Internal confidential working paper 19 October 2011

Proposed priorities for

Health research 2013

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

TO BE DEVELOPPED LATER

II PROPOSED CONTENT FOR CALLS 2013

0. HORIZONTAL TOPICS FOR COLLABORATIVE PROJECTS RELEVANT FOR THE WHOLE OF THEME HEALTH

This activity aims at supporting innovation through the exploitation and dissemination of results from FP funded projects and their transfer into innovative applications and policies.

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).

HEALTH.2013.0-1: Boosting the translation of FP projects' results into innovative applications for health. The main aim of this topic is to build on the results of projects funded under the Health theme of the EU Framework Programmes 6 and 7, to prove the viability of methodologies, processes, prototypes, models, technologies, clinical trials, etc. developed under these projects, with a potential for application. Eligible research activities under this topic will focus on specifications, testing and validation of results in order to reach the final development stage before products or processes enter into production and/or reach the market. Proposals must fit into the overall business and innovation needs of the partners involved and must demonstrate clear exploitation potential and socio-economic benefits for them and the society at large. Applicants must control the intellectual property rights of the results and knowledge to be used in their application and the proposals must clearly and convincingly describe how this knowledge/technology will be brought forward enough to reach the stage of application. **Note:** Limits on the EU financial contribution apply. These are implemented strictly as formal eligibility criteria.

Funding scheme: SME-targeted Collaborative Project (small or medium-scale focused research project)

One or more proposals can be selected.

Expected impact: Translation of high level scientific knowledge into applications and innovative products and services. Considering the specificities of the economic sectors falling under this activity of the Health theme, projects funded under this topic are expected to pave the way from the development of scientific knowledge and technologies to the market by stimulating the development of new products, tools technologies, patents, dedicated business path and innovative marketable 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 criteria:

The **requested European Union contribution** shall not exceed EUR 6 000 000 per proposal.

The proposed **project duration** indicated in the proposal shall not exceed 3 years.

SME-targeted Collaborative Projects will only be selected for funding on the condition that the estimated EU contribution going to ***SME(s)*** is 50 % 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.

Participation is restricted to entities established in EU Member States and Associated Countries. Any project activity must be performed by an entity in the EU Member States or Associated Countries (see also section III). SME(s) need to be 1) at least 51% owned and controlled by one or more individuals who are citizens of one of the EU Member States or Associated Countries or permanent residents in one of those countries, or 2) at least 51% owned and controlled by another business concern that is itself at least 51% owned and controlled by individuals who are citizens of, or permanent residents in those countries.

Justification*: This topic is in line with the innovation policy of the DG and provides the opportunity for applicants to further exploit, valorise, apply and disseminate their EU funded results to the benefit of European industry including SMEs. Such an opportunity has been requested by Member States and project leaders.*

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 2013

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, micro-systems, 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 imaging technologies for guiding therapeutic interventions 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).

HEALTH.2013.1.2-1. Development of imaging technologies for therapeutic interventions in rare diseases. The aim is to support development and/or proof of principle of new or improved combined imaging technologies for therapeutic interventions in rare diseases. Two

or more techniques, of which at least one should be molecular imaging, should be integrated into a complete simultaneous system for application in one or more rare diseases in the frame of personalised medicine, *i.e.* tailored medical interventions which are more effective and/or have fewer undesirable adverse effects in specific patients. The technologies should be of use as biomarkers during the therapeutic interventions. Clinicians should actively be included in the project. **Note:** Limits on the EU financial contribution apply. These are implemented strictly as formal eligibility criteria.

Funding scheme: SME-targeted Collaborative Project (small or medium-scale focused research project)

One or more proposals can be selected.

Expected impact: The development of new and improved technologies for therapeutic interventions in one or more rare diseases, facilitating 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). The projects shall contribute to the International Rare Diseases Research Consortium (IRDiRC).

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 criteria:

The **requested EU contribution per project** shall not exceed EUR 6 000 000

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*: Personalised medicine aims at tailoring medical interventions to be more effective and have fewer undesirable side effects in specifically defined patients. There are technical bottlenecks that need to be overcome for the rapid uptake of personalised medicine into clinical practice. Imaging is one of the potential tools to achieve it. This topic aims at supporting technology development, in particular the simultaneous use of several imaging technologies to improve treatment outcomes for rare diseases, contributing to the goals of the International Rare Diseases Research Consortium (IRDiRC): 200 new therapies for rare diseases (orphan drugs) and diagnostic tests for all rare diseases by 2020.*

1.3 SUITABILITY, SAFETY, EFFICACY OF THERAPIES

The development of novel therapeutics, vaccines or biomedical tools and devices is often severely impeded by safety and efficacy issues that should exhaustively be addressed already at an early stage of product development. The focus of this call is therefore to efficiently address aspects of toxicology, adverse immune reactions, reduced potency and impaired efficacy of novel medical products in a broad way, encouraging the employment of novel approaches including modeling efforts, novel tests, assays and preclinical models as well as

focused human studies, that help to assess earlier, better and more cost-efficiently safety and efficacy aspects of medical interventions and devices. Predictive toxicology and efficacy assessment should be validated by appropriate human studies.

Note: Applicants will have to follow the rules for **two-stage submission** procedure (see also respective call fiche in section III).

HEALTH.2013.1.3-1: Modelling toxic responses in case studies for predictive human safety assessment. The main objective of this topic is to exploit in case studies recent advances in computational chemistry and systems biology in order to provide the basis for innovative approaches to predictive human safety assessments. Integrated research should be undertaken that:

- Considers modelling transport and interactions from molecular to cellular/organelle levels;

- Integrates with *in vitro* experimentation designed specifically to inform this modelling activity;

- Couples directly to systems modelling from cellular to organ level;

- Takes account of mechanistic understandings of toxic responses in specific organs; and that

- Uses existing and appropriate infrastructure for computation data basing and sharing.

The project should address the following components:

- Identifications of metabolites (and metabolites of metabolites) and their reactivity, through a combination of computational chemistry, *in vitro* experimentation and enzyme expression profiling.

- Identification of the proteins and potentially other intracellular targets, affected by each metabolite, through computational chemistry and *in vitro* work.

- Identification of the pathways affected by these proteins, through *in vitro* cell assays and systems biology.

- Identification of cell functions affected by these pathways, by defining the boundaries of normal function, and understanding of the physiology and systems biology.

Note: Limits on the EU financial contribution apply. These are implemented strictly as formal eligibility criteria.

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

Only up to one proposal can be selected.

Expected Impact: It is expected that a truly integrated approach where modellers, chemists and biologists define and engage jointly on integrated research with shared goals will provide a platform for exploring innovative approaches to a better human safety assessment. It should be built on current attempts around the world that model specific organs. It should go beyond these to deliver an approach which is fit-for-purpose for predictive toxicology.

Additional eligibility criteria:

The **requested EU contribution per project** shall not exceed EUR 12 000 000

Projects will only be selected for funding on the condition that the estimated EU contribution going to ***industry including SME(s)*** is 15% or more of the total estimated EU contribution for the project as a whole. The requested minimum industry participation is an eligibility criterion

at the time of proposal submission, and will *be verified at the end of the negotiation, before signature of the grant agreement. Proposals not fulfilling this criterion will not be funded*.

Justification: Predictive toxicology moves at present from correlative considerations to the understanding of causalities and modes of action of chemicals and drugs in biological systems and to the respective development of predictive models based on the combination of computational chemistry and systems biology. The anticipated future directions will focus on improved in vitro assays to provide detailed understanding of toxicity pathways and from these the required dose response estimation. Although the US are heavily investing into this area, Europe is in a strong position, and this topic would further strengthen its competitiveness. Several member states have expressed their particular interest for this topic.

HEALTH.2013.1.3-2: Innovative approaches to address adverse immune reactions to biomedical devices, implants and transplant tissues. Administration of biomedical devices, implanted foreign materials or tissue transplants can cause severe and often chronic, adverse reactions of the human immune systems. A holistic systems approach to such adverse immune reactions should lead to the identification and validation of predictive biomarkers for the respective adverse immune reactions. Systems studies of adverse immune reactions should be based on the integration of omics, clinical and epidemiological data, and pertinent new *in silico* and *in vitro* models. Projects should allow identifying immunological signals and patterns indicative of adverse immune reactions. Supported projects may comprise systems immunological studies on adverse immune reactions to bio-devices or other medical materials or tissues including long term chronic inflammatory pathologies caused by such adverse immune reactions. Research consortia should be multidisciplinary, bringing together basic immunology, epidemiological and clinical expertise, with systems biology know-how and a thorough understanding of product development and regulatory issues. A strong participation of key players from industry and the clinical field is essential. **Note:** Limits on the EU financial contribution apply. These are implemented strictly as formal eligibility criteria.

Funding schemes: Collaborative Project (small or medium-scale focused research project)

One or more proposals can be selected.

Expected impact: A better holistic understanding of adverse immune reactions should allow to better design medical devices and materials for implants and transplantation, in order to minimise potential adverse immune reactions; and to develop novel therapeutic or preventive strategies to combat such adverse immune reactions.

