WORK PROGRAMME 2009

COOPERATION

THEME 1

HEALTH

(European Commission C(2008)4598 of 28 August 2008)

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I CONTEXT

The overall objective of the Health Theme is to improve the health of European citizens and increase the competitiveness and boost the innovative capacity of European health-related industries and businesses, while addressing global health issues including emerging epidemics. Emphasis will be put on translational research (translation of basic discoveries into clinical applications including scientific validation of experimental results), the development and validation of new therapies, strategies for health, promotion and prevention, child health and healthy ageing, diagnostic tools and medical technologies, as well as sustainable and efficient healthcare systems.

Approach

This work programme (referred as work programme 2009) aims to ensure continuity with the previous work programme and to start new activities within the budgetary constraints. The estimated total budget allocation for work programme 2009 is EUR 609 459 130 drawing from the 2009 budget[1]. Chapter II of this work programme describes the topics for which project proposals can be submitted in response to the 3rd call for proposals (July 2008 publication); chapters III and IV describe the modalities for implementation of the call and other actions. The estimated budget breakdown for work programme 2009 is provided in Chapter V.

Chapter I outlines the general approach used for the development of this work programme including: the policy issues concerning SME participation and International Cooperation with particular regard to the Health Theme; the cross-thematic aspects and dissemination actions; and some key elements in relation to the implementation.

In 2009, Theme 1 'Health' will focus on three main strategic axes: structuring and coordinating research in the context of the European Research Area (ERA), emphasising translational research and policy-driven research, in line with the specific programme 'Cooperation'.

Efforts to structure collaborative research will continue, building on the 6th Framework programme and on the first calls of the 7th Framework programme, where large-scale collaboration at the EU level is essential to exploit the full potential of research for applications to human health. Furthermore, an ERA-NET will enable integration of national and regional research programmes in the field of HIV/AIDS and should link with the European and Developing Countries Clinical Trials Partnership (EDCTP).

The focus on translational research is very strong across all activities of the work programme, where the inclusion of clinical research is expected in many topics, both in 'Biotechnology, generic tools and medical technologies for human health' and in 'Translating research for human health', while 'Optimising the delivery of healthcare' supports the translation of clinical results into clinical practice.

[1] Under the condition that the preliminary draft budget for 2009 is adopted without modifications by the budgetary authority.

Policy-driven research constitutes a third axis, underpinning public health and regulation. For instance, the research topic on adapting off-patent medicines for children supports the new EC regulation on medicinal products for paediatric use.

The general approach taken in the Health Theme is to cover the specific programme through two consecutive calls with some areas closed for one call or the other. Thus, the coverage of work programme 2009 shall be complemented by activities in the next work programme (4th call; 2010 budget). In this context, work programme 2009 does not include topics for 'human development and ageing' and 'cancer' which will be addressed in the next work programme as appropriate. Furthermore, under 'emerging epidemics', only one topic is published in work programme 2009 corresponding to an urgent public health need; coverage of 'emerging epidemics' will also be reinforced in the next work programme.

With regard to submission, evaluation and selection procedures for the call, work programme 2009 will be implemented following two distinct approaches: for most areas of the programme, a single-stage submission and evaluation procedure will be used, whereas 'high-throughput research', 'large scale data-gathering' and 'systems biology' will follow a two-stage submission and evaluation procedure.

'Predicting suitability, safety and efficacy of therapies' is currently being addressed through the Innovative Medicines Initiative (IMI)[2,3]. Synergies between the IMI priorities for 2008 and work programme 2009 have been ensured.

Clinical research will continue to be a main focus in work programme 2009. For clinical trials, EC contribution will be limited to phases I and II and only exceptionally to further studies[4]. Projects conducting clinical research must take account (in the research protocols, methodologies and analysis of results) of possible differences between women, men, children and the elderly.

- **SME relevant research**

For all areas of work programme 2009, the involvement of industrial participants, in particular research-intensive small and medium-sized enterprises (SME) continues to be encouraged. SME providing services (e.g. management, intellectual property expertise) are also eligible to participate. It is foreseen that future work programmes will include several SME-specific topics.

- **International Cooperation**

International cooperation is an integral part of the Health Theme. In the work programme 2009, international cooperation will be supported through various mechanisms as follows:

For all areas of the programme, project consortia are encouraged to include also participants from countries that are neither EU Member States (MS), nor countries Associated to FP7 (AC)[5]. Among the participants from non-Associated third countries, organisations established

[2] COUNCIL REGULATION (EC) No 73/2008 of 20 December 2007 setting up the Joint Undertaking for the implementation of the Joint Technology Initiative on Innovative Medicines

[3] http://imi.europa.eu/index_en.html

[4] *E.g.* in the topic HEALTH-2009-4.2-1 "Adapting off-patent medicines to the specific needs of paediatric populations", consideration may be given to studies including up to Phase IV clinical trials.

[5] The list of countries Associated to FP7 (Associated countries) is provided in Annex I of the Cooperation Programme

in international cooperation partner countries (ICPC)[6] are eligible for funding, whereas funding for organisations established in other countries may be provided on a case by case basis if considered essential for carrying out the project, or if a provision is made for this in the work programme. In recognition of the opening of NIH[7] programmes to European researchers, participants established in the United States of America are also eligible to participate and to be funded in the context of the Health Theme calls described in this work programme 2009.

Furthermore, collaborative research for cooperation actions dedicated to ICPC is promoted via a specific scheme, namely Specific International Cooperation Actions (SICA). Proposals responding to a SICA topic must involve at least two participants from different MS or AC plus two from different ICPC[8]. This work programme 2009 includes eight SICA topics which are described under a single section (see 4.3 in chapter II). Six SICA topics are area-specific and focus on 'neglected infectious diseases' and 'international public health and health systems'. The remaining two SICA topics target the participation of researchers established in Russia; the research priorities for these region-specific topics (areas of large-scale data gathering and cardiovascular diseases) have been identified in cooperation with Russia. In addition, several topics have been highlighted as being particularly well suited for international cooperation. For these topics, the active participation of relevant third country partners should add to the scientific and/or technological excellence for the project and/or lead to an increased impact. These aspects will be considered specifically during the evaluation of these topics.

Finally, programme level cooperation, where the EC-funded projects are expected to collaborate with other independent projects from third countries towards a common goal will be used for linking the projects, for example in the case of cancer genomics.

- **Cross-thematic approaches**

In this work programme, complementarity is ensured with other Themes of the Cooperation Programme. In particular, 'Optimising the delivery of healthcare to European citizens' in this work programme is complemented by work in the Themes Information & Communication Technologies and Food, Agriculture and Fisheries, Biotechnology. Also, 'Biotechnology, generic tools and medical technologies for human health' in this work programme complements activities in the Theme Nanosciences, Nanotechnologies, Materials and new Production Technologies.

[6] The list of international cooperation partner countries (ICPC)is provided in Annex I of the Cooperation Programme

[7] National Institute of Health of the US Department of Health and Human Services

[8] With the exception of Brazil, China, India and Russia, for which the required two or more ICPC participants can be located in the same country. However, in this case, at least two different participants must come from two different provinces, oblasts, republics or states within Brazil, China, India or Russia.

- **Dissemination**

The work programme includes 'Coordination and Support Actions across the theme' that will focus on technology transfer, on the dissemination of results and on tackling publication bias. Furthermore, innovation-related aspects need to be clearly addressed in all proposals with well-defined dissemination and exploitation plans. Open access to publications of research results is strongly encouraged.

- **Theme Specific Information**

In the 'Health' theme it is particularly important that applicants address the potential ethical issues of their proposals, both in the proposed methodology and the possible implications of the results. The specific requirements for addressing ethical issues are described in the Guide for Applicants (Annex 4, section 4).

The possibility of gender/sex differences in research (risk factors, biological mechanisms, causes, clinical manifestation, consequences and treatment of disease and disorders) must be considered where appropriate.

Research activities should take into account the Protocol on the Protection and Welfare of Animals and reduce and refine the use of animals in research and testing, with a view ultimately to replacing animal use (Decision 1982/2006/EC). The Three Rs (Replacement, Reduction and Refinement) principle should be applied in all research funded by the European Commission.

Funding schemes

The work programme 2009 is implemented through a range of funding schemes. The forms of the grants to be used for the various funding schemes under this Theme are described in Annex 3. For each funding scheme there are limits on the requested EC contribution (see table for details), with exceptions for some topics (see Section III on Implementation of calls). **It is important to note that the upper and lower funding limits will be applied as eligibility criteria so that proposals that do not respect these limits will be considered ineligible.**

Table: summary of rules for minimum and maximum EC contribution.

Funding scheme	Minimum requested EC contribution	Maximum requested EC contribution
Collaborative Project (Large-scale Integrating Project)	EUR 6 000 000	EUR 12 000 000
Collaborative Project (Small or medium-scale focused research Project)		EUR 3 000 000
Network of Excellence		EUR 12 000 000
Coordination and Support Action (Coordinating Action)		EUR 1 500 000
Coordination and Support Action (Supporting Actions)		EUR 500 000

Number of proposals per topic

For Large-scale Integrating Projects, Networks of Excellence, Coordination and Support Actions, only up to one proposal can be funded per topic, unless otherwise stated in Section III on Implementation of calls.

For small and medium-scale Focused Research Projects, one or more proposals can be funded per topic, unless otherwise stated in Section III.

However, for all funding schemes, there may be topics for which no proposals are of sufficient quality to be selected for funding, as there will be competition within topics and between topics on the basis of the quality of the proposals.

The proposers are requested to strictly follow the page limitation instructions and a minimum font size as set out in the Guide for Applicants. Parts of the proposals extending beyond these limitations will not be considered in the evaluation.

II CONTENT OF CALLS

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

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

1.1. HIGH-THROUGHPUT RESEARCH

The objective is to catalyse progress in developing new research tools for modern biology including fundamental genomics that will enhance significantly data generation and improve data and specimen (biobanks) standardisation, acquisition and analysis. The focus will be on new technologies for: sequencing; gene expression, genotyping and phenotyping; structural and functional genomics; bioinformatics and systems biology; other 'omics'.

Expected impact: The development of groundbreaking technologies will catalyse progress in biomedical research and support the competitiveness of European biotechnology industry (namely SMEs). The development of new computational tools for genome annotation and genotype/phenotype data integration will enable integration of vast amount of functional genomics data to facilitating data mining and catalysing progress in systems biology. The development of high throughput tools and technologies to phenotype large set of human biological samples will accelerate epidemiological studies and biomarker discovery by increasing the molecular analysing capacity. These tools and technologies will deliver high quality and reproducible data set to enable standardised approaches on large-scale biobanks. Proteomics techniques will help overcome bottlenecks in the investigation of protein functions in cells leading to a better understanding of biological processes in health and disease, and fostering European research excellence.

Topics for two-stage submission and evaluation; deadline 1st stage 3 December 2008:

- **HEALTH-2009-1.1-1: Computational tools for genome annotation and genotype/phenotype data integration. FP7-HEALTH-2009-two-stage.** The projects should develop new computational tools and methods for genome/proteome annotation to catalyse the progress of systems biology by describing, for example, molecular interactions, pathways and networks. The projects should enable the integration of the vast amount of data generated on gene function with a human genome browser to facilitate complex data search in systems biology approaches. **Funding scheme:** Collaborative Project (Large scale integrating project). **One or more proposals** are expected to be funded.

- **HEALTH-2009-1.1-2: High throughput tools and technologies to analyse samples in large-scale human biobanks. FP7-HEALTH-2009-two-stage.** The multidisciplinary projects should improve existing and/or develop and test new tools and technologies for phenotypic analysis of large numbers of human biological samples. The projects may also include enhancing and optimisation of the quality of the sample preservation technologies. This integrated set of tools and technologies should be able to deliver high quality and reproducible data for

standardised large-scale data gathering and high throughput functional genomics research in human biobanks. **Funding scheme:** Collaborative Project (Large scale integrating project). **One or more proposals** are expected to be funded.

- **HEALTH-2009-1.1-3: Tools, technologies and resources for the characterisation of protein functions. FP7-HEALTH-2009-two-stage.** The projects should aim at generating a large resource of molecules that bind to proteins in order to characterise the proteome and/or developing innovative tools and technologies that facilitate structure/function characterisation of protein complexes. Open-access to the resources generated within the project should be encouraged. **Funding scheme:** Collaborative Project (Large scale integrating project). **One or more proposals** are expected to be funded.

1.2. DETECTION, DIAGNOSIS AND MONITORING

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

Expected impact: Developments should lead to new technologies, methodologies and approaches for non-invasive prediction, diagnosis, monitoring and/or prognosis of diseases. Projects should also help to evaluate and monitor therapies and plan and guide therapeutic interventions. All applications should be of potential benefit to patients and should, whenever possible and appropriate, involve European industry, in particular SMEs.

Topics for single-stage submission and evaluation; deadline 3 December 2008:

- **HEALTH-2009-1.2-1: Development of tools for sensitive and specific in vitro detection of proteins and their interactions for diagnostic, prognostic and monitoring purposes. FP7-HEALTH-2009-single-stage.** The focus should be to develop tools and reagents for the identification of alterations of protein expression patterns, as well as modifications of and interactions among proteins in disease processes for early specific diagnosis, prognosis or monitoring. Deliverables should be innovative and improved molecular procedures, required to achieve the necessary sensitivity and specificity and to distinguish close variants. The procedures should be able to identify and quantify soluble proteins in body fluids and/or to image their distribution in cells and tissues, preferably for parallel analysis. Active participation of industry, especially SMEs, could lead to an increased impact of the research proposed, and this will be considered in the evaluation of the proposal. **Funding scheme:** Collaborative Project (Small or medium-scale focused research project).

