the next generation of researchers.

Submissions must clearly state which domain is addressed, including in the abstract. The aim is to achieve a balanced level of research carried out and participation for partner countries in collaboration with their European partners - this will be considered in the evaluation. Collaboration between the selected projects should be foreseen in the proposals in view of developing synergies with other EC and international activities in the field. Furthermore attention must be paid to developing synergies between selected projects regarding training

[15] See relevant FP7 projects (reference booklet public health research web pages)
[16] See FP7 relevant projects such as *SURE, BRIDGE & FIRE* (reference public health project booklet)

activities - this element will be an essential part that will be taken into account in the negotiation phase. Projects should generally be 5-6 years in duration. **Note:** Limits on the EU financial contribution apply. These are implemented strictly as formal eligibility criteria.

Funding scheme: Specific International Cooperation Action (**SICA)**, Collaborative Project (medium-scale focused research project) target regions: All international cooperation countries (ICPC)[17].

Requested EU contribution per project: Maximum EUR 6 000 000.

One or more proposals can be selected.

Expected impact: This research should allow the empowerment of national or regional decision-makers in low and middle income countries in the planning, management and organisation of health systems through contributing to a robust evidence base to support the theory and practice of strengthening health systems. Research should contribute to the development of innovative, effective and sustainable policies that motivate health workers to remain in their workplaces, support education and training for health workers, strengthen governance capacities, and subsequently improve overall access and quality of health care. Improved knowledge transfer mechanisms are expected to be developed building on best practice to ensure that research generated is put to use in the relevant context. Projects are expected to promote capacity building as a key to creating a sustainable and attractive research landscape for health systems/services research in these countries.

Justification: *In general this topic area is a priority for DG DEVCO and DG SANCO, in particular regarding access to universal coverage and the health work force, which has been underlined in the Council Conclusions on the EU role in Global Health adopted in May 2010[18]. Policy-makers in all countries, regardless of their level of economic development, struggle to achieve health equity and to meet the health needs of their populations, especially vulnerable and disadvantaged groups. This has also been recently highlighted by Council Conclusions[19] as well as recognised in the "WHO Code of Practice on the International Recruitment of Health Personnel" which the EU has recently adopted in the World Health Assembly[20] Promoting capacity building in terms of human resources, linked to the development of institutions and networks is a key element of the recent EC Communication "A strategic European Framework for international S&T cooperation" as well as complementing activities of DG DEVCO through the ACP Science and Technology Programme.*

[17] The list of international cooperation partner countries (ICPC) is provided in Annex I to the Cooperation Programme ftp://ftp.cordis.europa.eu/pub/fp7/docs/icpc-list.pdf

[18] Council Conclusions 3011th Foreign Affairs ,10 May 2010 and reflected at the 1st Global Symposium on Health Systems Research, Montreux November 2010, http://www.hsr.symposium.org/ where the Commission played an active part.

[19] Council Conclusions *"Investing in Europe's health workforce of tomorrow: scope for innovation and collaboration* 118280, 7 December 2010

[20] WHA63.16 WHO Code of Practice on the international Recruitment of Health Personnel, 21 May 2010

4. OTHER ACTIONS ACROSS THE HEALTH THEME

The objective of these actions is to contribute to the implementation of the Framework programmes and the preparation of future European Union (Community) research and technological development policy. The focus of this area in this work programme will be on the dissemination and exploitation of results and on assessing future needs.

4.1 COORDINATION AND SUPPORT ACTIONS ACROSS THE THEME

The objective of these actions is to contribute to the implementation of the Framework programmes and the preparation of future European Union research and technological development policy.

For this call the focus of this area will be on technology transfer and dissemination of results.