Additional eligibility criteria:

The **requested EU contribution per project** shall not exceed EUR 6 000 000

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. The requested minimum industry participation is an eligibility criterion at the time of proposal submission, and will *be verified at the end of the negotiation, before signature of the grant agreement. Proposals not fulfilling this criterion will not be funded*.

Justification: *There is a high increase of using new biomedical devices, tissue transplants and implanted materials in treatments. However, often adverse immune reactions against these foreign materials are observed in medical practice. Research is needed to study these adverse reactions in order avoid or exclude undesired side effects in the use of newly developed bio devices/therapeutic strategies.*

HEALTH.2013.1.3-3. Safety and efficacy of therapeutic vaccines. The aim is to advance promising new therapeutic vaccines into clinical safety and efficacy testing. Chronic infectious diseases, inflammatory and autoimmune diseases, degenerative, and metabolic diseases as well as vaccines against drug addictions, may be addressed. Excluded are cancer vaccines addressed in area 2.4.1-1. The suggested therapy should be based on an active vaccination effect triggering a human immune response as opposed to passive immunization. Projects should focus on therapeutic vaccines for which efficacy has been demonstrated in preclinical work e.g. in appropriate animal models. Projects must demonstrate that a therapeutic vaccine in the envisaged applicational area is superior to existing or competing therapies under development, and that the expected cost-medical benefits ratio meets public health needs. Consortia should be strongly product-focused and should comprise only an essential number of contributing partners. Participation of European industries in particular SME's is essential.

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

One or more proposals can be selected.

Expected impact: Promising therapeutic vaccine candidates should be further advanced in the development phase with a clear proof of concept for safety and efficiency, thus widely and profoundly boosting the field of vaccine R&D in Europe.

Additional eligibility criteria:

The **requested EU contribution** per project shall not exceed EUR 6 000 000

Projects will only be selected for funding on the condition that the estimated EU contribution going to ***industry including SMEs*** 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: *To prepare the grounds for expanded use of therapeutic vaccines for difficult-to-treat target diseases is both an important contribution to improving public health in Europe, and a promising investment in innovation of European pharmaceutical industries. Bottom-up support to therapeutic vaccines aims to mobilize European excellence in immunology and vaccine research into the innovative area of therapeutic vaccines, which is believed to account for most of the expected over proportional growth in the global vaccine market. This topic complements a major EU-funded High Impact Research Initiative on immunization technologies, which focuses on cross-cutting research supporting the development of protective vaccines for infectious diseases. So far no topic in FP7 has focused on therapeutic vaccines yet.*

HEALTH.2013.1.3-4: Development of alternative *in vitro*, analytical, immunochemical, and other test methods for quality control of vaccines. Novel technological approaches are needed to ensure faster and more reliable testing of vaccine products. While upholding full compliance with the regulatory requirements that govern the development and production of vaccine products, research activities shall be directed at exploring to which extent animal-based safety and potency testing of experimental or licensed vaccines can be replaced (in totality or partially) by alternative *in vitro*, analytical, immunochemical or other (e.g. molecular) tests or processes. Support is therefore given to studies aiming to develop and validate novel, rapid and reliable safety and potency assays that demonstrate correlation of

safety of vaccine products with animal-tested batches. Research consortia should be lead by regulatory or industry, including SME participants, familiar with all aspects of the development and the production of vaccines for use in humans. To fully exploit potentially synergistic expertise from the field of animal vaccines, key players from the field of veterinary vaccines can be useful partners in research consortia to be formed. **Note:** Limits on the EU financial contribution apply. These are implemented strictly as formal eligibility criteria.

Funding schemes: SME-targeted Collaborative Project (small-scale focused research project)

One or more proposals can be selected.

Expected impact: *An EU-supported research effort for the development of in vitro potency tests for vaccines closely coordinated with industry and regulatory bodies will complement existing efforts, and should prove the potential of new tests to reduce, refine and replace animals in vaccine research.*

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 criteria:

The **requested EU contribution per project** shall not exceed EUR 3 000 000

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*: Vaccines represent with about 15% annual increase a fast growing section of the pharma market with new both preventive and therapeutic vaccines entering into production process. Testing of vaccine products and individual batches often relies on extensive animal tests that do not always meet the criteria of modern predictive human safety assessment. Hence, new approaches to vaccine safety and potency testing, to some extent replacing animal tests are an identified industrial need. The European partnership for Alternative Approaches to Animal testing (EPAA) to which the Commission participates with several DGs supports a dedicated project on improved vaccine quality control, to which this call topic will contribute. IMI has supported in its 3rd call a project on immunosafety of vaccines focussing mainly however on surveillance and understanding of adverse effects after market authorization. This topic proposed instead should develop novel testing approaches to test the safety of vaccines and their production. This includes batch testing on safety. Since no alternatives to animal testing are accepted yet in a regulatory context, this topic is upstream in the development process and should develop new technologies ultimately being faster, more reliable, and with less variability than animal testing.*

1.4 INNOVATIVE THERAPEUTIC APPROACHES AND INTERVENTIONS

The focus of this year's topic is human stem cell research. Stem cells offer great promise for therapy but practical applications are still limited. This topic focuses on the key area of differentiation, proliferation and biological activity/potency where further knowledge of mechanisms of action, development of cell technology and fulfilment of regulatory standards are required[1].

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

HEALTH.2013.1.4-1. Controlling differentiation and proliferation in human stem cells intended for therapeutic use. The aim of this topic is to develop the application of stem cells towards new therapies. Projects should be developed around a concept for addressing an identified and justified therapeutic objective using a human cell-based product, which may consist of human stem cells and/or differentiated cells derived from human stem cells. Projects should then focus on control of differentiation and proliferation, and assessment of the biological activity/potency of the therapy. Proposals should not make cancer a target since this is covered in another part of the work programme and haematopoietic stem cells and their lineages are also excluded. Projects may include pre-clinical and clinical testing if required. Preference will be given to projects involving the use of advanced research tools and *in vivo* investigations. European industry, especially from the SME sector, should be included in consortia. **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)

One or more proposals can be selected.

Expected impact: New knowledge, new tools or new techniques that can progress the translation of stem cell research to the clinic.

Additional eligibility criteria:

The **requested EU contribution per project** shall not exceed EUR 6 000 000

Projects will only be selected for funding on the condition that the estimated EU contribution going to ***EU/Associated Country 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*: A large number of delegations have specifically requested that stem cell research be included in this work programme. The premise on which the topic has been drafted is that stem cell treatment offers great promise for therapy but that limitation in knowledge and techniques represents a bottleneck to greater clinical application. The approach taken is to focus on the priority area of differentiation, proliferation and potency and to permit researchers to choose to work where they wish so long as it is related to a specified translational setting. The only limitation is to exclude cancer research since this is covered in Section 2.4.1 Cancer and haematopoietic stem cells and their lineages. The topic would also enable scientists to address issues concerning therapeutic use of stem cells*

[1] See *Reflection Paper on Stem Cell-based Medicinal Products adopted by the European Medicine Agency's Committee for Advanced Therapies (EMA/CAT/571134/2009) on 14 January 2011, available at:*

http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2011/02/WC500101692.pdf

identified in a reflection paper adopted by the European Medicine Agency's Committee for Advanced Therapies (EMA/CAT/571134/2009) on 14 January 2011 and available at: http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2011/02/WC500101692.pdf

By targeting these issues, the topic contributes to the "Regulatory Science" thrust of the WP. The topic is complementary to the Infrastructures topic INFRA-2012-1.1.8. Stem cell banks and to the IMI 4th call Topic 6. Human induced pluripotent stem (HIPS) cells for drug discovery and safety assessment. Research on the more fundamental aspects of stem cell biology can be proposed for ERC support. The topic should be of interest to SMEs, who can provide research tools and services, and a route to therapeutic exploitation.

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 of this area is to use high-throughput technologies to generate data for elucidating the function of genes and gene products in biological processes.

In the post-genome era the omics technologies (genomics, proteomics, structural biology, epigenomics, interactomics, metabolomics, pharmacogenomics, etc.) enable new innovative approaches in diagnosis, drug development, and individualised therapy. The selected projects will set up the necessary data resource and technological platforms for developing novel approaches for diagnostic and treatment of diseases, including rare diseases.

The integration of data-dense information from the different omics platforms at the individual and population levels is an essential step to reap the benefits of omics technologies for healthcare.

For this call for proposals, topics focus on model systems and on the human microbiome. The first topic aims at the development of validated animal and cellular model systems to support the development of new predictive, preventive or therapeutic approaches, whereas the second topic aims to facilitating better prediction, prevention, treatment and cure of diseases on the basis of microbial characteristics of individual patients.

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).**

HEALTH.2013.2.1.1-1: Functional validation in animal and cellular models of genetic determinants of diseases and ageing processes. The project should use various animal and cellular models to discover and ascribe functions of genes known to be associated to human diseases and/or ageing processes. It should aim at better understanding of the disease and ageing processes in view of creating a portfolio of new and validated therapeutic targets. This project should include large-scale metabolic and molecular phenotyping in model organisms and *in vitro* model systems with priority given to the genes shown to be associated to human disease and/or involved in ageing. It should envisage generating models with the intention to investigate diseases variations in relation with different mutated human alleles. It would develop efficient, standardised and reliable tools, common ontology, standardised operating procedures and technologies for phenotyping. **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 research project).