- **HEALTH-2009-1.2-2: Design of methods suited to identify epigenetic factors and their use in the genetic diagnosis of relevant disorders. FP7-HEALTH-2009-single-stage.** The focus should be to develop novel strategies to determine the epigenetic profile of genes known to be subject to specific epigenetic processes (for example: imprinting or effect of microRNAs). Deliverables should be new diagnostic tests for epigenetic modifications in disorders where several genes and environment factors can contribute to causation. **Funding scheme:** Collaborative Project (Small or medium-scale focused research project).

- **HEALTH-2009-1.2-3: Novel MR-compatible PET detectors for simultaneous PET/MRI imaging**. **FP7-HEALTH-2009-single-stage.** The focus should be to develop novel magnetic-field-compatible nuclear detectors for PET imaging, aimed at maximizing the benefits of simultaneous PET/MRI acquisition, which can also be used efficiently and implemented in stand alone PET or SPECT applications. These detectors should operate in high magnetic fields, as used in MRI, without performance degradation, and have high spatial and time resolution. A dedicated integrated readout of high quality should also be developed. The full detector should be compact so as to allow good integration with an MRI system. Globally, it should allow fully exploiting the advantages of both PET and MR technologies in a simultaneous imaging modality and for implementation in both preclinical and clinical/human PET stand-alone systems beyond the state-of-the-art. Active participation of industry, especially SMEs, could lead to an increased impact of the research proposed, and this will be considered in the evaluation of the proposal. **Funding scheme:** Collaborative Project (Large scale integrating project).

- **HEALTH-2009-1.2-4: Novel imaging systems for in vivo monitoring and quality control during tumour ion beam therapy. FP7-HEALTH-2009-single-stage.** The focus should be to develop novel imaging instruments, methods and tools for monitoring, in vivo and preferably in real time, the 3-dimensional distribution of the radiation dose effectively delivered within the patient during ion beam therapy of cancer. The ions should be protons or heavier ions. The system should typically be able to quantify the radiation dose delivered, to determine the agreement between the planned target volume and the actually irradiated volume, and for decreasing localisation uncertainties between planned and effective positions (e.g. of tissues or organs), and between planned and effective dose distribution during irradiation. It should aim at improving quality assurance, increasing target site (tumour) to normal tissue dose ratio and better sparing normal tissue. **Funding scheme:** Collaborative Project (Small or medium-scale focused research project).

- **HEALTH-2009-1.2-5: Activatable or smart in vivo imaging agents reporting on physico-chemical or molecular changes relevant to the diagnosis and/or monitoring of diseases (in coordination with NMP theme)**. **FP7-HEALTH-2009-single-stage.** The focus should be to develop imaging agent(s) for the detection and/or monitoring of disease processes, that can be externally activated in vivo or react to disease-associated variations in the body. The variations can be endogenous disease-associated conditions such as special enzymes, pH or pO_2 changes, or other. In the case of external activation, it could be realised by applying radiofrequency, ultrasound, heat, light or magnetic fields. The proposed concept should be pre-clinically tested and potentially suited for later clinical

application. Active participation of industry, especially SMEs, could lead to an increased impact of the research proposed, and this will be considered in the evaluation of the proposal. **Funding scheme:** Collaborative Project (Small or medium-scale focused research project).

- **HEALTH-2009-1.2-6: Evaluation of the potential health impact of diagnostic imaging agents doses. FP7-HEALTH-2009-single-stage.** The focus should be to summarise and evaluate current knowledge on the impact on patients' health of small and non- or little-repetitive doses (amounts) of radioactive, biological and/or chemical substances, as currently used in diagnostic imaging procedures. Results should be reported and enable the development of recommendations and guidelines to drive scientific and technologic innovation to improve patient healthcare in medical imaging. If the study concludes that a clinical study is needed, it should detail it. People involved in legislative approval of these agents for human use should at least be consulted and, if possible, involved. A given proposal should focus on either radioactive or non-radioactive imaging agents. Projects should not exceed 18 months. A maximum of one project will be supported for each of these 2 areas. **Funding scheme:** Coordination and Support Action (Supporting Action).

1.3 Suitability, safety, efficacy of therapies

Alternative testing strategies

The objective is to develop and implement a co-ordinated approach towards the faster application of existing research results for safety testing in industry and for regulatory purposes, fully respecting existing legislation on animal protection. The pharmaceutical industry and several other industrial sectors largely depend upon animal studies for predicting human toxicity and efficacy of their products. In addition, several industrial sectors are already obliged to apply available methods to replace, reduce and refine animal use (3Rs) in safety evaluations. Therefore, faster progress in academic research needs to be matched with the faster uptake of alternative approaches in industry and regulation in order to significantly reduce the use of animal tests.

Expected impact: Bringing the specific know-how, valuable technologies, ideas and expertise developed by academic research in this field to the outside world will result in an optimised use of knowledge and know how and will significantly help to implement the Replace, Reduce and Refine strategy (3Rs). In this way all promising new technologies will be taken into consideration. The gap between university research and industrial demand will be closed and new synergies and interaction formats between industry and academia will be created in the field of the 3Rs.

Topic for 3rd call, single-stage submission and evaluation; deadline 3 December 2008:

- **HEALTH-2009-1.3-1: New initiatives towards the implementation of the Replace, Reduce and Refine strategy. FP7-HEALTH-2009-single-stage.** The development of new '3R'-methods as modern alternative approaches to safety testing requires a better co-ordination of the various activities involved. This

should start with the mapping of existing research results, followed by the development of new ideas for alternative approaches and strategies, and promotion of communication, education, validation and acceptance of alternative approaches. The funding scheme would be a support and co-ordination action aimed at bringing academic research in a pro-active way closer to the industrial landscape in order to effectively develop concrete collaboration projects with industrial partners. This coordination action should build particularly on the success of activities carried out in the EU RTD Framework Programmes and in national activities. **Funding scheme:** Coordination and Support Action (Coordinating Action).

1.4 INNOVATIVE THERAPEUTIC APPROACHES AND INTERVENTIONS

The focus is on regenerative medicine. Regenerative medicine offers hope for sufferers of diseases which are currently untreatable, where life is at stake and for regenerating diseased, damaged or defective tissues and organs. It also offers possibilities for addressing problems of an ageing population and has potential for combating rising healthcare costs. It is a high-value new technology offering Europe competitiveness and this opportunity is enhanced by the recent adoption of a European Regulation on advanced therapy medicinal products[9].

To meet the challenges and promise of regenerative medicine, three large Collaborative Project topics on related technological approaches are described below. Their common theme is the translation of promising therapeutic approaches from the pre-clinical to the clinical stage coupled with supporting research on refinements to the system and improving understanding of mechanisms. The essential feature of each project will thus be the identification of a potential therapy to move into the clinic and surrounding this with necessary ancillary research. Taken together the projects will form a collective series of regenerative medicine research activities covering different areas and offering real possibilities of application. Topic HEALTH-2009-1.4-2 would enable clinical studies to be made on materials developed in earlier EU research programmes on new materials.

Expected impact: The main impact of this work will be developing European capability in regenerative medicine. Projects are expected to carry out translational research and to include in-patient trials at some stage of their duration, paving the way towards therapeutic products. Proposals containing appropriate preliminary data will be able to proceed to in-patient trials earlier in the project. Projects are also expected to expand knowledge of mechanisms of the new therapies. Research projects should aim to develop technology with wide potential applications; however, research may also target particular therapeutic solutions, such as the treatment of a specific disease or condition. Research will be multidisciplinary and will boost the European biotechnology industry, especially the SME sector. It should also address societal and ethical issues as appropriate.

[9] Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007

Topics for single-stage submission and evaluation; deadline 3 December 2008:

Regenerative medicine

- **HEALTH-2009-1.4-1: Cell therapy for tissue and organs. FP7-HEALTH-2009-single-stage.** Proposals should focus on transplantation of cells for reconstruction and/or regeneration of diseased or injured tissue in systems which have potential for appropriate in-patient trials during the course of the project. Proposals with sufficient preliminary data to proceed to in-patient trials at an early stage of the project are preferred. Proposals involving in-patient trials at a later stage of the project will also be considered provided they include a road map to the clinic containing pre-determined milestones. Systems may be autologous or allogeneic and may include the use of modified cells; haematopoietic and immune reconstitution is excluded[10]. Projects should take a translational approach and remove bottlenecks/limitations identified through the clinical work. To complement in-patient trials, supporting research, such as improving understanding of mechanisms, immunogenicity, methodology to demonstrate whether the treatments are having a direct effect, or testing refinements to the system, should be carried out. Any justified disease or condition may be addressed. Proposals developing technology that will aid the establishment of regenerative medicine in a general way are encouraged. In addition to academic researchers, clinicians should be involved and relevant social, ethical and regulatory affairs should be addressed. Active participation of industry, especially SMEs, could lead to an increased impact of the research proposed, and this will be considered in the evaluation of the proposal. **Funding scheme:** Collaborative Project (Large scale integrating project). **One or more proposals** are expected to be funded.

- **HEALTH-2009-1.4-2: Regeneration of tissue using bio-compatible materials and cells. FP7-HEALTH-2009-single-stage.** Proposals should focus on the use of implantable bio-compatible materials as part of a regenerative medicine approach. The implant may be seeded with cells or, if not, should stimulate cell activity or tissue formation in the host organ. Projects should target systems which have potential for appropriate in-patient trials during the course of the project. Proposals with sufficient preliminary data to proceed to in-patient trials at an early stage of the project are preferred. Proposals involving in-patient trials at a later stage of the project will also be considered provided they include a road map to the clinic containing pre-determined milestones. Projects should take a translational approach and remove bottlenecks/limitations identified through the clinical work. To complement in-patient trials, supporting research, such as improving understanding of mechanisms, immunogenicity, methodology to demonstrate whether the treatments are having a direct effect, or testing refinements to the system, should be carried out. Any justified disease or condition may be addressed. Proposals developing technology that will aid the establishment of regenerative medicine in a general way are encouraged. In addition to academic researchers, clinicians should be involved and relevant social, ethical and regulatory affairs should be addressed. Active participation of industry, especially SMEs, could lead to an increased impact of the research proposed, and this will be

[10] Cell-based immunotherapy is expected to be included in a future work programme

considered in the evaluation of the proposal. **Funding scheme:** Collaborative Project (Large scale integrating project). **One or more proposals** are expected to be funded.

- **HEALTH-2009-1.4-3: Activation of endogenous cells as an approach to regenerative medicine. FP7-HEALTH-2009-single-stage.** Proposals should focus on regenerative medicine approaches involving the activation of endogenous cells (e.g. by growth/trophic factors, cell signalling molecules) for the structural and functional repair of diseased or injured tissue. Proposals should target systems which have potential for appropriate in-patient trials during the course of the project. Proposals with sufficient preliminary data to proceed rapidly to in-patient trials are preferred. Projects should take a translational approach and remove bottlenecks/limitations identified through the clinical work. To complement in-patient trials, supporting research, such as improving understanding of mechanisms, methodology to demonstrate whether the treatments are having a direct effect, or testing refinements to the system, should be carried out. Any justified disease or condition may be addressed. Proposals developing technology that will aid the establishment of regenerative medicine in a general way are encouraged. In addition to academic researchers, clinicians should be involved and relevant social, ethical and regulatory affairs should be addressed. Active participation of industry, especially SMEs, could lead to an increased impact of the research proposed, and this will be considered in the evaluation of the proposal. **Funding scheme:** Collaborative Project (Large scale integrating project). **One or more proposals** are expected to be funded.

2. TRANSLATING RESEARCH FOR HUMAN HEALTH

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

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

2.1.1. Large-Scale Data Gathering

The objective is to use high-throughput technologies to generate data for elucidating the function of genes and gene products and their interactions in complex networks in important biological processes. The focus will be on: genomics; proteomics; 'RNomics'; population genetics; comparative, structural and functional genomics.

Expected impact: The data generated by genomics and proteomics projects will continue to support the European research excellence in related fields by increasing our understanding of key biological processes and provide the foundation for more extensive functional studies concerning genetic variation, the way that genes interact with each other in health and disease, and to speed the search of genes that may underlie diseases in human. This in turn would aid the design of drugs and treatments, including

individualised treatments. For example, large-scale functional genomics studies in multi-cellular model organisms will generate new knowledge on human gene function in health and diseases and potential model systems for drug screening. The detailed functional genomics characterisation of a large number of cancer tumours will certainly advance our knowledge on the molecular origin of cancer and thereby opening new avenues for developing new therapies. A large-scale comparative study of genetic variation in human population in Europe will greatly facilitate ongoing and new epidemiological studies and fill in the information gaps on genetic variability (including structural variation) in healthy and/or disease phenotypes.

Topics for two-stage submission and evaluation; deadline 1st stage: 3 December 2008

- **HEALTH-2009-2.1.1-1: Large-scale functional genomics effort in multi-cellular organisms to elucidate the function of human genes products. FP7-HEALTH-2009-two-stage.** The projects should aim at understanding the functions of human gene products through systematic and multidisciplinary large-scale functional genomics in multi-cellular organisms relevant for human health and disease. The projects should where possible integrate with international efforts in this area. **Funding scheme:** Collaborative Project (Large scale integrating project). **One or more proposals** are expected to be funded.

- **HEALTH-2009-2.1.1-2: Large-scale functional genomics efforts to identify molecular determinants of cancer. FP7-HEALTH-2009-two-stage.** The projects should implement multidisciplinary functional genomics approaches (e.g. sequencing, transcriptomics and/or epigenetics) to characterise in detail a large number of human cancer tumour samples to identify molecular determinants that contribute to human oncogenesis, cancer progression and metastasis. The projects should structure European participation in the large international effort in this field (International Cancer Genomics Consortium). They should establish the standards and norms on the manipulation and storage of tumours samples thereby facilitating the comparison between different data sets. Primary data should be made available for the scientific community. **Funding scheme:** Collaborative Project (Large scale integrating project). **One or more proposals** are expected to be funded.