Note: For the topics listed below, applicants will have to follow the rules for **two-stage submission procedure (see also respective call fiche in section III).**

2012-4.1-1: Network to encourage technology transfer activity in FP-funded health research (especially in academic and governmental organisations). The objective of this three years coordination action is to further strengthen knowledge transfer offices in public research organisations and to promote industry-academia trans-national collaboration, with focus on the health sectors and its specificities, promoting the exploitation of innovative ideas. It will have to cover as many as possible of the following objectives: 1) It will create platforms for shared learning and networking for scientists, program managers and policy makers in a continuous manner. 2) It will establish a mechanism for identifying and promoting good knowledge management and knowledge transfer practices in the EU Member States and Associated, providing evidence on best practice on the transfer of knowledge, including standardization. 3) It will give visibility to the best achievements at the European level, including impact of legislation and tax incentives on technology transfer and innovative SMEs. 4) It will create an on-line repository of best practices for further reference and actively promote them. 5) It will promote interaction between the universities, industry, investors and the individual researchers with the organization of workshops and partnering events. 6*)* The consortium shall coordinate the tasks related to the organisation of national activities. 7) It will have to organize one conference during the project lifetime. It shall clearly promote collaboration and exchanges with Industry (SMEs in particular) and SME associations. It shall complement and not overlap with organisations like Enterprise Europe Network or existing technology transfer associations, working in synergy with them and with other EU funded supports. The proposal shall provide a detailed action plan with quantitative and measurable objectives. **Note:** Limits on the EU financial contribution apply. These are implemented strictly as formal eligibility criteria.

Funding scheme: Coordination and Support Action (coordinating action).

Requested EU contribution per project: Maximum EUR 2 000 000.

Only up to one proposal can be selected.

Expected impact: The network activity will promote exploitation of innovative ideas, promoting knowledge transfer between business and academia, addressing European fragmentation through trans-national activities. It will promote interaction among all relevant actors, involving stakeholders, fostering synergies and enhancing the capacity for knowledge transfer with the ultimate objective of valorisation of EU funded research results, in view of the commitments presented in the Innovation Union communication. It will promote best practice and success stories in Member States and Associated Countries.

***Justification**: This initiative is promoting innovation in healthcare and supporting the Innovation Union Flagship Initiative. It also supports Commission "Recommendation on management of intellectual property in knowledge transfer activities and Code of Practice for universities and other public research organisations"; published in April 2008 that is priming knowledge transfer initiatives in several Member States and Associated Countries. It will address the fragmentation of current initiatives; it will promote best practices and success stories, creating a positive momentum. At EU level it is important to develop a better understanding of public sector innovation, to give visibility to successful initiatives, and benchmark progress.*

2012-4.1-2: Training actions linked to intellectual property rights management and technology transfer. This three years coordination action shall address primarily participants to EU funded projects in health. The programme shall involved experienced practitioners that will provide concrete case studies (on the MBA model) to be discussed and analysed by participants and, as appropriate, provide coaching and advise on specific situations, whenever appropriate will provide evidence on best practice on the transfer of knowledge, including standardization. Hands-on training should be given in innovation management and economic exploitation of research results including (i) intellectual property rights and asset management courses (ii) courses on preparation of viable business plans (iii) training on launch successful new companies, (iv) ad-hoc technology transfer training for academia, with special attention to new members and candidates countries. It shall complement activities provided by organisations like Enterprise Europe Network or Fit for Health and National Contact Point activities, working in synergy with them and with other EU funded supports. Applications shall provide a detailed action plan with quantitative and measurable objectives. **Note:** Limits on the EU financial contribution apply. These are implemented strictly as formal eligibility criteria.

Funding scheme: Coordination and Support Action (coordinating action).

Requested EU contribution per project: Maximum EUR 2 000 000.

Only up to one proposal can be selected.

Expected impact: This initiative is targeting participants in EU funded projects in health, where a large percent are academics, with a programme tailored for the Healthcare sector and its specificities. It is promoting innovation in healthcare and supporting the Innovation Union Flagship Initiative, it will help researchers to lean towards inter-disciplinarity, entrepreneurship and stronger business partnerships. It will contribute creating an innovation culture in all Member States.

***Justification**: As stated in the Innovation Union communication, businesses shall be more involved in curricula development and doctoral training so that skills better match industry needs. In addition it is important to create a critical mass of public sector leaders who have the*

skills to manage innovation. This can be achieved through more sophisticated training, as well as opportunities to exchange good practice.