One or more proposals can be selected.

Expected impact: Validated animal and cellular models that can be used in the development of predictive measures, or in the development of preventive measures, or for new therapies for the selected diseases.

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(s) could 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 criteria:

The **requested EU contribution per project** shall not exceed EUR 12 000 000

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: *More than 1000 of genes have been discovered as being associated to human diseases through human genome studies. However, the roles and functions of the majority of these genes have not yet been identified. Discoveries from this project should bring forward our understanding of basic molecular, cellular and systems biology. It would feed the development of personalised medicine and enhance our understanding of individual genetic bases for diseases and ageing. Research studies about model systems or organisms are helpful to annotate the gene functions and to validate these genes as potential therapeutic targets. Two workshops highlighted the importance of functional validation of diseases biomarkers (1. "Omics in personalised medicine", Brussels, 29-30 April 2010 and 2. "Stratification of biomarkers in personalised medicine", Brussels, 10-11 June 2010). The workshop "Are mice relevant models for human disease" in London, 21 May 2010 underlined the added value of model organism for cost reductions in the preparation of drugs and the breakthrough discoveries for certain diseases.*

Projects should reduce the costs for genotype-phenotype annotations and it should generate technologies, knowledge and knowhow for increasing Europe's competitive position in exploiting the results of genomic studies. By creating common ontology and standardised

operating procedures the project should have a strong impact on the European Research Area.

HEALTH.2013.2.1.1-2: High impact research initiative on metagenomics for personalised medicine approaches. This project should build upon recent very promising research results on the composition of the human microbiome that highlighted the diagnostic potential and possible stratification of patients. The project should accelerate and promote research on the role of the human microbiome in health, diseases and ageing. Through metagenome profiling in large patient cohorts, the project should study the link between the microflora composition and diseases. This multi-component project should contribute to the International Human Microbiome Consortium (IHMC) and should include:

- **Metagenome profiling in health, diseases and ageing.** This component should investigate the composition of the human microbiome in different population cohorts with the intention to generate knowledge of functional composition of microbiomes within the human population. Profiling should also be done to find associations between microbiome and health or diseases in particular host/microbe interactions and immune system responses. The relevance of the frequency and stability of identified microbiomes should be determined.
- **Investigations of the potential role of the human microbiome and diets.** This component will investigate potential links between diets and the metagenomic characteristics.
- **Investigations of the potential role of the metagenome on drug response (drug absorption and metabolism).** This component should investigate the correlation between microbial symbiotic states and responses to medicinal products. Based on comparative metagenomics profiling the project should also develop new interventions that would modify the microbiome to improve response to drug treatment. This should also include interventions aiming to restore the microbiome following e.g. long antibiotic treatment, disruptive conditions, etc.
- **Development of new metagenome-based diagnostic and prognostic tools for personalised treatments.** This component will explore the potential of using human microbiome characteristics as predictive, diagnostic or preventive tools for disease.
- **Bioinformatic tools.** The project should establish means to collect, organise and annotate information and to deliver results in conformity with IHMC policies.
- **Cross boundary training and exchange programmes**. The project should facilitate the transfer of technologies and knowledge between the disciplines from basic research to the clinic, through cross boundary training and exchange programmes. It should allow for synergies between the different research disciplines in a better way than if these disciplines would be funded as separate projects.

The project should aim at developing metagenomics by further generating the technology, knowledge and know-how in this research area. It should increase Europe's competitive position in exploiting the vast amount of metagenomic data and related information. The project should encourage SME efforts towards research and innovation. Priority will be given to proposals demonstrating that industry is playing an important role. The expected project results should clearly be of interest and potential benefit to SME(s). **Note:** Limits on the EU financial contribution apply. These are implemented strictly as formal eligibility criteria.

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

Only up to one proposal can be selected.

Expected impact: Better knowledge of the human microbiome and its potential roles in health and disease. This identification of person-specific microbiomes and microbial markers should allow stratification and attribution of patients to different individual health situations or physical conditions. The project will address health care challenges by facilitating better prediction, prevention, treatment and cure of diseases on the basis of microbial characteristics of individual patients. It aims to foster innovation and strengthening the competitive position of the European health care industry.

Additional eligibility criteria:

The **requested EU contribution per project** shall not exceed EUR 30 000 000

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*: Promising research results became available concerning the species and functional composition of the human microbiome. There is a human symbiosis with bacteria which has been proven to give individual pictures of physical conditions, states of health and ageing. It has been highlighted that this bacterial microflora bears a huge diagnostic potential and possibilities for patient stratification and individual treatments. Past challenges and difficulties with isolating, culturing and sequencing all bacteria strains of a specific microflora have been overcome. Using high throughput sequencing a number of individual human metagenomes have been deciphered mainly through a large coordinated research effort in Europe. European researchers are at the forefront of this research (Nature 464, 59-65, 4 March 2010 and Nature 473, 174-180, 12 May 2011). The aim of this project is to encourage metagenomics research, to further characterise the human microbiome and to build knowledge for understanding health and disease situations. Several studies clearly indicate the role of the microbiome in chronic diseases (e.g. Crohn disease), in drug absorption and metabolism. Furthermore, it is well documented that the microbiome changes with the age. However, the impact of these changes on healthy ageing still needs to be further assessed. The project should support the excellence in Europe with the intention to demonstrate the clinical relevance of the microbiome in diseases and to develop new interventions that could improve health. Finally, this project will certainly contribute to increase the competitive position of the European food and pharmaceutical industries that are interested in the development of prebiotics, probiotics, food complements, drugs or medications.*

2.1.2 SYSTEMS BIOLOGY

Closed 2013

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

2.2.1 Brain and brain-related diseases

The area was open 4 times in the first 6 calls of FP7 resulting in 38 collaborative projects with an overall EC contribution of around €193 million. From a policy point of view, this area has been the subject of recent relevant initiatives including the Pilot Joint Programming Initiative on Neurodegenerative Diseases, in particular Alzheimer's disease (JPND), the European Pact for Mental Health, and the International Initiative for Traumatic Brain Injury Research (InTBIR)[2] that is being set up in cooperation with the US (NIH) and Canada.

The themes spelled out in the Specific Programme have been covered although to different extents. Less funded themes would benefit from additional support. For this reason, the effort on paediatric brain diseases started with the 2011 Health call will be completed in the current call with focus on paediatric aggressive and anti-social behaviour.

For this call for proposals, topics focus in particular on mental health (2 topics), on the implementation of a programme level cooperation with US and Canada on traumatic brain injury (1 topic), and on an important neurological disorder, epilepsy (1 topic).

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

HEALTH.2013.2.2.1-1: Prospective data collection and Comparative Effectiveness Research for traumatic brain injury (TBI). The present topic asks for an observational clinical trial on a cohort of minimum 10,000 TBI patients over 5 years or longer, with a view to identify the most effective clinical interventions to treat TBI. The idea is to collect a large set of harmonised clinical data for subsequent analysis using Comparative Effectiveness Research (CER). To optimise the standardisation and guarantee the quality of collected data, applicants are expected to collect a "core dataset" according to standardised modalities[3] defined by the International Initiative for Traumatic Brain Injury Research (InTBIR). Compliance to this requirement will be taken into consideration under the first criterion during evaluation. Collection of additional data to the core dataset is encouraged.

In addition to the data collection, dedicated project components should focus on:

- Establishing an open-source database for easy storage and analysis of the collected data. Wherever feasible, the possibility of integration with existing databases and biobanks should be explored.
- Applying CER to the collected data to identify the most effective treatment according to patient history and type of injury.
- Development and dissemination of updated clinical guidelines based on the results of the CER analysis.
- Communication activities (conferences, website, brochures) in support of networking and result dissemination within InTBIR and to the scientific community at large.

The management structure and provisions need to be adequate to the size and scope of the project. **Note:** Limits on the EU financial contribution apply. These are implemented strictly as formal eligibility criteria.

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

Only up to one proposal can be selected.

[2] Link to policy document to be added
[3] Link to technical specificities to be added

Expected impact: The funded project is expected to contribute towards the goals of the International Initiative for Traumatic Brain Injury Research (InTBIR)[4]. In particular, the project is expected to identify the most effective clinical interventions taking into consideration the type of brain injury and the history of the patient, and to contribute to the development of improved and harmonised clinical guidelines for the treatment of TBI.