- **HEALTH-2009-2.1.1-3: Characterisation of human genetic variation in Europe. FP7-HEALTH-2009-two-stage.** The projects should aim at characterising genetic variation (nucleotide and structural) in populations from different regions and ethnic minorities in Europe involving normal and/or disease phenotypes. This genetic variation dataset should generate a powerful tool to improve precision and accuracy of genome scale association studies in Europe and/or establish the relationship between genetic variation and common human disorders and traits. Data should be made available for the scientific community. The projects should, where appropriate, build links to international efforts and existing cohorts. **Funding scheme:** Collaborative Project (Large scale integrating project). **One or more proposals** are expected to be funded.

See also topic HEALTH-2009-4.3.3-1: Comparative population genetic studies on multifactorial diseases. FP7-HEALTH-2009-single-stage.

2.1.2. Systems Biology

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

Expected impact: The large-scale Collaborative Projects will create the critical mass of multidisciplinary expertise that is necessary for enabling complex systems approaches. These projects should increase European competitiveness and explore new directions for the field. They should deliver new knowledge on basic biological processes relevant to health and diseases. The quantitative data delivered should serve as the basis to design robust models using computational biology and systems approaches. From biological pathways in unicellular eukaryotic organisms to human cells and organs, there is a need to combine and integrate and extend existing data sources and screen the different heterogeneous data resources. These studies should increase our knowledge on the gene regulatory networks controlling important biological processes in health and disease.

Topic for two-stage submission and evaluation; deadline 1st stage: 3 December 2008

- **HEALTH-2009-2.1.2-1: Systems biology approaches for basic biological processes relevant to health and disease. FP7-HEALTH-2009-two-stage.** The projects should focus on modelling important biological processes at any appropriate levels of system complexity by generating and integrating quantitative data sets (e.g. transcriptomics, proteomics, metabolomics, structural biology, RNAi screening, physiology and/or patho-physiology). These large multidisciplinary efforts should integrate the critical mass of excellence in Europe that is necessary for generating and validating the models using systems biology approaches. **Funding scheme**: Collaborative Project (Large-scale integrating project). **One or more proposals** are expected to be funded.

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

2.2.1. Brain and brain-related diseases

The objectives are to better understand the integrated structure and dynamics of the brain, and to study brain diseases including relevant age related illness (e.g. dementia, Parkinson's disease) and search for new therapies. The focus will be to gain a global understanding of the brain by exploring brain functions, from molecules to cognition including neuroinformatics, and brain dysfunction, from synaptic impairment to neurodegeneration. Research will address neurological and psychiatric diseases and disorders, including regenerative and restorative therapeutic approaches.

Expected impact: Projects funded under this area will contribute to a better understanding of brain function and of dysfunction in disease. This knowledge will feed into translational clinical and industrial development leading to better diagnosis of brain diseases, new therapies or innovative brain-machine interfaces. Translational brain research will be a core element of each topic and may contribute to an improved management of brain diseases with the potential to reduce the high healthcare costs related to the treatment and care of patients. Potential user sector(s) can be biomedical/pharmaceutical, software or robotics industry. Expected mechanisms for disseminating and promoting uptake of the research will be via publications in high impact journals and international high level conferences, and/or via patents.

Topics for single-stage submission and evaluation; deadline 3 December 2008:

- **HEALTH-2009-2.2.1-1: Synaptopathies: genesis, mechanisms and therapy. FP7-HEALTH-2009-single-stage.** An increasing list of neurological and psychiatric disorders is caused by altered synaptic functioning linked to mutations or dysfunctions in synaptic proteins in the central nervous system. Research should aim at understanding the basis of aberrant synaptic transmission at the genetic, molecular and cellular level with a view to restoring normal synaptic function. Particular attention should be paid to the malfunctioning of pre- and post-synaptic ion channels and receptors during abnormal synaptic activity. The consortium should use biochemical, molecular, electrophysiological, imaging and neuroinformatics tools to study synaptic proteins and their role in human diseases. A translational component leading to the identification and validation of drug targets for therapeutic intervention in synaptopathies is an asset. Projects on the neuromuscular junction are excluded. **Funding scheme:** Collaborative Project (Large scale integrating project).

- **HEALTH-2009-2.2.1-2: Identifying genetic and environmental interactions in schizophrenia. FP7-HEALTH-2009-single-stage.** The project should aim at identifying genetic, clinical and environmental determinants playing a role in the development, severity and outcome of the disease in humans. Studies on schizophrenic patients and their families should be at the core of the project. The project has also to include a translational component leading to the development of tools for early prediction, diagnosis, and monitoring of the disease. **Funding scheme:** Collaborative Project (Large scale integrating project).

- **HEALTH-2009-2.2.1-3: Optimising current therapeutic approaches to schizophrenia. FP7-HEALTH-2009-single-stage.** The project should focus on the pathophysiology and treatment of schizophrenia, and has to include a preclinical (e.g.: neurophysiology, pharmacology, functional imaging) and clinical component (clinical trials). A strong translational approach with a view of developing new or optimising existing therapeutic tools is essential. **Funding scheme:** Collaborative Project (Large scale integrating project).

- **HEALTH-2009-2.2.1-4: Understanding the blood brain barrier (BBB) to improve drug delivery to the brain. FP7-HEALTH-2009-single-stage.** Understanding permeability across the BBB is fundamental to optimise delivery of drugs to the brain. To date, the BBB still represents an obstacle for penetration of large molecules (peptides, antibodies, enzymes) into the brain. This project should

increase our understanding of the molecular basis and functioning of the BBB in health and disease. In particular the transport mechanisms across the BBB, and how the integrity of BBB is altered in different diseases should be investigated. A translational component leading to the identification of methods/tools to bypass the BBB and improve delivery of large molecules to the brain should also be included. The participation of SME is encouraged. **Funding scheme:** Collaborative Project (small or medium scale focused project).

- **HEALTH-2009-2.2.1-5: Psycho-social factors of brain disorders. FP7-HEALTH-2009-single-stage.** Coordination of European research is needed to evaluate the psycho-social problems of people living with brain disorders. The initiative should compare and harmonise studies assessing the incidence of several specific disabling symptoms (e.g.: incontinence, sexual dysfunctions, sleep disturbances, depression/anxiety linked to living with the disease, psychotic and cognitive problems, reduced living skills, stigma, etc.) across brain disorders. The consortium should take a horizontal approach and evaluate the incidence of specific disabling symptoms across several brain diseases rather than a vertical approach focussing on the epidemiology of a specific brain disorder. **Funding scheme:** Coordination and Support Action (Coordinating Action).

2.2.2. Human development and ageing

No topics in this call.

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

2.3.1. Anti-microbial drug resistance including fungal pathogens

The strategic objective of this area is to confront the increasing emergence and spread of antimicrobial drug resistant pathogens in Europe and the rest of the world at broad fronts and in a multi-disciplinary approach through the development of effective infection prevention and control strategies. Focus will be on combining basic research on molecular mechanisms of resistance, microbial ecology and host-pathogen interactions with clinical research towards new interventions.

Expected impact: Reinforced research integration of European excellence in the field of antimicrobial drug resistance will be targeted towards a set of clearly defined objectives with the following expected impact: in a first attempt to address the fundamental questions of antimicrobial resistance at the global scale, an appreciation of the scale, nature and variability of the problem will be made possible and new strategies for controlling resistance in different parts of the world proposed. By studying the long-term impact of different antibiotics on the human host, it will, for the first time, be possible to weigh the clinical benefits of various antibiotic therapeutic interventions against their possible side-effects at the level of the individual patient. A feed-back system for clinical evaluation of new point-of-care diagnostic and susceptibility tests will accelerate and economise the implementation of diagnostic tests in the clinical setting, necessary to support for optimised prescription of anti-infective drugs.

Topics for single-stage submission and evaluation; deadline 3 December 2008:

- **HEALTH-2009-2.3.1-1: Global collaborative research on the prevention of antibiotic resistance. FP7-HEALTH-2009-single-stage.** The aim is to establish global collaboration of research and training in order to develop regionally adapted and cost-effective measures to prevent the emergence and spread of antibiotic resistance. Research objectives should include, but are not limited to, the development of a global map of bacterial clonality, resistance phenotypes, resistance genes and their mobile genetic elements, the correlation of antibiotic resistance with antibiotic consumption in various geographical regions, the association of risk factors for the spread of antibiotic resistance and the establishment of mathematical models for prediction of future resistance trends in different parts of the world. The active participation of partners from ICPC countries could add to the scientific and/or technological excellence of the project and/or lead to an increased impact of the research to be undertaken. **Funding scheme:** Collaborative Project (Large scale integrating project).

- **HEALTH-2009-2.3.1-2: Impact of specific antibiotic therapies on the prevalence of resistant bacteria in the human host. FP7-HEALTH-2009-single-stage.** The objective is to develop a multidisciplinary approach bridging bacterial genetics, clinical, and pharmacological research in order to study the impact of different existing antibiotics in selecting resistance. Research should envisage intervention studies, including randomised controlled trials, studies on the dynamics, transmission, and the biological cost of antibiotic resistance as well as an in-depth analysis of resistance mechanisms and their dissemination utilising state-of-the-art molecular techniques. **Funding scheme:** Collaborative Project (Small or medium-scale focused research project).

- **HEALTH-2009-2.3.1-3: Clinical evaluation of point-of-care diagnostic tests for microbial detection and identification, antibiotic susceptibility determination and biomarkers. FP7-HEALTH-2009-single-stage.** The objective is to address the current gap between technological advances and the actual clinical needs for optimised prescription of antibiotics by setting up an integrated tool for evaluation of new point-of-care diagnostic tests in the nosocomial and/or primary care setting. Evaluation criteria should include simplicity, sensitivity, specificity, reliability, speed, robustness, user-friendliness and cost-effectiveness. Projects should ensure that results of the clinical evaluation are fed back to the biotechnology sector and manufacturers of diagnostic tests. Social, ethical, environmental and economic (including cost/benefit) hurdles to the implementation of novel diagnostic tests into healthcare programmes should also be identified and a map-gap analysis of priority diseases for which current diagnostic options are particularly poor should be performed. The end-result should be a roadmap for research, development and efficient uptake of rapid diagnostics for patient benefit in Europe. **Funding scheme:** Collaborative Project (Small or medium-scale focused research project).

2.3.2. HIV/AIDS, malaria and tuberculosis

The focus will be on developing new therapies, diagnostic tools, and preventive tools such as vaccines and chemical transmission barriers such as HIV microbicides. Research efforts will confront the three diseases at global level, but will also address specific European aspects of the three diseases as well as Hepatitis. Preclinical and early clinical research activities will be emphasised, and where relevant (e.g. for HIV/AIDS vaccines) collaboration with European and global initiatives is foreseen.

Expected impact: The expected impact is enhanced output of research results essential for the development of new interventions to confront HIV/AIDS, malaria and tuberculosis. Europe shall thus be enabled to shoulder its due share of the global fight against the three major killer diseases. The large-scale integrating projects will increase our knowledge on the basic biological processes of the diseases and facilitate integration of European research in the area. The topics emphasising translational research will support discovery and development of more efficient microbicides against HIV/AIDS and vaccines against tuberculosis. This also provides a possibility to strengthen the European competitiveness in this area and to help to maintain the strong research momentum which has delivered promising results in FP6. The integration of expertise from different disciplines will be an extra asset in this area, and the formation of partnerships between public and private institutions, as well as the involvement of research groups from developing countries will strengthen the impact.

Topics for single-stage submission and evaluation; deadline 3 December 2008:

- **HEALTH-2009-2.3.2-1: Integration of European efforts in research on malaria. FP7-HEALTH-2009-single-stage.** Substantial support shall be given to solid and inclusive research networks active in the area of research on malaria. Joint research programmes will cover all thematic aspects stretching from basic research on the causative pathogen and its modes of transmission, to clinical investigation of pathogenesis. Successful proposals must show a sustainable concept and a demonstrated commitment to advance institutional integration towards forming a virtual European malaria research institute. Complementary and synergistic institutional research programmes, joint training schemes, shared technology platforms and common institutional approaches towards exploitation of relevant research results are indicative for a maturity of cooperation which allows for long-term institutional integration. Sustainable networking with research partners in disease-endemic countries is essential. **Funding scheme:** Network of Excellence.

- **HEALTH-2009-2.3.2-2: Identification and pre-clinical testing of new vaccine candidates for tuberculosis. FP7-HEALTH-2009-single-stage.** First generation of new TB vaccines are already in phase I clinical trials. However, innovative approaches are needed to develop second generation of TB vaccine candidates with emphasis on new antigens or new delivery systems. Projects could aim at developing new live vaccine candidates and/or could focus on rational selection and comparative evaluation of candidate antigens. Ideally, new vaccine candidates would contribute to prime-boost strategy and increase efficacy of other vaccines. Essential pre-clinical testing should be a part of the project. Active participation of industry, especially SMEs, could lead to an increased impact of the research

proposed, and this will be considered in the evaluation of the proposal. **Funding scheme:** Collaborative Project (Large scale integrating project).

- **HEALTH-2009-2.3.2-3: Discovery and/or development of new and promising anti-HIV microbicides. FP7-HEALTH-2009-single-stage.** Proposals should focus 1) on the discovery of new microbicide molecules and targets useful for the specific inhibition of HIV entry and/or replication at the vaginal and rectal mucosae, and/or 2) on the clinical development of promising anti-HIV microbicides; 3) the successful projects should also include studies on new and improved tools for in vitro research and for testing toxicity and efficacy in preclinical as well as in human studies. **Funding scheme:** Collaborative Project (Large scale integrating project)

- **HEALTH-2009-2.3.2-4: Mucosal and topical vaccines for poverty-related diseases (HIV/AIDS, malaria and/or TB). FP7-HEALTH-2009-single-stage.** Projects should take advantage of the newest available genetic and immunological information to design and develop vaccine candidates against HIV, malaria and/or TB for local application, such as mucosal and/or transcutaneous. Projects should include elements to identify new immunogens and adjuvants with a potential to elicit a prophylactic or therapeutic immune response. Active participation of industry, especially SMEs, and of partners from disease endemic areas could lead to an increased impact of the research proposed, and this will be considered in the evaluation of the proposal. **Funding scheme:** Collaborative Project (Large-scale integrated research project)).