2012-4.1-3: Support for Presidency events: Organisation of supporting actions and events related to the Presidency of the European Union. An integral part of the Health theme's activity is to organise, together with successive EU presidencies, events of a strategic nature. The proposed Support Action(s) should contribute to conferences or other appropriate events to be held in a Member State which will hold a forthcoming Presidency of the European Union, specifically 2012 and 2013 Presidencies, in any area of the Health Theme. In order to ensure high political and strategic relevance, the active involvement of the relevant national authority(ies) will be evaluated under criteria 'quality' and 'impact'. The proposed Support Action(s) should address topics that are of high relevance at the date of its taking place. An appropriate equilibrium should be present in the proposed action(s), with balanced presentation of various research, societal and industrial elements and points of view. Participation of non-EU stakeholders is possible. Outreach activities may be included such as *e.g.* a press programme and/or an event dedicated to raising awareness on a specific topic in schools. **Note:** Limits on the EU financial contribution apply. These are implemented strictly as formal eligibility criteria.

Funding scheme: Coordination and Support Actions (supporting actions).

Requested EU contribution per project: Maximum EUR 100 000.

One or more proposals can be selected.

Expected impact: (i) Review of research, industrial and/or societal developments linked to the areas of the Health Theme on specific programme level as appropriate; (ii) sharing of information and comparison of points of views; (iii) support to the activity of various stakeholders: ethicists, researchers, industrialists, investors, museums and/or schools.

***Justification**: This topic has been repeatedly requested by all Member States to enhance the awareness of for theme Health activities. The topic is supporting all initiatives under Theme Health, ongoing ones as well as new initiatives.*

4.2 RESPONDING TO EU POLICY NEEDS

Closed in 2012

OTHER ACTIVITIES

Human Frontier Science Programme Organisation

An annual subscription to the international Human Frontier Science Programme Organisation (HFSPO)[21] will be made jointly with the Information and Communication Technologies (ICT) Theme. This will allow EU non-G8 Member States to fully benefit from the Human Frontier Science Programme (HFSP) and provide increased visibility for European research. Out of the total Community subscription of EUR X XXX 000 for 2012, EUR X XXX 000 will be paid from this theme, and the remainder from the ICT Theme. **Funding scheme:** CSA – subscription.

Preparing the future: emerging health research innovation areas

Proposals for coordination actions are called for in important emerging areas of health research, where there is a need to step up coordinated research efforts between European key players. Different actors from academia, industry, academia, national programmes and other relevant organisations, should come together to develop a strategy plan for the further development of health research areas with high impact on competitiveness, healthcare system and benefit for European citizen' health. Activities to be funded under this topic may comprise: supporting active European participation in pertinent international health research initiatives, efforts aimed at standardisation of methodologies and protocols, participation in joint technology platforms, reference centres and exchange schemes. For all funded activities European added value must clearly be discernible. Projects should contribute to strengthening European influence and visibility in key areas of health research, where important societal and/or economic return is expected. **Funding scheme:** Coordination and Support Action – public procurement[22]: to be implemented through a Framework Contract in 2010/2011 and/or experts appointment (indicative budget: EUR 500 000).

Justification: *Major health challenges issues most often concern many countries, both in Europe and globally: increasingly burdened health systems due to ageing societies in the industrialised countries, or linked to poverty in developing, epidemics of major diseases, life style-related or in the wake of natural disasters, constant need of new drugs and vaccines. These global health challenges require huge research and innovation efforts and investments, rendered by many and diverse stakeholders, from diverse geographical regions, and/or from very diverse institutional nature (ministries, international bodies, industries, charities, users or patients associations, finance entities). Coordination of these research and innovation efforts becomes a prime importance, focussing on nuclei for potential European innovation partnerships around identified major heath issues, or helping to coordinate European research efforts contributing to major international research initiatives, thus allowing to form European initiatives in health research and innovation areas, where global programmes requiring a unified European partnership.*

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[21] The European Community is a member of the HFSP Organisation (HFSPO) and has funded HFSP under previous Framework Programmes.

[22] In accordance with Art 14 (b+c) of Regulation (EC) No 1906/2006 of 18 December 2006 laying down the rules for the participation of undertakings, research centres and universities in actions under the Seventh Framework Programme and for the dissemination of research results (2007-2013).