Additional eligibility criterion:

The **requested EU contribution** per project shall not exceed EUR 30 000 000

Justification: *The heterogeneity of both traumatic brain injury (TBI) patients and injuries represents the main obstacle to finding a validated therapy applicable to a broad patient population. Major advances in the care for TBI patients to date have resulted from observational studies and meta-analyses of individual patient data. In contrast, randomized controlled trials have yielded few breakthroughs, as trial success is achieved through the use of very specific protocols and narrow enrolment criteria that severely limit the ability to generalize the results. Therefore it is likely that clinical advancements in this field will come from sophisticated statistical analysis of individual patient data. The uniform collection of high quality clinical data via a large observational study, associated with Comparative Effectiveness Research (CER) analysis has the potential to provide clinically meaningful results and finally improve clinical practice in the field of TBI. CER analysis statistically measures the benefits and harms of an intervention in ordinary settings and broader populations. It is therefore relevant to clinical guidelines development, policy evaluation and health care decisions of providers and patients. This topic was defined during the joint EC/NIH Workshop of 16 June 2010 in Las Vegas[5] and will contribute to InTBIR, the International Initiative for Traumatic Brain Injury Research that is being set up in cooperation with the US (NIH) and Canada. As a further point, brain trauma has not yet been covered in FP7 Health.*

HEALTH.2013.2.2.1-2: Development of more effective imaging tools for diagnosis, monitoring and management of psychiatric disorders. This topic invites researchers, industry and SMEs to develop new and/or optimise existing imaging technology for psychiatric disorders. The goal is to increase our understanding of the patho-physiology of such disorders as well as to allow their diagnosis at the pre-symptomatic stage, more accurate patient stratification and better measurement of disease progression. **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)

One or more proposals can be selected.

Expected impact: This topic is expected to develop new or optimise existing imaging technology for the benefit of patients with psychiatric disorders. It will also encourage SME participation and foster innovation in Europe in line with the Europe2020 agenda. In addition, it will support the goals of the European Pact for Mental Health.

Additional eligibility criteria:

The **requested EU contribution** per project shall not exceed EUR 6 000 000

[4] Link to policy document to be added.
[5] http://www.ncbi.nlm.nih.gov/pubmed/21545277

Projects will only be selected for funding on the condition that the estimated EU contribution going to ***industry including 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: *Neuro-imaging facilitates the diagnosis of psychiatric disorders and the development of new medications. The lack of quantitative objective measures of psychiatric diseases is one reason that the causative factors of some of such diseases remain obscure. Europe has an important tradition in the field of neuro-imaging, both at academic and industrial level. Recently, the emerging field of molecular imaging, in which the tools of molecular and cell biology are being combined with state-of-the-art technology for non-invasive imaging, as well as several technical advances on existing imaging technologies (such as advanced contrast agents and tracers) have opened new venues for studying biological processes in the brain, as well as diagnosing, monitoring and managing psychiatric diseases.*

This topic is targeted to industry and SMEs as it demands a high level of industrial technology and technical expertise. Such key expertise is well present in Europe, from large global corporations to small and medium-sized companies. The rationale behind the focus on psychiatric disorders is twofold: 1) to complete the coverage of psychiatric disorders that was started in earlier calls and 2) to support the European Pact for Mental Health. It should also be considered that neurological disorders have already been extensively covered in the past FP7 calls.

HEALTH.2013.2.2.1-3: Paediatric conduct disorders characterised by aggressive and/or anti-social traits: from preclinical research to treatment. This topic aims at gaining new insights into the mechanisms underlying pathological aggression as well as developing preventative and therapeutic strategies for paediatric conduct disorders characterised by aggressive and anti-social traits. Applicants should apply a multidisciplinary approach to translate pre-clinical findings to therapies for the benefit of patients. Research proposed may address key issues such as genes/environment interactions, neurobiology of aggression and violence, identification of predictors of persistence and/or remission of symptoms in adulthood, development of strategies to prevent and treat aggressive/anti-social behaviours and/or enhance remission. Active participation by SMEs is required and 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 (large-scale integrating project).

One or more proposals can be selected.

Expected impact: To further the understanding of the neurobiology of aggressive and antisocial behaviour and the development of new psychological and pharmacological interventions for prevention and treatment of these disorders.

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 criteria:

The **requested EU contribution** per project shall not exceed EUR 6 000 000

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: *Aggressive and anti-social traits are present in many psychiatric disorders (such as, but non exhaustively - Attention Deficit Hyperactivity Disorder, Oppositional Defiant Disorder, Conduct Disorder and other impulsive disorders) and pose an important societal, forensic and medical problem. Recent findings suggest that violence is the outcome of interactions between individual vulnerability (genetic predisposition) and influences of the environment (social stressors) during critical stages of development. Further research is needed to shed light on such interactions and develop preventive and therapeutic strategies applicable to children to prevent further disorders in adulthood.*

Never addressed previously in FP7, this topic has been requested by several PC delegations (HU, FR, NL, UK, CH, EE, NO, SE, PT, PL, DE) and by the recent Consensus Document on European Brain Research (Eur. J. Neurosci. (2011) 33: 768 – 818).

HEALTH.2013.2.2.1-4: Patho-physiology and therapy of epilepsy. Applicants are expected to use multidisciplinary strategies in support of preclinical and clinical research on epilepsy. The goal is to better understand the complex patho-physiology of epilepsy in order to develop novel preventative strategies in at-risk patients, achieve better patient stratification and put more effective therapeutics on the market. Research proposed may address key issues such as genetics of epilepsy, mechanisms of ictiogenesis, prevention of the development of epilepsy after potentially epileptogenic brain insults, mechanisms and/or epidemiology of refractory epilepsy, identification of age- and aetiology-specific drug targets for input in drug discovery process. Active participation by SMEs and/or industry is required and 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 (large-scale integrating project).

One or more proposals can be selected.

Expected impact: This theme is expected to improve our understanding of the aetiology and mechanisms of epilepsy. It will also help preventing the development of the disease after potentially epileptogenic brain insults. The presence of industry and SMEs will help translating the molecular and cellular targets identified in basic and clinical research into a rational drug discovery process.

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:

The **requested EU contribution** per project shall not exceed EUR 12 000 000

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: *Approximately 6 million people in Europe have epilepsy, and more are at risk of developing it as a result of brain trauma and genetic defects. Although anti-epileptic drugs are available, 30 to 40% of patients are resistant to treatment. This represents an important unmet clinical need as alternative interventions to existing drugs are scarce or effective only on a limited number of patients. Further research is needed towards anti-epileptogenic drugs (drugs capable of preventing the onset of the disease) and disease-modifying agents capable to stop the detrimental course of the disease. This subject has not yet been covered in FP7. Supported by the MT, UK, DK, PT, IT, NL and FR delegations to the Health Programme Committee and the recent Consensus Document.*

2.2.2 Human development and ageing

Closed 2013

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

The aim of this area is to confront major threats to public health with emphasis on HIV/AIDS, malaria, tuberculosis, hepatitis, neglected infectious diseases, emerging epidemics and anti-microbial drug resistance, including fungal pathogens.

2.3.0 Cross-cutting priorities

This sub-area will focus on research that covers issues related to two or more of the disease-oriented sub-areas under area 2.3 through three different actions: Firstly, the development of new concepts for vaccines in the areas of emerging epidemics and against bacterial infections for which there is declining therapeutic options due to drug resistance. Secondly, a first step towards a global mapping of antimicrobial resistance in all pathogens and finally, the development of a global microbial detection system.

Note: Applicants will have to follow the rules for **two-stage** submission procedure (see also respective call fiche in section III).

HEALTH.2013.2.3.0-1: Innovation in vaccines. This topic supports the development of new, safe and efficacious prophylactic vaccines. Projects must be sufficiently advanced to initiate clinical testing during the project period. Projects must focus on:

1) Emerging or re-emerging infectious diseases with a pandemic potential; or
2) Bacterial pathogens for which there is a diminishing repertoire of effective anti-microbials available, or
3) Any of the neglected infectious diseases; or
4) Any of the major poverty-related diseases (HIV/AIDS, malaria and tuberculosis).

Note: Limits on the EU financial contribution apply. These are implemented strictly as formal eligibility criteria.

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

One or more proposals can be selected.

Expected impact: The project is expected to engage research intensive SMEs into the development of new, innovative vaccines with a real potential to contribute significantly to human health.

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 criteria:

The **requested EU contribution** per project should depend on the needs of the project and shall not exceed EUR 6 000 000

Projects will only be selected for funding on the condition that the estimated EU contribution to ***SME(s)*** is 30% or more of the total estimated EU contribution to the whole project. 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*: European vaccine research is world class and European pharmaceutical industries play a significant role in the production of vaccines against a wide variety of diseases. This topic should encourage more SMEs to engage in vaccine discovery research, thereby contributing to maintain Europe's leading role in this area of health research. This topic would also cover the recommendation issued in the Trans-Atlantic Task Force on antimicrobial resistance (TATFAR).*

2.3.1 Anti-microbial drug resistance

The strategic objective of this area is to confront the increasing emergence and spread of antimicrobial drug resistant pathogens in a multi-disciplinary approach through the development of effective infection prevention and control strategies.

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

HEALTH.2013.2.3.1-1: Novel antimicrobials. Projects shall aim to develop novel, safe and efficacious antimicrobials. Projects may include different components of the drug development pipeline from pre-clinical research to clinical trials. Priority will be given to projects with a convincing potential to demonstrate proof of concept for one or more novel antimicrobials within the project period. **Note:** Limits on the EU financial contribution apply. These are implemented strictly as formal eligibility criteria.

Funding scheme: SME-targeted "SBIR-like" Collaborative Project (small or medium-scale focused research project)

One or more proposals can be selected.