- **HEALTH-2009-2.3.2-5: Translational vaccine research for poverty-related diseases (HIV/AIDS, malaria and/or TB). FP7-HEALTH-2009-single-stage.** Support will given to early human testing of promising vaccine candidates. The vaccine candidates must already have been selected through vigorous pre-clinical testing and must have demonstrated efficacy in recognised animal models. Projects will support phase I and IIa clinical trials activities with a view of preparing the most successful candidates for later development, e.g. through the EDCTP. Activities related to the preparation of human clinical trials, including GMP production, formal pre-clinical toxicology, and protocol writing may be included in the projects. Active participation of industry, especially SMEs and/or Product Development Public-Private Partnerships organisations, could lead to an increased impact of the research proposed, and this will be considered in the evaluation of the proposal. **Funding scheme:** Collaborative Project (Small or medium-scale focused research project).

- **HEALTH-2009-2.3.2-6: ERA-NET for stepping up European co-operation in HIV/AIDS research[11]. Not FP7-HEALTH-2009-single-stage (see footnote 11).** The project should aim at improving linking and integration of national and/or regional research programmes in the field of HIV/AIDS. Participation of new Member States is particularly encouraged. **Funding scheme:** Coordination and Support Action (Coordinating Action).

[11] This topic will be subject of a joint call for ERA-NETs across the Themes FP7-ERANET-2008-RTD co-ordinated call – See Annex 4 of the Cooperation work programme. Indicative maximum requested EC contribution for this ERA-NET is € 2 M.

2.3.3. Potentially new and re-emerging epidemics

The focus will be on confronting emerging pathogens with pandemic potential including zoonoses (e.g. SARS and highly pathogenic influenza). Call topics aim to cover the full 'value chain of health research: from innovative basic research to early stage clinical trials of new prevention, diagnostic and therapeutic measures all the way to implementation research supporting effective public health responses. This includes the vital need for new rapid and reliable diagnostic tools, the search for more efficient and broadly protecting vaccines, and the study of alternative treatment strategies and non-pharmaceutical approaches in patient management.

Expected impact: The results of research in this area will integrate European scientific excellence and make Europe better prepared for emerging epidemics: Influenza containment and mitigation strategies are a vital tool to limit spread of the disease, and recommendations regarding the use (and possible stockpiling) of personal protection equipment, especially in the case of a pandemic are a major challenge to national public health authorities, since the evidence base in this case is insufficient.

Topics for single-stage submission and evaluation; deadline 3 December 2008:

- **HEALTH-2009-2.3.3-1: Efficacy and effectiveness of personal protection equipment and other measures against influenza transmission. FP7-HEALTH-2009-single-stage.** The project should determine the efficacy and effectiveness of contact, droplet, and airborne precautions in reducing the risk for influenza infection with particular regard to the role of surgical- and respirator-type masks. The objective is to demonstrate through appropriately designed experimental human and/or animal studies the relative contribution of different modes of influenza transmission (such as large droplets and droplet nuclei) as well as through a controlled human in vivo study the protection afforded by the use of surgical- vs. respirator-type masks (prevention of influenza in the individual wearing the mask) as well as other measures (e.g. isolation, distancing, hygiene, air sterilisation). The study questions should be formulated such that results will directly inform recommendations for use of particular mask types in specified settings for the prevention of seasonal and pandemic influenza transmission. The study setting for the in vivo study will necessarily be during the season during which influenza and other respiratory diseases are most prevalent, in healthcare or other sites where there is greatest risk for transmission (and therefore the best place to detect differences in effectiveness and efficacy), in multiple sites and over multiple influenza seasons. The study may also consider potential barriers to use of masks and other measures, such as user acceptability. **Funding scheme:** Collaborative Project (Small or medium-scale focused research project).

2.3.4. Neglected infectious diseases

All topics in this area are labelled SICA. See Section 4.3.1

2.4. TRANSLATIONAL RESEARCH IN OTHER MAJOR DISEASES

2.4.1. Cancer

No topics in this call.

2.4.2. Cardiovascular diseases

The focus will be on diagnosis, prevention, treatment and monitoring of heart and blood vessel diseases (including vascular aspects of stroke) using broad multidisciplinary approaches. Hypothesis driven research projects with preliminary data available will be supported.

Expected impact: The knowledge gained from research performed in this area will lead to an improvement in the prevention and treatment of cardiovascular diseases, which are a major cause of ill health and death in Europe and world wide. This can for example be through the identification and validation of novel drug targets, devising and validating diagnostic tests or imaging approaches, or the development and validation of strategies for prevention and clinical management of the diseases, as appropriate.

Topics for single-stage submission and evaluation; deadline 3 December 2008:

- **HEALTH-2009-2.4.2-1: Improved or new therapeutic approaches for the treatment of heart failure. FP7-HEALTH-2009-single-stage.** Academic, investigator-driven multicentre phase III clinical study to provide new evidence – not yet addressed by ongoing / previous trials - for new strategic decisions in the management of heart failure. The project can address validation of new therapies or strategies, or identification of the most effective ones among those already available, but not well exploited. The study population should well address gender balance and may include patients with different degree of functional impairment (as in the NYHA functional classification). **Funding scheme:** Collaborative Project (Large scale integrating project).

- **HEALTH-2009-2.4.2-2: Cardiac arrhythmias: from genes to improved management of patients. FP7-HEALTH-2009-single-stage.** The project is expected to elucidate the genetic and environmental components that contribute to cardiac arrhythmias, the relative importance of each of these factors and interactions between them. Achieving this aim should be ensured by a multidisciplinary approach bringing together basic research studies with clinical investigation, and the involvement of industry and especially SMEs in the consortium. Active participation of industry, especially SMEs, could lead to an increased impact of the research proposed, and this will be considered in the evaluation of the proposal. **Funding scheme:** Collaborative Project (Large scale integrating project).

- **HEALTH-2009-2.4.2-3: Translation of basic knowledge on inherited cardiomyopathies into clinical practice. FP7-HEALTH-2009-single-stage.** A multidisciplinary approach bringing together genomics, proteomics, structural and functional studies with clinical investigation should lead to the development of new treatments. **Funding scheme:** Collaborative Project (Small or medium-scale focused research project).

See also topic HEALTH-2009-4.3.3-2: Mechanisms of diabetic and weight-related co-morbidity in heart failure. FP7-HEALTH-2009-single-stage.

2.4.3. Diabetes and obesity

For the former, the focus will be on aetiologies of the different types of diabetes, and their related prevention and treatment. For the latter, the focus will be on multidisciplinary approaches including genetics, life style and epidemiology. For both diabetes and obesity, special attention will be given to juvenile diseases and factors operating in childhood.

Expected impact: It is expected that the following topics will contribute not only to research breakthroughs in the diabetes/obesity treatments but also in prevention and treatment of complications. Considering the heavy toll taken on life expectancy by these diseases, particular attention should be given to paediatric aspects, whenever possible. Healthy life styles being a pre-requisite to any stabilisation of escalating costs of diabetes/obesity, projects should also examine how their results will contribute to the societal issues linked to the diseases.

Topics for single-stage submission and evaluation; deadline 3 December 2008:

- **HEALTH-2009-2.4.3-1: Novel therapeutical approach to pregnancy-induced diabetes. FP7-HEALTH-2009-single-stage.** Research should aim at developing life-style interventions and new treatments in order to prevent gestational diabetes which is endangering the health of the pregnant mother and of her offspring. The identification of the best available prevention measures would be an asset, as well as collection-analysis of epidemiological data. **Funding scheme:** Collaborative Project (Small or medium-scale focused research project.

- **HEALTH-2009-2.4.3-2: Novel immunotherapies for type 1 diabetes. FP7-HEALTH-2009-single-stage.** The project should focus on reversing autoimmunity in type 1 diabetic patients by modulating the immune system to a minimal degree and providing interventions for beta-cell protection and restoration. Transfer of experimental findings into clinical application should be considered. Interaction with ongoing projects in type 1 diabetes could be an asset to allow synergies. **Funding scheme:** Collaborative Project (Large scale integrating project).

- **HEALTH-2009-2.4.3-3: Molecular pathways in food intake at CNS-liver-gut regulation level. FP7-HEALTH-2009-single-stage.** Research should aim at better understanding the function of the brain in the initiation of obesity and as a

target organ of peripheral feedback signals that regulate food or beverages. A clinical / therapeutic perspective must be included. **Funding scheme:** Collaborative Project (Small or medium-scale focused research project).

2.4.4. Rare diseases

The focus will be on Europe-wide studies of natural history, pathophysiology and on development of preventive, diagnostic and therapeutic interventions. This sector will include rare Mendelian phenotypes of common diseases.

Expected impact: This area should help identifying and mobilising the critical mass of expertise in order (i) to shed light on the course and/or mechanisms of rare diseases, or (ii) to test diagnostic, preventive and/or therapeutic approaches, to alleviate the negative impact of the disease on the quality of life of the patients and their families, as appropriate depending on the level of knowledge concerning the specific (group of) disease(s) under study.

Topics for single-stage submission and evaluation; deadline 3 December 2008:

- **HEALTH-2009-2.4.4-1: Rare neurological diseases. FP7-HEALTH-2009-single-stage.** Support will be given to an innovative, multidisciplinary project investigating (on a Europe-wide scale) the natural course, pathophysiology (including when relevant the analysis of genetic risk factors), and diagnostic and therapeutic approaches of (a) non-infectious, non-malignant rare disease(s) affecting primarily the nervous system. Attention should be given to the development / use of adequate models (in vitro and animal models) in identifying / testing new targets for diagnostic, therapeutic and potentially preventive approaches. A translational approach linking basic and clinical research and aiming at the development of new or more effective diagnostics and therapies is mandatory. Child health and ageing aspects should be taken into consideration whenever appropriate. **Funding scheme:** Collaborative Project (Small or medium scale focused project).

- **HEALTH-2009-2.4.4-2: Preclinical development of substances with a clear potential as orphan drugs. FP7-HEALTH-2009-single-stage.** Support will be provided to preclinical studies (pharmacological, pharmacokinetics and toxicological) of EU designated orphan medicinal products[12]. Involvement of industry is strongly recommended. Cancer therapies will not be considered. The orphan medicinal product will need to be granted the EU orphan designation at the latest on the date of the call closure. **Funding scheme:** Collaborative Project (Small or medium-scale focused research project).

2.4.5. Other chronic diseases

The focus will be on non-lethal diseases with a high impact on the quality of life at old age such as functional and sensory impairment and other chronic diseases (e.g. arthritis,

[12] The European register of designated Orphan Medicinal Products is available from http://ec.europa.eu/enterprise/pharmaceuticals/register/orphreg.htm

rheumatic and musculo-skeletal diseases and respiratory diseases including those induced by allergies).

Expected impact: Collaborative research in this area will develop improved diagnostics and/or intervention strategies with the expected impact of delaying the onset of chronic diseases and improving quality of life.

Topics for single-stage submission and evaluation; deadline 3 December 2008:

- **HEALTH-2009-2.4.5-1: Prevention and treatment of non-alcoholic fatty liver disease (NAFLD). FP7-HEALTH-2009-single-stage.** The project should increase our understanding of the initiating mechanisms and risk factors for the development of non-alcoholic chronic liver disease, as well as to identify means of its prevention, diagnosis and treatment. Clinical and epidemiological data should be used to identify the groups at risk and to suggest preventive and therapeutic strategies. **Funding scheme:** Collaborative Project (Small or medium-scale focused research project).

- **HEALTH-2009-2.4.5-2: Cellular and molecular mechanisms of the development of chronic kidney disease (CKD). FP7-HEALTH-2009-single-stage.** The purpose of this research topic is to identify molecular and cellular mechanisms underlying CKD in persons at risk and already affected ones, to determine markers of CKD, to enable monitoring of its progression, and to develop innovative approaches to its treatment. The final goal of this project should be the development of new diagnostic tools (e.g. biomarkers) in blood and urine to detect renal disorders in a very early stage and development and testing of novel therapeutic protocols that would halt CKD progression and prevent renal failure. An interdisciplinary collaboration of clinicians, clinical scientists, and basic scientists, as well as implementation of simple screening systems, animal models, clinical data, molecular biology and genetic tools is anticipated. **Funding scheme:** Collaborative Project (Large scale integrating project).

3. OPTIMISING THE DELIVERY OF HEALTHCARE TO EUROPEAN CITIZENS

This Activity aims at developing new research methods and generating the necessary scientific basis to underpin informed policy decisions on health systems and more effective and efficient evidence-based strategies of health promotion, disease prevention, diagnosis and therapy. It is recognised that the health systems of the EU are a central part of Europe's high levels of social protection and contribute to social cohesion and social justice as well as to sustainable development. The health systems of the EU reflect the overarching values of universality, access to good healthcare, equity and solidarity, aiming to make provision that is patient-centred and responsive to individual need. The principal target users of new knowledge within the Commission include the Directorate-General for Health and Consumer protection, the Directorate-General for Employment, Social Affairs and Equal Opportunities, and also the Directorate-General for Development and the Directorate-General for EuropeAid. In particular the research undertaken will generate the scientific evidence to meet the objectives of the proposed new Programme of Community Action in the field of Health (2007-2013). The principal targeted users outside the Commission include the Member States (Health Ministries and Pubic Health Institutes), the World Health Organization (WHO) (both Headquarters and the Regional Office for Europe), the Organization for Economic

Cooperation & Development (OECD) as well as clinicians, service providers, patients and other stakeholders.