Action in support to the preparation of the second phase of the European and Developing Countries Clinical Trial Partnership (EDCTP 2) - (early 2012)

In line with the Communication from the Belgium Presidency of the Council of the European Union to the Competitiveness Council on a second phase of the EDCTP the main objectives of the action are: to launch preparatory activities in view to expand the scope of EDCTP to potentially address large scale phase II and III trials, other topical diseases, diagnostic tools, intervention and health service research; to prepare a comprehensive mapping exercise of existing national programmes on research, development and external action related to poverty related infectious diseases and other tropical diseases; to seek further integration and profile of African sites, centre and researchers; to develop further links with industry, like-minded funders, non-EDCTP Member-States and other bodies working in the field; to strengthening the training activities undertaken by EDCTP-I in coordination with training programmes from other organisations e.g. TDR, African Network for Drugs and Diagnostics Initiative (ANDI) and Member States activities; to prepare an assessment of the future education and training needs and prepare a proposal for common curricula for health professionals and researchers e.g. EU-Africa PhD in infectious disease; to organise a conference in Brussels involving high-level representatives from African countries, Member States and countries associated to Framework Programme, European Parliament, donor organisations and industry in view of featuring African participating countries and the impact of EDCTP in Spring 2012.

Funding scheme: Coordination and Support Action – named beneficiary (indicative budget: EUR 10 000 000). Grant to: European and Developing Countries Clinical Trials Partnership-European Economic Interest Grouping (private non-profit organisation, 27259980, Laan Van Nieuw Ooest Indie, 334; 2593 CE; The Hague; The Netherlands)

Justification: *In line with the Communication from the Belgian Presidency of the Council of the European Union to the Competitiveness Council on a second phase of the EDCTP (26 November 2010) and the draft impact assessment, this action aims to prepare for the second phase of the EDCTP in order to ensure that EDCTP-2 will be fully operational from its official starting date. The importance of EDCTP has been recognised by both DG SANCO and DG DEVCO.*

The impact of ethics review on health research

The objective is to examine the impact of ethics committees on the output and quality of scientific research. The work should foresee well-structured and innovative approaches to provide data regarding the different methodologies used for ethics review across the EU, to determine best practice and draft recommendations. It should include the systematic review of recent literature, the use of small but focused surveys, evaluation of conference abstracts and discussions with key opinion leaders and stakeholders. **Funding scheme:** Coordination and Support Action – public procurement[23]: to be implemented through a Framework Contract in 2010/2011 and/or experts appointment (indicative budget: EUR 100 000).

[23] In accordance with Art 14 (b+c) of Regulation (EC) No 1906/2006 of 18 December 2006 laying down the rules for the participation of undertakings, research centres and universities in actions under the Seventh Framework Programme and for the dissemination of research results (2007-2013).

***Justification**: There has been an increase in the number and in the activity of ethics committees world-wide. These ethics committees have an important role in protecting the patient, and high ethics standards add to the quality of research and social impact. This has protected patients, but lately, editors of peer-reviewed papers have expressed concern over a lack of quality control within the field. Reports have indicated that the ways ethics committees function may be highly variable in quality and may lead to some months of delays. Delays of this nature are not conducive to good clinical practice in health research and may create barriers to rapid robust health research. Standards vary in ethics committees, with many different approaches coexisting. This study should lead to recommendation of best practice. Such progress would be a major achievement, and one that could increase quality, reduce delays and avoid bottlenecks in health research. Failure to undertake rigorous and standardized high quality ethics evaluations in a prudent manner has major ramifications for the health of EU citizens and there is an ethical imperative and a significant challenge to ensure that finite health research resources are better used. Furthermore, confusion exists of the role of the autonomy of the ethics committees, and insights into this would be invaluable.*

Production and distribution of short video documentaries on EU-funded health research

The production and distribution of a series of documentaries is foreseen in order to communicate to wide audiences the results of EU-funded health research projects and the benefits of collaborative research. At least twelve short films of broadcast quality on success stories of interest to the general public, plus several related viral clips, should be produced and adequately distributed to maximise TV broadcasting and internet dissemination in Europe and abroad. **Funding scheme:** Coordination and Support Action – public procurement[24]: to be implemented through a Framework Contract in 2010/2011 and/or experts appointment (indicative budget: EUR 600 000).

***Justification**: improved visibility of EU-funded research is important to promote research, the role of the EU in research and the benefits of the EU in general.*

[24] In accordance with Art 14 (b+c) of Regulation (EC) No 1906/2006 of 18 December 2006 laying down the rules for the participation of undertakings, research centres and universities in actions under the Seventh Framework Programme and for the dissemination of research results (2007-2013).