Expected impact: The research is expected to stimulate a better integration of research and development activities between different players and boost the development of novel antimicrobials. Research projects funded here are expected to be complementary to any possible upcoming activities undertaken in the context of the Innovative Medicines Initiative (IMI) in relation to antimicrobial resistance.

Specific feature:

- Specific SME innovation initiative designed to encourage stronger SME efforts towards research and innovation.
- SMEs will need to have a leading role in the project.
- Applicants invited to present a full proposal for stage 2 are requested to submit a exploitation plan clearly describing the valorisation of the technology to be developed.
- Expected project results should be of clear interest and potential benefit to SME(s).

Additional eligibility criteria:

The **requested EU contribution** per project should depend on the needs of the project and shall not exceed a maximum of EUR 6 000 000.

The proposed **project duration** indicated in the proposal shall not exceed 3 years.

Projects will only be selected for funding on the condition that the estimated EU contribution to ***SME(s)*** is 50% or more of the total estimated EU contribution to the whole project. 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.

The **financial viability of all partners** in projects needs to fulfil the Commission requirements. This will be checked at the stage 2 evaluation.

Number of participants: minimum 3 up to maximum 5, established in at least three different EU Member States or Associated Countries.

Participation is restricted to entities established in EU Member States and Associated Countries. Any project activity must be performed by an entity in the EU Member States or Associated Countries (see also section III). SME(s) need to be 1) at least 51% owned and controlled by one or more individuals who are citizens of one of the EU Member States or Associated Countries or permanent residents in one of those countries, or 2) at least 51% owned and controlled by another business concern that is itself at least 51% owned and controlled by individuals who are citizens of, or permanent residents in those countries.

Justification: *The pipeline for developing novel antibiotics is nearly empty while the levels of resistance to the currently available treatment options are continuously on the rise. This topic should encourage more SMEs to engage in development of new antimicrobials.*

HEALTH.2013.2.3.1-2: Stratified approaches for pathogen-host interactions. In order to improve the use of antimicrobials (dosage, duration, indication, and combinations), antimicrobial administration need to be better targeted to the actual needs of individual patients. Projects should aim to gain a better understanding of both pathogen and host factors as well as their interaction with the objective to allow for more stratified treatment options and improved antimicrobial administration. **Note:** Limits on the EU financial contribution apply. These are implemented strictly as formal eligibility criteria.

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

One or more proposals can be selected.

Expected impact: Enabling the prescription of antimicrobials specifically tailored to the needs of individual patients will clearly decrease use of unnecessary or ineffective antimicrobials. This in turn is expected to slow down the emergence of antimicrobial resistance.

Additional eligibility criterion:

The **requested EU contribution** per project shall not exceed EUR 6 000 000

Justification: *Currently the prescription of antibiotics is often not evidence based. Improving prescription practices based on patients' needs and adapting the use of antibiotics based on up-to-date clinical data is needed to address the individual needs of patients and to combat antimicrobial resistance.*

HEALTH.2013.2.3.1-3: Contribution to global mapping of drug resistance and identification of pathogens of major importance for public health. This topic should contribute to develop an integrated system for global mapping of drug resistant pathogens and identification of pathogens of major importance for public health. The project should develop a system to rapidly identify and characterize microbial pathogens causing human diseases. The methodology should be based on sequence data, and should be rapid, reliable, sensitive, user-friendly, and affordable including in low-income countries. The sequence information should also allow assessing the sensitivity of the pathogens to drugs in order to improve clinical treatment of affected patients. The project should allow for harmonizing data formats and open data sharing, including clinical data, with similar initiatives which may be underway in the world. Projects should therefore aim to establish a global standard for data collection and develop a universally accessible tool to gather and compile knowledge about antimicrobial drug resistance and pathogens as well as their spread. Particular attention should be given to areas of the world, where little information is available. **Note:** Limits on the EU financial contribution apply. These are implemented strictly as formal eligibility criteria.

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

Only up to one proposal can be selected.

Expected impact: The project should contribute to a global mapping of antimicrobial drug resistance as well as the identification of pathogens, and thereby provide comprehensive information about the burden of drug resistance. It is expected that this action will deliver a universally accessible tool to provide an overview of the global burden of drug resistance and the spread of pathogens, and thereby increase the public health response to microbial threats, allow for a better prevention and control of emerging infectious diseases while at the same time allow for the delivery of more appropriate effective treatments to patients. The project is expected to contribute to future global initiatives.

Additional eligibility criterion:

The **requested EU contribution** per project shall not exceed EUR 25 000 000

Justification: *Across the world drug resistance is on the rise. In many parts of the world little effort has been devoted to map this problem in order to develop measures to manage it. This topic could make a contribution to a broader global initiative of AMR mapping since the development of resistance to drugs required to treat infectious diseases is a global problem.*

Utilising modern genomics/proteomics technologies and bioinformatics capacities can allow for a new approach to establish more rapid global pathogen detection, surveillance and improved interventions.

Planned workshops/events related to this topic: Discussion at the HIRO meeting in December 2011 in order to explore the possibility for launching a global coordinated initiative.

2.3.2 HIV/AIDS, malaria and tuberculosis

Closed 2013

2.3.3 Potentially new and re-emerging epidemics

The focus will be on confronting emerging pathogens with pandemic potential. The results of research in this area will integrate European scientific excellence and make Europe better prepared for emerging epidemics.

For this (these) call(s) for proposals, topics focus on building European preparedness to respond to emerging epidemics of any kind, including prions, viruses, bacteria and protozoans.

Note: Applicants will have to follow the rules for two-stage submission procedure (see also respective call fiche in section III).

HEALTH.2013.2.3.3-1: Clinical management of new and re-emerging epidemics. The objective is to set up a multidisciplinary hospital-based consortium that should be able to rapidly deliver a harmonized and optimized clinical management of any new infectious outbreak that has a potential for pandemic or for significant damage to health and socio-economics in the EU. The consortium should address severe acute respiratory infections, as well as other infections (e.g. hemorrhagic fevers, encephalopathy, severe diarrhoeas, etc.) The consortium should ensure methodological standardization (pre-approval of protocols, etc) and rapid sharing of high quality data and samples that should build large-scale studies in response to an emerging threat. It should address inter-pandemic research such as, but not restricted to sample collection, treatment strategies, host-pathogen interactions, immune responses. It should also explore ways to speed-up the identification and characterisation of pathogens with a pandemic potential. Training activities should be elaborated to spread the new insights into optimal clinical management of emerging epidemics to clinical centres. The project should structure the European contribution towards the international initiatives existing or under development in this field. The consortium is expected to provide input to the European Centre for Disease Prevention and Control (ECDC) in order to improve the European preparedness and response to any emerging threat. A carefully elaborated work plan for both the pandemic and inter-pandemic research as well as a strategy for rapid adaptation to an outbreak situation will be a prerequisite for funding. **Note:** Limits on the EU financial contribution apply. These are implemented strictly as formal eligibility criteria.

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

Only up to one proposal can be selected.

Expected impact: The research should provide technical and scientific support as well as standardised protocols/definitions/strategies for the clinical management of severe epidemic infections to help designing a coherent, adequate, global and rapid public health response to emerging threats. The consortium should have a broad range of expertise that would enable it to tackle in a flexible way any pathogen with a pandemic potential. The consortium should link with national and international public health agencies to ensure the quick implementation of its findings into optimized clinical practices in the EU member states and other countries in the world.

Additional eligibility criterion:

The **requested EU contribution** per project shall not exceed EUR 20 000 000

Justification*: Clinical management of (re-)emerging epidemics is paramount to safe lives and restore health of affected patients once prevention attempts have failed. A broad network of scientists and clinicians would be required to combine their expertise and resources in order to conduct clinical studies of a sufficient scale for drawing conclusions and to be able to tackle any novel threats that are by their nature unpredictable. Responding effectively to an emerging infectious disease of an unknown type will thus require wide geographic coverage and a broad expertise.*

2.3.4 Neglected infectious diseases

The aim of this area is to establish an integrated approach for the development of preventive, therapeutic and diagnostic, tools for neglected infectious diseases. Activities will address, but not be limited to, parasitic diseases caused by Trypanosomatidae species (Trypanosomiasis, Chagas disease, Leishmaniasis), bacterial diseases such as Buruli ulcer, leprosy and trachoma, helminth diseases such as schistosomiasis, as well as co-morbidities that can be caused by a combination of pathogens, such as diarrhoeal and respiratory diseases. Projects should address preclinical and early clinical activities, as well as the particular public health conditions and health needs of disease endemic countries. Proposals should provide an integrated, multidisciplinary approach, including significant participation of partners from disease-endemic areas and, where relevant, industry partners. Where applicable, technology transfer, training activities and human capacity building should also be part of the projects.

Note: Applicants will have to follow the rules for **two-stage** submission procedure (see also respective call fiche in section III).