Important notice: This activity is complemented by work in the Themes Information & Communication Technologies and Food, Agriculture and fisheries, Biotechnology of the Cooperation Programme. Therefore it excludes support for proposals where the predominant activity is the development or application of new information, communication technologies or proposals where the predominant activity is food or nutrition related research.

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

In contrast to Activity 2, the 'translation of research' in Area 3.1 is understood to take a general approach across diseases and not be disease-specific. Topics under this area will address issues that are fundamental for the improvement of quality of health services as such. However, it will be possible for proposals to focus on a particular disease if the findings are expected to have an impact on service provision for other diseases or conditions as well. Research will primarily focus on improving the use of interventions and products that are already evidence-based and not on the development and validation of such interventions or products.

Special attention will be given to patient safety, including adverse effects of medication: to identify the 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. Focus will be on the scientific benchmarking of strategies; investigating outcomes of different interventions including medicines, scientifically tested complementary and alternative medicines, and new health therapies and technologies taking into consideration prescription strategies, some aspects of pharmacovigilance evidence, specificities of the patient (e.g. genetic susceptibility, age, gender and adherence) and cost benefits.

Expected impact: Projects should advance the application of evidence-based medicine in Europe. The improved use of clinical research findings in clinical diagnosis and treatment as well as patient self-management of disease should be demonstrated and the cooperation between researchers in Europe and other geographic regions enhanced to promote integration and excellence of European research in the area. Findings should be scientifically validated in different settings and be applicable beyond the national level. Scientific methodologies that allow tools for benchmarking and comparative analysis at the European level will be considered an asset.

Topics for single-stage submission and evaluation; deadline 3 December 2008:

- **HEALTH-2009-3.1-1: Patient Safety: Effective implementation of prevention strategies for healthcare associated infections. FP7-HEALTH-2009-single-stage.** Effective interventions that are already evidence-based to control transmission of healthcare associated infections should be identified. Their large-scale implementation should be evaluated regarding its effect on disease-control

outcomes. Knowledge gaps in implementation need to be addressed. Factors determining the successful implementation of effective interventions should be identified and validated. This research should lead to a better understanding on how the implementation of interventions that are already evidence-based can be improved. **Funding scheme:** Collaborative Project (Small or medium-scale focused research project).

- **HEALTH-2009-3.1-2: Improve quality and safety of hospital care. FP7-HEALTH-2009-single-stage.** Study the relationship of organisational quality management and culture, professionals' involvement, and patient empowerment with the quality of hospital care, including clinical effectiveness, patient safety and patient involvement. Identify organisational and cultural characteristics of hospitals and professional- and patient-related tools that are associated with better quality of care. This research should serve to guide hospitals to develop their own effective safety and quality improvement programmes and provide the basis for assessing hospital quality of care by purchasers and national and local governments. **Funding scheme:** Collaborative Project (Small or medium-scale focused research project).

- **HEALTH-2009-3.1-3: Complementary and Alternative Medicine. FP7-HEALTH-2009-single-stage.** In order to create the knowledge base concerning the demands for Complementary and Alternative Medicine (CAM) and the prevalence of its use in Europe, consensus on the terminology of CAM and the definition of respective CAM methods needs to be established. The current state with respect to the provider's perspective as well as needs and demands of the citizens should be explored; the different legal status of CAM in EU Member States needs to be taken into account. A roadmap for future European research in this area should be developed. **Funding scheme:** Coordination and Support Action (Coordinating Action).

- **HEALTH-2009-3.1-4: Improved treatment of chronic diseases in developing countries. FP7-HEALTH-2009-single-stage.** Develop a formulation that combines existing safe and effective drugs for treating (non-infectious) chronic diseases in a single daily pill. This fixed-dose-combination pill should be low-cost and suitable for production and widespread use in resource-poor countries. Evaluate its safety and adherence in relation to conventional treatment in a controlled trial. The target population of this combination pill should be clearly identified to ensure safety and effectiveness. Recommendations for implementation should be developed in order to provide equitable access to this pill in developing countries. Findings of this research should serve to address two major challenges of effective secondary prevention and treatment of chronic diseases: adherence to treatment and access to treatment in developing countries. The active participation of partners from ICPC could add to the scientific and/or technological excellence of the project and/or lead to an increased impact of the research to be undertaken. **Funding scheme:** Collaborative Project (Small or medium-scale focused research project).

  See also topic HEALTH-2009-4.3.2-1: Strategies and interventions for improving reproductive health (SICA).

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

The objective is to provide, in the light of new knowledge, scientifically validated tools to allow countries to learn from the experience of other health systems and their sustainability, taking into account the importance of national contexts and population characteristics (ageing, mobility, migration, education, socioeconomic status and the changing world of work etc). Focus will be on organisational, financial and regulatory aspects of health systems (assessing the cost, efficiency and benefits of different interventions including as regards patient safety), their implementation and their outcomes in terms of effectiveness, efficiency and equity (including disadvantaged groups). Special attention will be paid to investment issues and human resources, including home care strategies.

Expected impact: Projects should advance the state of the art in the field of health systems research and enhance cooperation between researchers in Europe and other geographic regions to promote integration and excellence of European research in the field. This research should develop the scientific evidence base that supports the Member States to organise better their health systems according to the common principles of equity, solidarity, and universality. The knowledge generated should empower the policy and decision maker better to manage and reform healthcare systems in view of common challenges and within the common framework of the European Union.

Topics for single-stage submission and evaluation; deadline 3 December 2008:

- **HEALTH-2009-3.2-1: Organisation of dementia care. FP7-HEALTH-2009-single-stage.** Assess European health and social care systems as regards the organisation and financing of prevention, diagnosis, medical treatment and social care for dementia patients. Identify/develop approaches/models that can be integrated into existing European health and social care systems which addresses the need for specific care and living conditions, the specificities of formal and informal care arrangements, and supports families living with dementia patients for more effective and sustainable dementia care in Europe. Findings of this research should enable national decision makers to base their decisions on the best knowledge available when they reform the organisation of dementia care. **Funding scheme:** Collaborative Project (Small or medium-scale focused research project).

- **HEALTH-2009-3.2-2: Healthcare outcomes and cost-benefits. FP7-HEALTH-2009-single-stage.** Investigate the relationship between quality of care with costs, efficiency, and accessibility by identifying and assessing existing approaches. Develop/identify approaches/models to describe the balance between quality of care and costs, taking patient satisfaction and the benefits of healthcare into account. Analyse how the transition of changing treatment practice is tackled across Europe. A multi level approach is needed, also taking into account the diversity of European health systems (e.g. degree of centralisation, models of financing, and cultural and historical determinants of models). Findings should support national decision makers when reforming health systems and aim to support development of the European Community Health Indicators managed by the European Commission's Directorate-General for Health and Consumer

Protection. **Funding scheme:** Collaborative Project (Small or medium-scale focused research project).

- **HEALTH-2009-3.2-3: Primary care quality linkage to costs. FP7-HEALTH-2009-single-stage.** The focus should be on the analysis of different organisational models for primary care treatment across Europe and to develop models linking the quality of care to costs, taking into account access, self payment, equity issues and patient satisfaction. Relationship between primary and secondary care should be explored including different models of 'gate keeping', and how quality and costs in primary care are affected. Recommendations on best practice should be developed and results should support Member States when they reform the organisation of primary care. **Funding scheme:** Collaborative Project (Small or medium-scale focused research project).

- **HEALTH-2009-3.2-4: Impact of cross border collaboration on health services. FP7-HEALTH-2009-single-stage.** Identify and analyse arrangements of cooperation between actors located in different EU countries that aim to transfer patients, providers, products, services, funding or knowledge across the border which separates them. Current gaps in documentation of already existing cross-border collaboration activities as regards geographical coverage, availability and quality of data need to be addressed. On this basis a systematic in-depth analysis of the potential impact of cross-border collaboration on the wider healthcare system should be undertaken. Primary data collected in this project should close existing gaps and the findings of this research should enable national and European decision makers to correctly assess the scale of existing cross border care cooperation and its potential implications for the national healthcare system. **Funding scheme:** Collaborative Project (Small or medium-scale focused research project).

- **HEALTH-2009-3.2-5: Research access to comparable healthcare data. FP7-HEALTH-2009-single-stage.** Identify and analyse the availability and comparability of healthcare related data and the access for health services researchers to this data across EU member states. Develop recommendations to improve access to healthcare related data for health services researchers taking into account national barriers and opportunities for more effective comparative cross-national health systems research. Account should be taken of existing data (e.g. as maintained by OECD, WHO, EUROSTAT). **Funding scheme:** Coordination and Support action (Coordinating action).

- **HEALTH-2009-3.2-6: Scoping study to address the methodological challenges of quantifying the socio-economic burden of brain diseases in the enlarged European Union compared to other major diseases. FP7-HEALTH-2009-single-stage.** The project should include data collection from primary sources and analysing of the incidence, economic and social costs of brain diseases. **Funding scheme:** Coordination and Support Action (Supporting Action).

  See also topics HEALTH-2009-4.3.2-2: Access to medicines (SICA) and HEALTH-2009-4.3.2-3: Integration of Disease Surveillance and Health Systems Response (SICA).

3.3. ENHANCED HEALTH PROMOTION AND DISEASE PREVENTION

The objective of this area is to provide scientific evidence for the best public health measures in terms of life styles, work and living circumstances and interventions at different levels and in different contexts. Focus will be on the wider determinants of health and how on the basis of new knowledge they interact at both the individual and community level (e.g. diet, stress, tobacco, alcohol and other substances, physical activity, cultural context, socio-economic and environmental factors). In particular, mental health will be addressed in a life-course perspective.

Expected impact: Projects should advance the state of the art in the field of health promotion and primary prevention research and enhance cooperation between researchers in Europe and other geographic regions to promote integration and excellence of European research in the area. This research should provide the evidence base to empower the individual to change and sustain healthy behaviour and the policy and decision makers at European, national and local level to develop and implement effective public health interventions and incorporate health goals in the definition and implementation of all policies. Findings should be applicable to the general population and be validated in different settings, translating research into practice. Where applicable scientific methodologies that allow tools for benchmarking and comparative analysis at the European level will be considered an asset.

Topics for single-stage submission and evaluation; deadline 3 December 2008:

- **HEALTH-2009-3.3-1: Child and adolescent mental health. FP7-HEALTH-2009-single-stage.** Identify and evaluate interventions to prevent mental disorders in children and young adolescents. Identify interventions that are most effective in mitigating risk factors of developing mental health disorders and that strengthen mental health protective factors and help avoid crisis. Specific needs relating to specific contexts should be addressed, as well as different settings such as families, schools, sports and leisure activities. This research should define a set of effective intervention methods and programmes for children at risk and/or their families. **Funding scheme:** Collaborative Project (Small or medium-scale focused research project).

- **HEALTH-2009-3.3-2: Environmental prevention of substance abuse by adolescents. FP7-HEALTH-2009-single-stage.** Analyse the effect of current environmental strategies for the prevention of substance abuse (tobacco, alcohol, and illicit drugs) on adolescents in Europe. Determine the effect on early adolescent smoking and alcohol use, the relation to its effect on use of illicit drugs, and the effect on long term substance use, and its additional effect when combined with behavioural measures, particularly in vulnerable population groups. This research should advance knowledge on the effectiveness of environmental prevention strategies, the role of normalisation around drug use and associated problem behaviours, and the spin-off effect of environmental prevention strategies on illicit drug use. **Funding scheme:** Collaborative Project (Small or medium-scale focused research project).

- **HEALTH-2009-3.3-3: Ageing cohorts**. **FP7-HEALTH-2009-single-stage.** Undertake multidisciplinary cohort work addressing the health of two ageing population groups, one group of ~50 to 70 years of age, and one group of ~65 to

85 years of age, to focus on developing robust health-related data at the EU level over a substantial time period - ~15 years. Such research should build on and complement work to-date (such as the European SHARE data set) to empower researchers and policy makers in various domains (healthcare, social care, pension provision) to take informed decisions. EU Member States should be covered and relevant European Commission services (Directorate-General for Health and Consumer protection, Directorate-General for Employment, Social Affairs and Equal Opportunities) and EUROSTAT be consulted. **Funding scheme:** Collaborative Project (Large-scale integrating project).

- **HEALTH-2009-3.3-4: Birth/Mother - Child Cohorts co-ordination. FP7-HEALTH-2009-single-stage.** The focus should address the challenge of assessing and preparing for developing robust health data for birth/mother child cohorts over a substantial time period - +/- 15 years - at the European Union level, and in doing so identify a strategic approach to child health research as well as addressing policy concerns about children life trajectories, such as reducing health inequalities. EU Member States should be covered and relevant European Commission services (Directorate-General for Health and Consumer protection, Directorate-General for Employment, Social Affairs and Equal Opportunities) and EUROSTAT be consulted. Work should take stock and evaluate existing registers and value provided by existing birth/mother child cohorts, taking into account if possible prenatal and perinatal variables, identify key areas and gaps in knowledge and develop recommendations for research action at the European level in the context of child health. **Funding scheme:** Coordination and Support Action (Coordinating Action).

- **HEALTH-2009-3.3-5: European child health research platform**. **FP7-HEALTH-2009-single-stage.** Address the diversity and fragmentation in child health research in Europe in a an inclusive multidisciplinary way, identifying existing research programmes in Member States, recent advances and identification of gaps to explore road maps for the future of child health research in Europe. **Funding scheme:** Coordination and Support Action (Coordinating Action).

4. OTHER ACTIONS ACROSS THE HEALTH THEME

4.1. COORDINATION AND SUPPORT ACTIONS ACROSS THE THEME

Dissemination and Knowledge Transfer

The objective of these actions is to contribute to the implementation of the Framework Programmes and the preparation of future Community research and technological development policy. The focus of this area will be on technology transfer, dissemination of results and tackling publication bias.

Topics for single-stage submission and evaluation; deadline 3 December 2008:

- **HEALTH-2009-4.1-1: Monitoring tool and technology transfer analysis for health grants during FP7. FP7-HEALTH-2009-single-stage.** The objectives

are: (i) to offer stakeholders a public internet-based electronic tool for online monitoring of grants funded by the Health Theme to facilitate research collaboration within the academic environment and between academia and industry, (ii) to provide the Commission Services with a number of analyses, such as on technology transfer aspects, of the different modalities of grants, the different stakeholders and their competencies in Europe and their interaction, as well as analysis of industry/academia collaboration, plus the evolution of SME interfaces with other participants in time, the results obtained by the grants for the different disease and research areas together with horizontal coordination activities. These analyses will be used in the active management of the calls and instruments in the Health theme to achieve the optimum usage of the funds allocated during the 7th Framework Programme. The project should complement and collaborate with existing support structures and already funded projects relevant to the health sector. **Funding scheme:** Coordination and Support Action (Supporting Action).

Expected Impact: The monitoring tool provided and the related analysis will help policy makers and programme managers to define new research policy objectives by monitoring intermediate performance targets for FP7. The mapping of health research competencies in the European Research Area is expected to stimulate collaboration among different players in Health research, in particular academia, SMEs and larger companies.

- **HEALTH-2009-4.1-2: Dissemination of results from research in Life Sciences and Biotechnology for Health to the general public and/or information multipliers. FP7-HEALTH-2009-single-stage.** Proposals should offer well-structured, innovative approaches, networks or strategies to convey through appropriate communication channels the vast amount of data and knowledge generated by the research funded by the Framework Programmes and other European stakeholders in the fields related to health research. Proposals should include the production and development of multilingual, communication-oriented information networks or resources for different countries, the collection of information in a timely way and the adaptation of the contents/language/media to relevant target audiences (for example: general public, journalists from general or specialised media and press, youngsters, etc.). They should also aim to improve the clarity of primary research reports and new information resources based on such reports. The potential applications and benefits for the citizens should be highlighted in particular. The resources should be rigorous in their contents, reviewed by scientists and professionally developed. **Funding scheme:** Coordination and Support Action (Coordinating Action or Supporting Action). **One or more proposals** are expected to be funded.

  Expected Impact: The expected outcome of these projects is the generation of strategies, resources and networks that are needed at European level to communicate more efficiently health research results to general audiences, either directly or through information multipliers.

- **HEALTH-2009-4.1-3: Targeting publication bias. FP7-HEALTH-2009-single-stage.** The objective is to explore, identify and overcome failure to publish negative results of health research. Proposals should offer well-structured and

innovative approaches to overcome publication bias via, successively, surveys and/or analysis of literature, evaluation of study protocols, conference abstracts and discussions with key opinion leaders and stakeholders, such as research journal publishers, the pharmaceutical industry, including small and medium sized enterprises, research institutions, study registries and funding bodies. These approaches should include an inventory of existing sites and publications, presentation of current data on the impact of failure to publish negative results. Interactions with major journals and international groups active in publishing should be sought in order to point out ways to change practice. **Funding scheme:** Coordination and Support Action (Supporting Action).

Expected Impact: Publication bias is commonly understood as the failure to publish entire studies with negative results. Although the importance of bias is increasingly being recognised, more empirical evidence is needed to gain insight into this issue, in order to evaluate an important primary source of information on planned studies. A new initiative should assess the impact and seek ways effectively to detect and reduce the impact of non-publication of negative studies and study results, and provide insights on how to avoid duplication of research efforts and allow a more effective funding of health research.

4.2. RESPONDING TO EU POLICY NEEDS

The objective of these actions is to contribute to the support and follow-up of other Community policies. The focus of these actions will be on research into paediatric use of medicines, drug safety research and impact of vaccination.

Topics for single-stage submission and evaluation; deadline 3 December 2008:

- **HEALTH-2009-4.2-1: Adapting off-patent medicines to the specific needs of paediatric populations. FP7-HEALTH-2009-single-stage.** Proposals should provide evidence for specific paediatric use of off-patent medicinal products currently used off-label. Studies include the assessment of non-clinical safety, pharmacokinetics (as well as data analysis and extrapolation by means of *in silico* models), clinical efficacy and safety, and/or the development of appropriate formulations. With a view to benefit from the broadest possible expertise, the participation of research centres from Third countries already active in this field is also strongly encouraged. Project proposals must take account of the priority list of Off-Patent Medicinal Products of the Paediatric Committee of the European Medicines Agency (EMEA)[13], and of the Regulation of the European Parliament and of the Council on Medicinal Products for paediatric use and amending Regulation (EEC) N° 1768/92, Directive 2001/83/EC and Regulation (EC) N° 726/2004, Brussels, 29.9.2004, COM(2004) 599 final, 2004/0217 (COD). **Funding scheme:** Collaborative Project (Small or medium-scale focused research project).

[13] The priority list is available at the following address: http://www.emea.europa.eu/htms/human/paediatrics/prioritylist.htm.

Expected Impact: To provide evidence for a better use of off-patent medicinal products in paediatric populations. The acquired knowledge should aim at new Paediatric Use Marketing Authorisations (PUMAs).

- **HEALTH-2009-4.2-2: Study of the Arrhythmogenic potential of different classes of medicines. FP7-HEALTH-2009-single-stage.** The objective is to analyse the cardiac safety profile of one of the following commonly-used classes of medications: antipsychotics, anti-infectives and H1-anti-histamines. Specific issues to consider are potential QTc interval prolongation, *Torsades de Pointes*-related symptoms, syncope, palpitations and premature ectopic beats and potential molecular-genetic interactions. Specific research outputs will be the generation and analysis of data that will allow for a robust and reliable comparison of the relative risks of different drug substances to be made and for the identification of at-risk patient groups.

  Funding scheme: Collaborative project (Small or medium-scale focused research project).

  Expected Impact: In line with new Pharmaceutical Legislation, a more proactive conduct of Pharmacovigilance is envisaged. This is due to a number of emerging issues, which often require intensive monitoring in a clinical or academic setting in large numbers of patients. In addition, safety issues may only emerge when a product or class of products have been on the market for some time and where different stand-alone databases and other facilities exist in several centres that contain the necessary data on both exposure and medical outcomes. The results of this research should allow for evidence-based regulatory and treatment decisions to be made.

- **HEALTH-2009-4.2-3: Human Papillomavirus Vaccination (HPV) and cervical cancer screening programmes: estimate of impact of different policy options by way of disease modelling and health economics. FP7-HEALTH-2009-single-stage.** The project should evaluate the possible impact of HPV vaccination in terms of disease burden reduction and cost-effectiveness using mathematical modelling and health economics. The objective is to identify best policy options (priority age groups, catch-up programmes, male vaccination, number of doses) for the vaccination programme and assess the probable impact of vaccination on the existing cervical cancer screening programmes. The study should be designed taking into consideration available data on coverage and outcomes from existing cervical cancer screening programmes in EU, and the most up-to-date data on HPV vaccines and the epidemiology of HPV infection and disease. Attention should also be given to sub-populations that are less likely to access health services. The study should also take into account the relation of HPV infection to other cancers and health outcomes. Study results will inform national decision-makers supporting them in implementing effective (and cost-effective) HPV immunisation programmes. **Funding scheme:** Collaborative Project (Small or medium-scale focused research project).

  Expected Impact: Research performed under this topic will deliver the necessary evidence-based knowledge for best policy options on the new vaccine programmes about to be introduced by the majority of EU Member States and Associated

Countries. It should help maximising the impact of financial investment into these vaccination programmes on women's health in Europe as well as world-wide

- **HEALTH-2009-4.2-4: Coordinating action on organ procurement and transplantation with a focus on new EU Member States. FP7-HEALTH-2009-single-stage.** In this period of reform of the health systems within the new Member States, this coordinating action is expected to be of major importance to contribute towards an efficient coordination between the research programmes, the organisational structures and the national authorities dedicated to organ donation and transplantation. This research coordination activity is expected to result in a model for the efficient transplantation activity particularly for the new Member States. It should also address the aspects of organ circulation to better approach the problem of organ shortage. **Funding scheme:** Coordination and Support action (Coordinating action)

  Expected Impact: Resulting advances in understanding are expected to contribute to improving the quality and safety for human organs, promoting the good medical practices and identifying the research activities and future needs.

4.3. SPECIFIC INTERNATIONAL COOPERATION ACTIONS (SICA)

One of the objectives of international cooperation in FP7 to address specific problems that third countries face or that have a global character. Under this area, Specific International Cooperation Actions (SICAs) can address particular needs of developing and emerging economies, by means of dedicated cooperative activities.

SICAs are dedicated to non-Associated third countries and respond to mutual interest in cooperating on particular topics which have been selected with a view to their scientific and technological level and needs. The identification of specific needs and priorities is closely linked to relevant bilateral cooperation agreements and with ongoing multilateral and bi-regional dialogues between the EU and these countries or groups of countries and international forums, as well as within the context of the Millennium Development Goals. Priorities are identified based on the particular needs, potential and level of economic development in the region or country and may include: health policy research, health systems and healthcare service research, maternal and child health, reproductive health, control and surveillance of neglected communicable diseases and emerging unforeseen policy needs in those regions.

4.3.1. Neglected infectious diseases.

The aim is to establish an integrated approach for the development of preventive, therapeutic and diagnostic tools for neglected infectious diseases. Activities in this area will include, but not be limited to, parasitic diseases caused by Trypanosomatidae species (e.g. Trypanosomiasis, Chagas Disease, Leishmaniasis), bacterial diseases such as Buruli ulcer, leprosy and trachoma, helminth diseases such as schistosomiasis, filariasis as well as other neglected infectious diseases such as infantile diarrhoea

Projects should address preclinical and early clinical activities, as well as the particular health conditions and health needs of disease endemic countries. Proposals involving an integrated multidisciplinary approach, including significant participation of partners from disease-endemic areas and, where relevant, industry partners, will be strongly encouraged. Where applicable, technology transfer, training activities and human capacity building should also be part of the projects.

Expected impact: Research in this area will gather the necessary critical mass in several fields of expertise to achieve integration of basic science and enabling technologies with the aim of expediting the discovery and development of vaccine and new drug candidates. The European added value will be to increase the innovation potential and competitiveness of translational research. It will enhance the cooperation between scientific disciplines and stakeholders at European level with disease-endemic countries on the basis of mutual interest and shared benefits. It will provide sound scientific substantiation for developing new prophylactics or new drug candidates that can address the therapeutic gap of existing treatments.

Topics for single-stage submission and evaluation; deadline 3 December 2008:

- **HEALTH-2009-4.3.1-1: Discovery and development of new vaccines or drugs for helminth infections. FP7-HEALTH-2009-single-stage.** State-of-the-art technologies, including bioinformatics and applied genomics, where available should be used to identify and develop candidates for either prophylactic vaccines or for new treatments for helminth infections such as schistosomiasis and lymphatic filariasis. Projects may also focus on identification of new lead compounds or improvement of existing compounds to overcome drug resistance. Pre-clinical testing in vitro and in vivo should be an intrinsic part of the project, which may also include early clinical testing. Inclusion of participants from disease-endemic countries is expected. Active participation of industry, especially SMEs, could lead to an increased impact of the research proposed, and this will be considered in the evaluation of the proposal. **Target Regions:** All International Cooperation Partner Countries, see annex I of the work programme. **Funding scheme:** Collaborative Project **(SICA)** (Small or medium-scale focused research project).

- **HEALTH-2009-4.3.1-2: Identification and development of vaccine candidates for neglected bacterial infections. FP7-HEALTH-2009-single-stage.** Projects should aim to identify and develop new vaccine candidates for neglected bacterial, including mycobacterial infections, with priority given to pathogens causing trachoma, leprosy and/or Buruli ulcer. Essential pre-clinical testing in vitro and in vivo should be an intrinsic part of the project, which may also address correlates of protection, disease immunopathology, and advancement of existing vaccine lead candidates to phase I clinical trials. Recent scientific advances in bioinformatics and applied genomics should be used whenever relevant. Active participation of industry, especially SMEs, could lead to an increased impact of the research proposed, and this will be considered in the evaluation of the proposal. **Target Regions:** All International Cooperation Partner Countries, see annex I of the work programme. **Funding scheme:** Collaborative Project **(SICA)** (Small or medium-scale focused research project).

- **HEALTH-2009-4.3.1-3: Human immune responses to co-infections of poverty-related (HIV, malaria, TB) and neglected infectious diseases. FP7-HEALTH-2009-single-stage.** Lack of a thorough understanding of the human immune responses to co-infections by virus, unicellular eukaryotic parasites, bacteria or worm infections as well as the influence of such co-infections on the pathogenesis of the involved diseases are causing a severe disease burden in Developing Countries. This is hampering the efficient use of antimicrobial agents as well as the development of potent prophylactic vaccines. Projects need to address the identification of immune surrogates of protection and, the elucidation of the role of the innate immune system in triggering an efficient immune response in individuals affected by two or more infectious diseases. Sustainable networking with research partners in disease-endemic countries should be an essential part of the project, which should provide an integrated immunological research effort across disciplines and diseases. Child health and ageing aspects should be taken into consideration wherever appropriate. **Target Regions:** ACP Countries see annex I of the work programme. **Funding scheme:** Collaborative Project **(SICA)** (Large scale integrating project).