Health.2013.2.3.4-1: Emerging infectious diseases in Central- and Eastern Europe. This action will support highly meritorious, innovative, collaborative biomedical research proposals that address emerging and re-emerging infectious diseases, which disproportionately affect Central and Eastern Europe[6]. All projects must focus on one or more of the following viral (tick-borne encephalitis, rabies), bacterial (Borrelioses and tick-borne rickettsioses), protozoan (Babesia, giardiasis), and/or helminthic (Trichinellosis, taeniasis and

[6] For the purposes of this topic, Central and Eastern Europe (CEE) is defined using the classification established by the European Center for Disease and Prevention Control (ECDC). This classification includes: Albania, Bosnia and Herzegovina, Bulgaria, Croatia, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Former Yugoslav Republic of Macedonia, Montenegro, Poland, Romania, Slovakia, Slovenia, Serbia and Turkey.

human echinococcosis) agents of human disease. **Note:** Limits on the EU financial contribution apply. These are implemented strictly as formal eligibility criteria.

Funding scheme: Collaborative Project (small-scale focused research project)

One or more proposals can be selected.

Expected impact: Projects are expected to deliver new knowledge about the biological mechanisms and pathology of neglected infectious diseases, which are disproportionately affecting Central- and Eastern Europe. This knowledge should be obtained and analysed in such a way that it can contribute positively to the future prevention, treatment or diagnosis of the disease(s) in question.

Additional eligibility criterion:

The **requested EU contribution** per project shall not exceed EUR 3 000 000

Justification: *Recent years have seen an increased prevalence and incidence of several neglected infectious diseases in Central- and Eastern Europe (reviewed in Hotez, PJ and Gurwith, M: "Europe's neglected infections of poverty", International journal of Infectious Diseases (2011). These issues have not yet been address in FP7.*

Health.2013.2.3.4-2: Drug development for parasitic diseases. This activity should gather promising European and global attempts to discover and develop drugs for parasitic diseases. The aim should be to establish a common drug discovery platform by joining experts in the field from industry and the public sector in Europe and disease-endemic countries. The project should undertake screening of compound libraries, lead development, animal testing, toxicology and safety testing as well as early clinical development. The project should operate in the model of open innovation, Data generated should be included in a unique database with open access. **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)

One or more proposals can be selected.

Expected impact: In recent years, European and global studies have been ongoing to discover new drug leads or screen approved drugs for activity against parasitic infections. This action is expected to gather a comprehensive portfolio of drug leads, and develop the most promising of these into drug candidates that can be tested in early clinical trials.

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 criteria:

The **requested EU contribution** per project shall not exceed EUR 12 000 000

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**: For many parasitic diseases there are no or limited drug regimens available and many of these are associated with serious adverse effects. Without a larger, more diverse arsenal of drug therapies, there is an increased risk for organisms to develop resistance against the few existing drugs. Globally, more than 1 billion people are affected by neglected infectious diseases, but during the last 30 years, only10 new drugs have been put on the market (Chirac P, Torreele E (2006) Global framework on essential health R&D. Lancet 367(9522): 1560–1). There is therefore an apparent market failure, which justifies public support.*

2.4 TRANSLATIONAL RESEARCH IN OTHER MAJOR DISEASES

2.4.1 Cancer

Research in this area will focus on disease aetiology; identification and validation of drug targets; prevention, early diagnosis and treatment biomarkers; as well as on assessment of preventive, diagnostic, prognostic, and therapeutic interventions. In the long term, this area will contribute to reducing cancer incidence, morbidity and mortality and to improving the patients' quality-of-life and treatment with fewer side-effects.

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

HEALTH.2013.2.4.1-1: Investigator-driven treatment trials on advanced therapies to combat metastases in patients with solid cancer. The successful consortium will perform multicentre clinical trials assessing advanced therapeutic strategies to treat metastases in patients with solid cancers. Consortia are required to use state-of-the-art, technologies to ensure proper patient staging and assessment of treatment efficacy. The following requirements and exclusions apply: endpoints, inclusion and exclusion criteria must be clearly described. The primary endpoint should be progression-free survival. The outcome of this research should be relevant for patients and have a potential to lead to changes in clinical practice. 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 and their results published in peer reviewed journals. 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. **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)

One or more proposals can be selected

Expected Impact: The results of research in this area should ultimately benefit survival for a number of metastatic cancer subtypes with dismal survival rates, by providing stratified therapies with a higher therapeutic index.

Additional eligibility criterion:

The **requested EU contribution per projec**t shall not exceed EUR 6 000 000

Justification: *90% of cancer patients die of metastases due to the lack of efficacious therapies to treat metastatic disease. Cancers of the blood and lymphatic system rarely metastasise, in contrast to solid cancers.*

HEALTH.2013.2.4.1-2: Strengthening the cancer patient's immune system. The successful consortium will translate clinical observations concerning cancer immunotherapy into improving treatment efficacy of future immunotherapeutic strategies. It could address: (1) cell- or antibody-based immunotherapy; (2) therapeutic cancer vaccines directed against clinically relevant tumour and/or host antigens; (3) immune evasion impacting on clinically relevant tumour-host microenvironment interactions in localised or systemic disease. Appropriate tumour response criteria must be implemented and existent or newly developed assays harmonised while validating cancer immunotherapeutic regimens in preclinical models or first-in-human trials. Involvement of industry, in particular SMEs, is strongly recommended. **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).

One or more proposals can be selected

Expected Impact: The expected results of research in this area will contribute to improving the efficacy of cancer immunotherapeutic regimens and clearly be of interest and potential benefit to SME(s).

Additional eligibility criteria:

The **requested EU contribution per project** shall not exceed EUR 6 000 000

Projects will only be selected for funding on the condition that the estimated EU contribution allocated 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: *Early translational research into cancer immunotherapeutic strategies was extensively funded under FP6, but has not been addressed under FP7 despite the steady progress made over the past years in the clinic, in particular for metastatic melanoma and prostate cancer, by EU and other networks. Strengthening the adaptive immune system by means of immunotherapy and vaccination holds great potential as a successful and cost-effective, long-term targeted treatment strategy to combat systemic disease with high precision and minimal side effects in cancer patients. Traditional RECIST criteria and assays have come under increasing scrutiny due to difficulties in properly assessing antitumour treatment responses in patients treated with immunotherapy. Several PC delegations have repeatedly requested this research area to be opened.*

HEALTH.2013.2.4.1-3. Investigator-driven supportive and palliative care clinical trials. The successful consortiums will perform multicentre clinical trials aiming at improving quality-of-life of cancer patients or cancer survivors. The trials could address management of symptoms caused by cancer, by cancer treatment, by long-term side-effects in cancer survivors or address symptoms that occur at the end of life. The following requirements and exclusions apply: endpoints, inclusion and exclusion criteria must be clearly described. The outcome of this research should be relevant for patients and have a potential to lead to

changes in clinical practice. Applicants must demonstrate that clinical trials are appropriately powered to produce robust evidence and a biostatistician must be part of the consortium. 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 and their results published in peer reviewed journals. 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. **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).

One or more proposals can be selected.

Expected Impact: The results of research in this area will ultimately lead to improved comfort and quality-of-life of cancer patients and cancer survivors.

Additional eligibility criterion:

The **requested EU contribution per project** shall not exceed EUR 6 000 000

Justification: *Overall, cancer mortality in Europe stands at 60%. Both patients who relapse and those who survive suffer from mild to severe side-effects and symptoms during and/or after treatment, respectively. Given the complexity and debilitating short- and long-term side-effects associated with this disease and the necessity to carefully integrate supportive care with treatment through a multidisciplinary tumour board treating the patient, a cancer-specific focus is warranted Very few CTs have been performed so far despite the fact that palliative care has been shown to improve quality-of-life and increase treatment efficacy in cancer patients. Second, as a result of the introduction of screening procedures in the various member states and more effective cancer treatments, the population of cancer survivors - including those who require supportive care- is increasing.*

2.4.2 Cardiovascular diseases

This area was open in the first five calls of FP7. In total, 25 collaborative research projects on cardiovascular diseases (CVD) have been supported for an overall financial contribution of some € 163 million. This has allowed addressing the areas of atherosclerosis, aneurysm, congenital diseases, cardiomyopathies, CVD imaging, pharmacogenomics, systolic and diastolic heart failure, translational research and clinical trials in stroke, stem cell therapy for the treatment of heart ischemia, ventricular arrhythmias, atrial fibrillation, stent thrombosis and cardio-protection. For this call for proposals, topics focus on the identification and validation of novel therapeutically relevant targets for the development of new medication for cardiovascular pathologies as well as on the clinical studies of cardiovascular devices and imaging tools.
Note: Applicants will have to follow the rules for **two-stage** submission procedure (see also respective call fiche in section III).

HEALTH.2013.2.4.2-1. Discovery research to reveal novel targets for cardiovascular disease treatment. The cutting edge research projects should explore further available and emerging molecular, genomic and other omics data from large-scale patient studies and lead

to the identification and characterisation of in vitro and in vivo models of novel therapeutically relevant targets. Achieving this aim should be ensured by multidisciplinary research consortia with advanced biotechnological tools available. **Note:** Limits on the EU financial contribution apply. These are implemented strictly as formal eligibility criteria.

Funding scheme: SME-targeted Collaborative Project (small or medium-scale focused research project)

One or more proposals can be selected.

Expected impact: purpose of this research is to provide new targets for further drug discovery and development in CVD area.

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 criteria:

The **requested EU contribution per projec**t shall not exceed EUR 6 000 000

SME-targeted Collaborative 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: *Despite the progress of medical science over the past 30 years, which allowed a substantial increase in life expectancy for patients with CVD, these diseases remain the main cause of death worldwide. To improve further the survival and quality of life of patients with CVD requires continued investment into improving our approach to CVD treatment. The post-genomic era brought forward thousands of new gene sequences and significant amount of data on functional gene products However, exploitation of this knowledge into fully characterised therapeutically relevant targets has been limited. It is therefore important to continue investing efforts in this area. Collaboration of academic research with private enterprises has huge potential as initiator of discovery of novel targets that may result in successful drug development.*

HEALTH.2013.2.4.2-2 Comparative effectiveness research of existing tools for diagnosis and treatment of cardiovascular diseases. Cardiovascular technologies used in clinical practice including those used for imaging and therapeutic procedures may vary widely in different countries and even amongst centres. In addition, systematic evidence regarding how approaches to prediction, diagnosis, treatment, monitoring and prognosis compare with one another is lacking. The project shall compare the *currently available* imaging tools and/or devices in the selected area. A comprehensive array of clinical and safety, as well as socio-economic outcomes (e. g. quality of life, patient mortality, morbidity, costs, and performance of the health system) for chosen CVD patient populations must be assessed. The study population should well address gender balance. Data sources to be used and methods to assess comparative effectiveness and cost effectiveness must be clearly defined. The project may include the development of clinical data networks, databases or patient registries. **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).

One or more proposals can be selected.

Expected impact: purpose of this research is to inform patients, health care providers, and decision-makers, about which imaging tools and technologies are most effective for CVD patients.

Additional eligibility criterion:

The **requested EU contribution per projec**t shall not exceed EUR 6 000 000

Justification: *Cardiovascular diseases are the number 1 killer worldwide and a major source of disability. The improved survival and quality of life of patients with CVD comes at a high economic cost. Interventions, device therapy, and imaging take up a large share of the cost. A large number of advanced technologies are currently available for disease detection and treatment. However, for the use of many of these tools there are often no guideline documents and the linkage with outcomes is less well established. The lack of comparison studies for effectiveness results in a suboptimal use of the technologies at hand and growth in healthcare expenditures.*

2.4.3 Diabetes and obesity

Closed 2013

2.4.4 Rare diseases

Closed 2013

2.4.5 Other chronic diseases

Closed 2013

3. OPTIMISING THE DELIVERY OF HEALTHCARE TO EUROPEAN CITIZENS

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

This area focuses on better use of medicines and appropriate use of behavioural and organisational interventions as well as therapies and health technologies. Special attention will be given to patient safety to define best clinical practice, to understand decision making in clinical settings in primary and specialised care and to foster applications of evidence-based medicine and patient empowerment.

HEALTH.2013.3.1-1: Comparative Effectiveness Research (CER) in health systems and health services interventions. The projects should evaluate the impact of two or more alternative health system and health services interventions on patient outcomes including patient needs, patient safety, effectiveness and quality of care, in terms of their health benefit and cost. Research should include the structural and policy components, cost effectiveness, in a multidisciplinary approach. Research may analyse very different approaches, for instance surgery and preventive interventions, or the uptake of new approaches such as stratified, individualised or personalized medicine. It may also compare the effectiveness of different quality improvement strategies in disease prevention, acute care, chronic care and rehabilitation services for diverse populations of children and adults. **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)

One or more proposals can be selected.

Expected impact: Results should assist policy makers and decision makers to make informed decisions regarding the implementation or improvement of health system and health services interventions closely aligned with daily care decisions in view of improving patient outcomes and increase the cost-effectiveness of interventions.

Additional eligibility criterion:

The **requested EU contribution** per project shall not exceed EUR 6 000 000

Justification: *Recommendations from the conference "European Perspectives in Personalised medicine" held in Brussels 12-13may 2011**.** The results will support health care professionals, patients and policy makers to make informed decisions that are both evidence based and cost effective. CER is also one way of moving towards the setting of gold standards to reduce intervention inequalities between countries. The topic has not been addressed before and will make a bridge to Horizon 2020 where CER will be further supported.*

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

Closed 2013

3.3 HEALTH PROMOTION AND PREVENTION

This area focuses on developing evidence for best and most efficient public health measures with an impact on life style and interventions at different levels and in different contexts. Focus will be on the wider determinants of health and how they interact at both individual and community level.

HEALTH.**2013.3.3-1: Social innovation[7] for health promotion.** EU research should aim to identify and better understand innovative approaches to enhance society's capacity reduce sedentary behaviour. Research should include the evaluation of innovative implemented initiatives that enhance the level of physical activity combined with dietary or other interventions, for the population at large, including the elderly, children and patients with chronic diseases and people living in deprived areas. In this context, research should include the identification of 'good practices' as well as the analysis of economic and social benefits of innovative initiatives. Cultural, institutional, political and economic barriers to improve the individuals capacity to increase physical activity and self-regulate their dietary or other behaviour that enhances sedentary behaviour need to be detected. Comparative research should cover various areas (e.g. sports, health, education, transport, urban planning, working environment, leisure) and different levels (local, national, European), and should verify the role of divers public and private entities, such as business, including social enterprises, civil society organisations and public authorities, and their interaction. **Note:** Limits on the EU financial contribution apply. These are implemented strictly as formal eligibility criteria.

Funding scheme: SME-targeted Collaborative Project (small-scale focused research project)

One or more proposals can be selected.

Expected impact: The relevant research would provide the necessary basis for a scale up of innovative initiatives that empower society to increase physical activity in everyday life and improve dietary behaviour, thus ultimately contributing to the prevention of major lifestyle related diseases. This includes more effective and efficient evidence-based strategies of health promotion and disease prevention to increase physical activity together with supportive (multi-disciplinary) policy environments. This will result in a greater uptake of innovative approaches by policy makers and making it more appealing to citizens to choose a healthy lifestyle. The project should integrate a strong communication strategy, whereby the views of potential end-users are fully integrated in developing the methodologies for assessing impact and outcomes throughout the project.

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).

[7] Social innovation relates to new responses to pressing social demands by means which affect the process of social interactions. It is aimed at improving well being. It covers wide fields which range from new models of childcare to web-based social networks, from the provision of domestic healthcare to new ways of encouraging people to exchange cars for bicycles in cities, and the development of global fair-trade chains. It may be a new product, service, initiative, organisational model or approach to the delivery of public services.

Additional eligibility criterion:

The **requested EU contribution** per project should depend on the needs of the project and shall not exceed EUR 3 000 000

The proposed **project duration** indicated in the proposal shall not exceed 3 years.

Projects will only be selected for funding on the condition that the estimated EU contribution to **SME(s)** is 15 % or more of the total estimated EU contribution to the whole project. 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: *Social innovation concept of increasing importance for Europe. Given the importance of a healthy life style and the crucial role of a variety of different actors this topic could foster important ground-breaking activities. This topic would complement the first social innovation topic offered in WP 2012 which addresses ageing.*

3.4 INTERNATIONAL PUBLIC HEALTH & HEALTH SYSTEMS

Closed 2013

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 programme and the preparation of future European Union innovation, research and technological development policy.

For this call for proposals 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).**

HEALTH.2013.4.1-1: Support to high-technology research-intensive SMEs, operating in the Health sector. The objectives are: *(i)* to promote participation of SMEs with the focus on high-technology, research intensive SMEs in European research funding programmes in health. The promotional activity should include participation in relevant events and organisation of workshops, as appropriate, with special attention to the enlarged Europe, acceding and candidate countries; *(ii)* to assist SMEs in participating into EU-funded research proposals in the health area with training activities and tools; *(iii)* to encourage cooperation between SMEs and academia; *(iv)* to provide support for consortium building and matchmaking for SMEs and academia in preparing EU project proposals with the help of a matchmaking database; *(v)* to provide tools and advice for improving the quality of research proposals submitted and increase the participation rate of SMEs. *(vi)* For the participants of health theme proposals in negotiation, to provide support, tools and training to facilitate a successful negotiation of grant agreements; *(vii)* to provide support on IPR issues that may rise during negotiation or during funded projects' lifetime; *(viii)* to assist SMEs participating into EU funded research projects, with training activities and tools; *(ix)* to provide advise/information/training on valorisation of project results in view of future commercialization covering for example business management, innovation financing sources, organisation of partnering events. The project should collaborate, complement and develop synergistic approach with existing support structures like National Contact Points and already funded support projects relevant for SMEs working in health sector, like the IPR helpdesk. **Note:** Limits on the EU financial contribution apply. These are implemented strictly as formal eligibility criteria.

Funding scheme: Coordination Action or Support Action (coordinating action)

Only up to one proposal can be selected.

Expected impact: The promotional activity is expected to support the increase of high-tech SMEs participation in the Health Theme, enhancing Lisbon objective for contributing to technological evolution, competitiveness of European industry, economic growth and employment. Participation of industry and SMEs in particular in health projects, will enhance the dissemination and exploitation of research results generated in the activities funded by this

Theme, which has the political objective of giving to SMEs 15% of the EU contribution. The project is expected to help SMEs in successfully participating into framework projects.