4.3.2. International Public Health and Health Systems

Research policy can make an important contribution to development. This has been recognised by the EU, when in 2005 it committed itself to policy coherence for development in 12 policy areas, including research and innovation[14], as well as at the international level with the 2005 Millennium Declaration. The Council in its conclusion on the Policy Coherence for Development report[15] considers that EU research policies, both at EC and national level, should contribute to overall development policy objectives by supporting research activities in areas of interest for developing countries, and continue supporting specific international cooperation projects involving research centres, universities and other stakeholders from developing countries.

The principal users include, Member States (Health Ministries and Public Health Institutes) and Commission services, stakeholders in the various ICPC Regions including Ministries of Health, the World Health Organisation (both Headquarters and the Regional Office for Europe), and various NGO stakeholders in the global health research community. Targets in the International Cooperation Partner Countries include universities and research institutes, research units in ministries and other stakeholders in the international public health and health systems fields. Focus will be particular on strategies and interventions for improving reproductive health, access medicines arising out of the WHO Inter-governmental Working Group on Public health, Innovation and IPR, and integrating diseases surveillance and health systems response.

In preparation for the work programme of the Health Theme for the Call that will be published in 2009, particular attention will be paid to Africa. The scope of the international cooperation activities, in collaboration with WHO, will focus on a new

[14] Conclusions of the Council and the Representatives of the Governments of the Member States Meeting within the Council on 'Millennium Development Goals: EU Contribution to the Review of the MDGs at the UN 2005 High Level Event, 24 May 2005. See also the resolution of the European Parliament on the importance of supporting measures to improve international scientific cooperation with Africa, 21 February 2008

[15] Conclusions of the Council and the Representatives of the Governments of the Member States Meeting within the Council on 'Policy Coherence for Development', 20 November 2007

strategic health agenda aimed at better health systems performance and informing future EC development cooperation in Africa. This is also in line with the Council conclusion on the Policy Coherence for Development report[16] considers that EU research policies, both at EC and national level, should contribute to overall development policy objectives by supporting research activities in areas of interest for developing countries, and continue supporting specific international cooperation projects involving research centres, universities and other stakeholders from developing countries.

Expected impact: Topics under this area have direct relevance to the international dimension of the public health policy of the European Community by contributing to health protection, prevention and promotion, while at the same time generating new knowledge relevant to health, social, environmental and economic issues. Through cross-sectoral and multi-disciplinary approaches the research will contribute to initiatives such as the Millennium Development Goals, the Ministerial Declarations on Global Health Research[17] and the European policy coherence framework for development, with particular regard for the attainment of the health MDGs, including child health, maternal health and reproductive health. One specific objective is to provide a scientific base for ICPCs to improve their health service delivery including aspects of accessibility, effectiveness, efficiency, quality of care and user-friendliness.

Topics for single-stage submission and evaluation; deadline 3 December 2008:

- **HEALTH-2009-4.3.2-1: Strategies and interventions for improving reproductive health. FP7-HEALTH-2009-single-stage.** The focus should be on impact-oriented research on the effectiveness and acceptability of strategies and/or specific interventions to promote reproductive health with an emphasis on sexually transmitted diseases and the prevention of unwanted conceptions and related ill-health. Such strategies and interventions may cover areas ranging from community-based health promotion to improved management schemes for preventive and curative health services and to specific innovations in treatment and diagnostics. In particular the specific needs and characteristics of adolescents should be taken into account, including their requirements for information, communication and counselling. The study approaches should relate to real life settings and aim at providing evidence on effective strategies and interventions that are relevant and applicable in local contexts. **Target Regions:** All International Cooperation Partner Countries, see annex I of the work programme. **Funding scheme:** Collaborative Project **(SICA)** (Small or medium-scale focused research project).

- **HEALTH-2009-4.3.2-2: Access to medicines. FP7-HEALTH-2009-single-stage.** Analyse how economic policies (including patents) affect the access to essential medicines in developing countries. Develop models that would underpin policy recommendations for low-income countries, how access to medicines, particularly for lower socioeconomic and vulnerable population groups, could be improved at the national level. This research should advance knowledge on the effect of patents, access to generics, poverty, characteristics of the national market,

[16] Conclusions of the Council and the Representatives of the Governments of the Member States Meeting within the Council on 'Policy Coherence for Development', 20 November 2007

[17] Mexico Statement from the Ministerial Summit on Health Research, Mexico, 16-20 November 2004

and other important determinants on the access of the most vulnerable to essential medicines. Target Regions: International Collaboration Partner Countries (ICPC), see Annex I of the work programme. **Funding scheme:** Collaborative Project **(SICA)** (Small or medium-scale focused research project).

- **HEALTH-2009-4.3.2-3: Integration of Disease Surveillance and Health Systems Response. FP7-HEALTH-2009-single-stage.** Identify and evaluate the integration of surveillance of infectious diseases and their control into regular healthcare provision. Determine the long- and short-term effectiveness of such integration in comparison to vertical surveillance and control programmes and identify factors crucial for the successful implementation of such integration. Findings of this research should advise national decision makers who plan to integrate existing vertical control programmes into the regular healthcare system. Target Region: ACP, Asia. **Funding scheme:** Collaborative Project **(SICA)** (Small or medium-scale focused research project).

4.3.3. Coordinated topics with Russia

The objective of the coordinated topics with Russia is to support projects that will engage a balanced number of research actors in Russia and the EU/AC[18]. The projects should not include participants from other countries. The proposals shall be submitted in English and will be evaluated by European and Russian experts according to the rules of FP7. Resulting contracts, one in each topic, awarded to the highest ranking proposals, which are also supported by the Russian Federal Agency for Science and Innovation, will be signed by all participants. The EC grant will cover the expenses to the participants in EU Member States and Associated countries according to the FP7 rules, while the expenses to the participants based in Russia shall be covered by own funds. The latter shall not be included in the EC grant proposal. However, an amount not exceeding 5% of the estimated EU/AC costs may be included in the EC grant to cover additional expenses such as translations, travel and other management costs to the Russian partners. This amount shall be managed by a single participant. The projects will be Small or Medium Scale Focused Research Projects for Specific International Cooperation Actions (SICA), where the minimum number of participants is 2 from the EU (and/or AC) plus 2 from different regions in Russia. The maximum EC contribution (including the 5% amount) is 3 million Euros.

Expected impact: The projects in these topics are expected to lead to a much closer cooperation between the EU/AC and Russia than is the case for traditional FP projects. The topics were selected at a workshop jointly organised by DG Research (Health Directorate) and the Russian Federal Agency for Science and Innovations, in St. Petersburg in September 2007. Both selected topics represent areas of high importance, scientifically and medically.
They are also areas where both the EU/AC and Russia have highly developed skills and knowledge and which will benefit from mutual exchange of information and combination of efforts.

[18] AC: Associated Countries to FP7

Topics for single-stage submission and evaluation; deadline 3 December 2008:

- **HEALTH-2009-4.3.3-1: Comparative population genetic studies on multifactorial diseases. FP7-HEALTH-2009-single-stage.** Genome-wide association studies have been shown to be a powerful approach to study genetics of common diseases. The project should focus on comparative population genomics studies on several multifactorial diseases in populations in the EU/AC and Russia. **Funding scheme:** Collaborative Project **(SICA)** (Small or medium-scale focused research project).

- **HEALTH-2009-4.3.3-2: Mechanisms of diabetic and weight-related co-morbidity in heart failure. FP7-HEALTH-2009-single-stage.** The presence of type-2 diabetes, obesity or cachexia as co-morbidities in heart failure cause significant increase in morbidity and mortality. The project should focus on the role of these co-morbidities in the disease deterioration process of heart failure at molecular, cellular and vascular levels. The research should aim at elucidating the pathogenesis and pathophysiology of this condition to allow tailored therapeutic interventions. **Funding scheme:** Collaborative Project **(SICA)** (Small or medium-scale focused research project).

5. Call for tenders

A study will be supported to evaluate progress towards the realisation of the European Research Area in Health. It will identify the strengths and weaknesses of research in this (these) domain(s) and identify any sector specific barriers impeding the realisation of ERA. (Call for tenders, estimated maximum cost EUR 200 000 in 2009.

Further details will be provided in the text launching the service request.

III IMPLEMENTATION OF CALLS

Call identifier: FP7-HEALTH-2009-single-stage

Proposal submission and evaluation: Single-stage procedure

Date of publication: 3 September 2008[19].

Deadline: 3 December 2008 at 17.00.00 (Brussels local time).[20]

Indicative budget: EUR 476 million from the 2009 budget[21]

The budget for this call is indicative. The final budget awarded to this call, following the evaluation of proposals, may vary:

- by up to 10% of the total value of the call; and
- the repartition of sub-budgets awarded within this call, following the evaluation of proposals, may vary by up to 10% of the total value of the call.

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[19] The Director-General responsible for the call may publish it up to one month prior or after the envisaged date of publication.

[20] At the time of the publication of the call, the Director-General responsible may delay this deadline by up to two months.

[21] Under the condition that the preliminary draft budget for 2009 is adopted without modifications by the budgetary authority.

	4.3.2. International Public Health and Health Systems	12
	4.3.3. Coordinated topics with Russia	6

Table 2: Topics called:

Activity/Area	Topics called	Funding Schemes
1.BIOTECHNOLOGY, GENERIC TOOLS AND MEDICAL TECHNOLOGIES FOR HUMAN HEALTH		
1.2 DETECTION, DIAGNOSIS AND MONITORING		
1.2	HEALTH-2009-1.2-1: Development of tools for sensitive and specific in vitro detection of proteins and their interactions for diagnostic, prognostics and monitoring purposes.	*Collaborative Project (Small or medium-scale focused research project)*
1.2	HEALTH-2009-1.2-2: Design of methods suited to identify epigenetic factors and their use in the genetic diagnosis of relevant disorders.	*Collaborative Project (Small or medium-scale focused research project)*
1.2	HEALTH-2009-1.2-3: Novel MR-compatible PET detectors for simultaneous PET/MRI imaging**.**	*Collaborative Project (Large-scale integrating project)*
1.2	HEALTH-2009-1.2-4: Novel imaging systems for in vivo monitoring and quality control during tumour ion beam therapy.	*Collaborative Project (Small or medium-scale focused research project)*
1.2	HEALTH-2009-1.2-5: Activatable or smart in vivo imaging agents reporting on physico-chemical or molecular changes relevant to the diagnosis and/or monitoring of diseases	*Collaborative Project (Small or medium-scale focused research project)*
1.2	HEALTH-2009-1.2-6: Evaluation of the potential health impact of diagnostic imaging agents doses**.**	*Coordination and Support Action (Supporting Action)*
1.3 SUITABILITY, SAFETY, EFFICACY OF THERAPIES		
1.3	HEALTH-2009-1.3-1: New initiatives towards the implementation of the Replace, Reduce and Refine strategy.	*Coordination and Support Action (Coordinating Action)*
1.4 INNOVATIVE THERAPEUTIC APPROACHES AND INTERVENTIONS		
1.4	HEALTH-2009-1.4-1: Cell therapy for tissue and organs.	*Collaborative Project (Large-scale integrating project)*
1.4	HEALTH-2009-1.4-2: Regeneration of tissue using bio-compatible materials and cells.	*Collaborative Project (Large-scale integrating project)*
1.4	HEALTH-2009-1.4-3: Activation of endogenous cells as an approach to regenerative medicine.	*Collaborative Project (Large-scale integrating project)*
2. TRANSLATING RESEARCH FOR HUMAN HEALTH		
2.2. RESEARCH ON THE BRAIN AND RELATED DISEASES, HUMAN DEVELOPMENT AND AGEING		
2.2.1. Brain and brain-related diseases		
2.2.1.	HEALTH-2009-2.2.1-1: Synaptopathies: genesis, mechanisms and therapy.	*Collaborative Project (Large-scale integrating project)*
2.2.1.	HEALTH-2009-2.2.1-2: Identifying genetic and environmental interactions in schizophrenia.	*Collaborative Project (Large-scale integrating project)*
2.2.1.	HEALTH-2009-2.2.1-3: Optimising current therapeutic approaches to schizophrenia.	*Collaborative Project (Large-scale integrating project)*

2.2.1.	HEALTH-2009-2.2.1-4: Understanding the blood brain barrier (BBB) to improve drug delivery to the brain.	*Collaborative Project (Small or medium-scale focused research project)*
2.2.1.	HEALTH-2009-2.2.1-5: Psycho-social factors of brain disorders.	*Coordination and Support Action (Coordinating Action)*
2.3. TRANSLATIONAL RESEARCH IN MAJOR INFECTIOUS DISEASES: TO CONFRONT MAJOR THREATS TO PUBLIC HEALTH		
2.3.1. Anti-microbial drug resistance including fungal pathogens		
2.3.1	HEALTH-2009-2.3.1-1: Global collaborative research on the prevention of antibiotic resistance	*Collaborative Project (Large-scale integrating project)*
2.3.1	HEALTH-2009-2.3.1-2: Impact of specific antibiotic therapies on the prevalence of resistant bacteria in the human host.	*Collaborative Project (Small or medium-scale focused research project)*
2.3.1.	HEALTH-2009-2.3.1-3: Clinical evaluation of point-of-care diagnostic tests for microbial detection and identification, antibiotic susceptibility determination and biomarkers.	*Collaborative Project (Small or medium-scale focused research project)*
2.3.2. HIV/AIDS, malaria and tuberculosis		
2.3.2.	HEALTH-2009-2.3.2-1: Integration of European efforts in research on malaria.	*Network of Excellence*
2.3.2.	HEALTH-2009-2.3.2-2: Identification and pre-clinical testing of new vaccine candidates for tuberculosis.	*Collaborative Project (Large-scale integrating project)*
2.3.2.	HEALTH-2009-2.3.2-3: Discovery and/or development of new and promising anti-HIV microbicides.	*Collaborative Project (Large-scale integrating project)*
2.3.2.	HEALTH-2009-2.3.2-4: Mucosal and topical vaccines for poverty-related diseases (HIV/AIDS, malaria and/or TB).	*Collaborative Project (Large-scale integrating project)*
2.3.2.	HEALTH-2009-2.3.2-5: Translational vaccine research for poverty-related diseases (HIV/AIDS, malaria and/or TB).	*Collaborative Project (Small or medium-scale focused research project)*
2.3.3. Potentially new and re-emerging epidemics		
2.3.3.	HEALTH-2009-2.3.3-1: Efficacy and effectiveness of personal protection equipment and other measures against influenza transmission.	*Collaborative Project (Small or medium-scale focused research project)*
2.4. TRANSLATIONAL RESEARCH IN OTHER MAJOR DISEASES		
2.4.2. Cardiovascular diseases		
2.4.2.	HEALTH-2009-2.4.2-1: Improved or new therapeutic approaches for the treatment of heart failure.	*Collaborative Project (Large-scale integrating project)*
2.4.2.	HEALTH-2009-2.4.2-2: Cardiac arrhythmias: from genes to improved management of patients.	*Collaborative Project (Large-scale integrating project)*
2.4.2.	HEALTH-2009-2.4.2-3: Translation of basic knowledge on inherited cardiomyopathies into clinical practice.	*Collaborative Project (Small or medium-scale focused research project)*
2.4.3. Diabetes and obesity		
2.4.3.	HEALTH-2009-2.4.3-1: Novel therapeutical approach to pregnancy-induced diabetes.	*Collaborative Project (Small or medium-scale focused research project)*