Additional eligibility criterion:

The **requested EU contribution** per project shall not exceed EUR 2 000 000

***Justification**: This topic was last published in 2010 call; the current project is coming to an end in 2012 (?). It would be good to ensure that ongoing projects and projects started in 2012 and 2013 also benefit from support for exploitation of results. It would ensure that support mechanism is in place for the launch of the next EU funding programme.*

HEALTH.2013.4.1-2: Impact of EU legislation on health research. The action should aim to evaluate the impact of specific EU legislation and related guidelines, including where applicable the way they are applied at national level, on research activities within the Health theme, including related developments and applications. Each action is expected to address a specific issue relating to an EU legislation of major importance for the research and outcome performed within this theme. **Note:** Limits on the EU financial contribution apply. These are implemented strictly as formal eligibility criteria.

Funding scheme: Coordination Action or Support Action (supporting action)

One or more proposals can be selected.

Expected impact: to better assess the consequences of EU legislation on research activities and related developments supported within this theme using scientific analysis based on facts and figures. In particular, such projects are expected to constitute the evidence base that will help the European Commission to anticipate the needs for eventual revision of current EU legislation or elaboration of new legislation.

Additional eligibility criteria:

The **requested EU contribution** per project shall not exceed EUR 500 000

***Justification**: This topic was last published in 2010 call; the current projects are coming to an end in 2012 (?). This is a useful topic, with a bottom-up approach, to fund such studies.*

HEALTH.2013.4.1-3: 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 2014 and 2015 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 Action (supporting action)

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.

Additional eligibility criterion:

The **requested EU contribution** per action shall not exceed EUR 100 000

Justification*: This topic was last published in 2010 call; the current projects are coming to an end in 2012 (?). This is a useful topic, with a bottom-up approach, to fund such studies.*

HEALTH.2013.4.1-4: Preparing the future for health research and innovation. Proposals for coordination actions are sought in important and/or emerging areas of health research, where there is a need to step up coordination efforts between European key players. Academia, industry, national programmes and other relevant organisations, should come together to develop a strategy plan for the further development of the targeted health research area with high impact on competitiveness, healthcare systems and benefit for European citizens' health. For all proposed activities European added value must clearly be discernible. Under this topic activities will be supported with the aim of assessing profoundly the research and/or innovation resources, gaps and needs of the thematic target area, and to evaluate its potential as a focal area for a future innovative partnership. Expert advice may be sought, and industry interest may be probed, such that in case of positive outcomes detailed roadmaps may be developed. Existing activities, such as project(s) aiming at the development of SRAs or roadmap-oriented activities must be taken into account and - where relevant - coordination with these shall allow for synergies and exclude competition or duplication. In addition, the proposal should demonstrate how it intends to ensure maximum transparency and openness to all relevant stakeholders. Where health issues are at stake that go beyond the confines of Europe, consideration may be given to integration of European coordination efforts with pertinent other international initiatives such that Europe may play an active and leading role in the respective thematic area of health research. Relevant target institutions and channels for diffusion of the deliverables (reports, recommendations, roadmaps, etc.) have to be clearly identified. The timeframe considered for implementation should also be duly justified. **Note:** Limits on the EU financial contribution apply. These are implemented strictly as formal eligibility criteria.

Funding scheme: Coordination and Support Action (supporting action)

One or more proposals can be selected.

Expected impact: Projects should contribute to preparing strong partnerships in key areas of health research, where important societal and/or economic return is expected. Where health issues go beyond Europe, projects may be used to coordinate the European participation in pertinent international activities.

Additional eligibility criterion:

The **requested EU contribution** per action shall not exceed EUR 500 000

Justification*: This topic is a repetition of the topic included in 2012, which provides a broad opening for studies, roadmaps, etc to help plan future research investments.*

4.2 RESPONDING TO EU POLICY NEEDS

The objective of these actions is to contribute to the support and follow-up of other European Union Community policies. The focus of these activities will be on research into age-appropriate use of medicines, drug safety research and methodologies for clinical trials in small populations in view of supporting regulatory decisions related to orphan drugs and personalised medicine approaches.

Note: Applicants will have to follow the rules for **two-stage** submission procedure (see also respective call fiche in section III).

2013-4.2-1: Investigator-driven clinical trials for off-patent medicines using innovative, age-appropriate formulations and/or delivery systems addressing one of the options below:

A) for use in children (Regulation (EC) No1901/2006[8]): Projects are expected to contribute to expanding the availability of medicines for children. Particular attention should be paid to age-appropriate formulations and of specific delivery systems for children. Projects will be required to conduct appropriate clinical trials in children, respecting the current legislation and considering the ethical aspects and the particular needs of children and their families. Patient advocacy groups should be involved where possible and appropriate. The aim is to conduct clinical trials with the view of obtaining a PUMA (Paediatric Use Marketing Authorisation). Priority will be given to following areas, as mentioned in the EMA list of priorities for paediatric medicines:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000092.jsp&murl=menus/regulations/regulations.jsp&mid=WC0b01ac05800260a4&jsenabled=true

B) for use in the elderly Projects are expected to contribute to expanding the availability of better suited medicines for the elderly by conducting clinical trials validating new drug formulations adapted to the needs of the elderly. Specificities such as potentially different drug absorption rates, metabolism particularities and co-morbidities should be taken into account 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 focused research project)

One or more proposals can be selected.

Expected impact: Increased availability of medicines adapted to the specific needs of children or the elderly.

Additional eligibility criteria:

The **requested EU contribution** per project shall not exceed EUR 6 000 000

Projects will only be selected for funding on the condition that the estimated EU contribution going to ***industry including SME(s)*** is 30% (percentage still to be discussed) or more of the total estimated EU contribution for the project as a whole. *This will be assessed at the end of*

[8] Link: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:378:0001:0019:en:PDF

the negotiation, before signature of the grant agreement. Proposals not fulfilling this criterion will not be funded.

Justification: Considering the demographic dynamics leading to an aging European population, specific needs will have to be taken into account. In both situations, introducing innovative age-appropriate delivery systems or formulations will be highly appreciated, as a way to better answer the specific needs of these particular age categories.

HEALTH.2013.4.2-2: Adverse drug reaction research. Experiences with medicines that have been on the market for many years have shown that potentially serious adverse events may only become apparent long after their marketing authorisation. Projects to be funded in this topic should generate new knowledge on severe drug reactions and provide scientific evidence for post-authorisation risk assessment of medicinal products. Proposals should be based on pharmaco-epidemiological approaches focusing on adverse drug reaction research in one of the areas indicated below. **Note:** Limits on the EU financial contribution apply. These are implemented strictly as formal eligibility criteria.

- Long term safety of antipsychotic medication in patients with dementia
- Genetic causes of adverse drug reactions: angiotensin-converting enzyme inhibitors and angioedema, and statin-induced myopathy
- Proton Pump Inhibitors and risk of myocardial infarction

Further details of the research objectives and expected deliverables are available on the website: (to be defined)

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

One or more proposals can be selected.

Expected impact: Research should generate new knowledge on severe drug adverse events with potential implications in public health, i.e. those impacting on the balance of benefits and risks of medicinal products. This should be directed towards regulatory decisions on marketing authorisations for medicinal products including the warnings in product information for doctors and patients. A safer and more effective use of medicines should result with positive implications for public health.

Additional eligibility criteria:

The **requested EU contribution** per project shall not exceed EUR 3 000 000

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: *The new EU legislation on pharmacovigilance (Directive and Regulation), which will become applicable in July 2012, foresees a more proactive conduct of pharmacovigilance. This entails increasing emphasis on defining and managing the risk-benefit profile not just of new but also existing medications. Safety issues might only emerge when a product or classes of products with similar physiochemical characteristics have been on the market for a long time. Active participation of the various stakeholders and the use of different information sources will lead to new insights into drug-related adverse*

events that constitute major public health concerns. The specific adverse reactions and classes of products included in the topic are based on the priority list adopted by the Committee for Medicinal Products for Human Use (CHMP) at the European Medicines Agency (EMA).

HEALTH.2013.4.2-3: New methodologies for clinical trials for small populations. Research should aim to develop new or improved methodologies for clinical trials in small populations for rare diseases or stratified, personalised or individualised medicine approaches. These new methodologies should allow the efficient assessment of the safety and/or efficacy of the treatment in small patient groups. Research should be multidisciplinary and should involve all relevant stakeholders including industry and patient advocacy groups as appropriate. Research should also address regulatory issues. Clinical trials as such will not be funded. Collaboration with relevant organisations outside Europe is welcomed. **Note:** Limits on the EU financial contribution apply. These are implemented strictly as formal eligibility criteria.

Funding scheme: Collaborative Project (small-scale focused research project)

One or more proposals can be selected.

Expected Impact: Cost efficient clinical trials deriving reliable results from trials in small population groups.

Specific feature: Regulatory science topic.

Additional eligibility criterion:

The **requested EU contribution** per project shall not exceed EUR 3 000 000

Justification: *There is a need for new methodologies for clinical trials for small populations in particular in the context of developing orphan drugs and for stratified and personalised medicine approaches.*

OTHER ACTIVITIES

Not yet developed