2.4.3.	HEALTH-2009-2.4.3-2: Novel immunotherapies for type 1 diabetes.	*Collaborative Project (Large-scale integrating project)*
2.4.3.	HEALTH-2009-2.4.3-3: Molecular pathways in food intake at CNS-liver-gut regulation level.	*Collaborative Project (Small or medium-scale focused research project)*
2.4.4. Rare diseases		
2.4.4.	HEALTH-2009-2.4.4-1: Rare neurological diseases.	*Collaborative Project (Small or medium-scale focused research project)*
2.4.4.	HEALTH-2009-2.4.4-2: Preclinical development of substances with a clear potential as orphan drugs.	*Collaborative Project (Small or medium-scale focused research project)*
2.4.5. Other chronic diseases		
2.4.5.	HEALTH-2009-2.4.5-1: Prevention and treatment of non-alcoholic fatty liver disease (NAFLD).	*Collaborative Project (Small or medium-scale focused research project)*
2.4.5.	HEALTH-2009-2.4.5-2: Cellular and molecular mechanisms of the development of chronic kidney disease (CKD).	*Collaborative Project (Large-scale integrating project)*
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 MEDICINES, AND APPROPRIATE USE OF BEHAVIOURAL AND ORGANISATIONAL INTERVENTIONS AND NEW HEALTH THERAPIES AND TECHNOLOGIES		
3.1.	HEALTH-2009-3.1-1: Patient Safety: Effective implementation of prevention strategies for healthcare associated infections.	*Collaborative Project (Small or medium-scale focused research project)*
3.1.	HEALTH-2009-3.1-2: Improve quality and safety of hospital care.	*Collaborative Project (Small or medium-scale focused research project)*
3.1.	HEALTH-2009-3.1-3: Complementary and Alternative Medicine.	*Coordination and Support Action (Coordinating Action)*
3.1.	HEALTH-2009-3.1-4: Improved treatment of chronic diseases in developing countries.	*Collaborative Project (Small or medium-scale focused research project)*
3.2. QUALITY, EFFICIENCY AND SOLIDARITY OF HEALTHCARE SYSTEMS INCLUDING TRANSITIONAL HEALTH SYSTEMS		
3.2.	HEALTH-2009-3.2-1: Organisation of dementia care.	*Collaborative Project (Small or medium-scale focused research project)*
3.2.	HEALTH-2009-3.2-2: Healthcare outcomes and cost-benefits.	*Collaborative Project (Small or medium-scale focused research project)*
3.2.	HEALTH-2009-3.2-3: Primary care quality linkage to costs.	*Collaborative Project (Small or medium-scale focused research project)*
3.2.	HEALTH-2009-3.2-4: Impact of cross border collaboration on health services.	*Collaborative Project (Small or medium-scale focused research project)*

3.2.	HEALTH-2009-3.2-5: Research access to comparable healthcare data.	*Coordination and Support Action (Coordinating Action)*
3.2.	HEALTH-2009-3.2-6: Scoping study to address the methodological challenges of quantifying the socio-economic burden of brain diseases in the enlarged European Union compared to other major diseases.	*Coordination and Support Action (Supporting Action)*
3.3. ENHANCED HEALTH PROMOTION AND DISEASE PREVENTION		
3.3.	HEALTH-2009-3.3-1: Child and adolescent mental health.	*Collaborative Project (Small or medium-scale focused research project)*
3.3.	HEALTH-2009-3.3-2: Environmental prevention of substance abuse by adolescents.	*Collaborative Project (Small or medium-scale focused research project)*
3.3.	HEALTH-2009-3.3-3: Ageing cohorts.	*Collaborative Project (Large-scale integrating project)*
3.3.	HEALTH-2009-3.3-4: Birth/Mother - Child Cohorts co-ordination	*Coordination and Support Action (Coordinating Action)*
3.3.	HEALTH-2009-3.3-5: European child health research platform	*Coordination and Support Action (Coordinating Action)*
4. OTHER ACTIONS ACROSS THE HEALTH THEME		
4.1. COORDINATION AND SUPPORT ACTIONS ACROSS THE THEME		
4.1.	HEALTH-2009-4.1-1: Monitoring tool and technology transfer analysis for health grants during FP7.	*Coordination and Support Action (Supporting Action)*
4.1.	HEALTH-2009-4.1-2: Dissemination of results from research in Life Sciences and Biotechnology for Health to the general public and/or information multipliers.	*Coordination and Support Action (Coordinating or Supporting Action)*
4.1.	HEALTH-2009-4.1-3: Targeting publication bias.	*Coordination and Support Action (Supporting Action)*
4.2. RESPONDING TO EU POLICY NEEDS		
4.2.	HEALTH-2009-4.2-1: Adapting off-patent medicines to the specific needs of paediatric populations.	*Collaborative Project (Small or medium-scale focused research project)*
4.2.	HEALTH-2009-4.2-2: Study of the Arrhythmogenic potential of different classes of medicines.	*Collaborative project (Small or medium-scale focused research project).*
4.2.	HEALTH-2009-4.2-3: Human Papillomavirus Vaccination (HPV) and cervical cancer screening programmes: estimate of impact of different policy options by way of disease modelling and health economics.	*Collaborative Project (Small or medium-scale focused research project)*
4.2.	HEALTH-2009-4.2-4: Coordinating action on organ procurement and transplantation with a focus on new EU Member States.	*Coordination and Support action (Coordinating action)*
4.3. SPECIFIC INTERNATIONAL COOPERATION ACTIONS (SICA)		
4.3.1. Neglected infectious diseases.		
4.3.1.	HEALTH-2009-4.3.1-1: Discovery and development of new vaccines or drugs for helminth infections (SICA).	*Collaborative Project (Small or medium-scale focused research project)*

4.3.1.	HEALTH-2009-4.3.1-2: Identification and development of vaccine candidates for neglected bacterial infections (SICA).	*Collaborative Project (Small or medium-scale focused research project)*
4.3.1.	HEALTH-2009-4.3.1-3: Human immune responses to co-infections of poverty-Related (HIV, malaria, TB) and neglected infectious diseases (SICA).	*Collaborative Project (Large-scale integrating project)*
4.3.2. International Public Health and Health Systems		
4.3.2.	HEALTH-2009-4.3.2-1: Strategies and interventions for improving reproductive health (SICA).	*Collaborative Project (Small or medium-scale focused research project)*
4.3.2.	HEALTH-2009-4.3.2-2: Access to medicines (SICA).	*Collaborative Project (Small or medium-scale focused research project)*
4.3.2.	HEALTH-2009-4.3.2-3: Integration of Disease Surveillance and Health Systems Response (SICA).	*Collaborative Project (Small or medium-scale focused research project)*
4.3.3. Coordinated topics with Russia		
4.3.3.	HEALTH-2009-4.3.3-1 (SICA): Comparative population genetic studies on multifactorial diseases.	*Collaborative Project (Small or medium-scale focused research project)*
4.3.3.	HEALTH-2009-4.3.3-2: Mechanisms of diabetic and weight-related co-morbidity in heart failure (SICA).	*Collaborative Project (Small or medium-scale focused research project)*

Eligibility conditions:

The general eligibility criteria are set out in Annex 2 of the work programme. In addition, specific criteria apply to this call as set out below.

Eligibility criteria for each proposal are checked by Commission staff before the evaluation begins. Proposals which do not fulfil these criteria will not be included in the evaluation. For this call a proposal will only be considered eligible if it meets all of the following conditions:

- It is received by the Commission via the electronic proposal submission system respecting the deadline (date and time) as set out above.
- It involves at least the minimum number of participants as set out in the table below
- It is complete (i.e. both the requested administrative forms and the proposal description are present)
- The content of the proposal relates to the topic(s) and funding scheme(s), including any special conditions set out in the relevant parts of the work programme

It is important to note that the following ceilings for maximum EU contribution will be applied as an additional eligibility criterion and that proposals which do not respect these limits will be considered as ineligible:

- Large-scale integrating projects: the requested EC contribution shall be over EUR 6 million and not exceed EUR 12 million.

- Small or medium-scale focused research projects: the requested EC contribution shall not exceed EUR 3 million unless otherwise indicated in table 4.
- Coordination Actions: the requested EC contribution shall not exceed EUR 1.5 million unless otherwise indicated in table 4.
- Support Actions: the requested EC contribution shall not exceed EUR 0.5 million unless otherwise indicated in table 4.

The minimum number and type of participating legal entities for all funding schemes is set out in the FP7 Rules for Participation and summarised in the following table. There may be exceptions to the minimum number and participant type, which are specified in table 4.

Table 3: Eligibility conditions for each funding scheme

Funding scheme	Minimum conditions
Collaborative Project	At least 3 independent legal entities, each of which is established in a MS or AC, and no 2 of which are established in the same MS or AC
Networks of Excellence	At least 3 independent legal entities, each of which is established in a MS or AC, and no 2 of which are established in the same MS or AC
Collaborative project for specific cooperation Action (SICA) dedicated to international cooperation partner countries	At least 4 independent legal entities. Of these, 2 must be established in different MS or AC. The other 2 must be established in different international cooperation partner countries (ICPC).
Coordination and Support Action (coordinating action)	At least 3 independent legal entities, each of which is established in a MS or AC, and no 2 of which are established in the same MS or AC
Coordination and Support Action (supporting action)	At least 1 independent legal entity.

For some topics, additional eligibility criteria apply, over and above the criteria stated above (see table 4):

Table 4: Particular requirements for specific topics

Area	Topics	Particular requirements
1.2	HEALTH-2009-1.2-1: Development of tools for sensitive and specific in vitro detection of proteins and their interactions for diagnostic, prognostics and monitoring purposes.	The requested European Community contribution in each project shall not exceed EUR 6 000 000.
1.2	HEALTH-2009-1.2-4: Novel imaging systems for in vivo monitoring and quality control during tumour ion beam therapy.	The requested European Community contribution in each project shall not exceed EUR 6 000 000. Only up to one project can be selected.
1.2	HEALTH-2009-1.2-5: Activatable or smart in vivo imaging agents reporting on physico-chemical or molecular changes relevant to the diagnosis and/or monitoring of diseases	The requested European Community contribution in each project shall not exceed EUR 6 000 000.

1.2	HEALTH-2009-1.2-6: Evaluation of the potential health impact of diagnostic imaging agents doses**.**	Maximum of one project to be selected for each of the two areas specified in the topic description.
1.3	HEALTH-2009-1.3-1: New initiatives towards the implementation of the Replace, Reduce and Refine strategy.	The requested European Community contribution in each project shall not exceed EUR 1 000 000.
1.4	HEALTH-2009-1.4-1: Cell therapy for tissue and organs.	One or more projects can be selected.
1.4	HEALTH-2009-1.4-2: Regeneration of tissue using bio-compatible materials and cells.	One or more projects can be selected.
1.4	HEALTH-2009-1.4-3: Activation of endogenous cells as an approach to regenerative medicine.	One or more projects can be selected.
2.3.1	HEALTH-2009-2.3.1-2: Impact of specific antibiotic therapies on the prevalence of resistant bacteria in the human host.	The requested European Community contribution in each project shall not exceed EUR 6 000 000.
2.3.1.	HEALTH-2009-2.3.1-3: Clinical evaluation of point-of-care diagnostic tests for microbial detection and identification, antibiotic susceptibility determination and biomarkers.	The requested European Community contribution in each project shall not exceed EUR 6 000 000.
2.3.2.	HEALTH-2009-2.3.2-5: Translational vaccine research for poverty-related diseases (HIV/AIDS, malaria and/or TB).	Only up to one project can be selected.
2.3.3.	HEALTH-2009-2.3.3-1: Efficacy and effectiveness of personal protection equipment and other measures against influenza transmission.	Only up to one project can be selected.
2.4.3.	HEALTH-2009-2.4.3-1: Novel therapeutical approach to pregnancy-induced diabetes.	Only up to one project can be selected.
2.4.3.	HEALTH-2009-2.4.3-3: Molecular pathways in food intake at CNS-liver-gut regulation level.	Only up to one project can be selected.
2.4.4	HEALTH-2009-2.4.4-1: Rare neurological diseases.	The requested European Community contribution in each project shall not exceed EUR 6 000 000.
2.4.5.	HEALTH-2009-2.4.5-1: Prevention and treatment of non-alcoholic fatty liver disease (NAFLD).	The requested European Community contribution in each project shall not exceed EUR 6 000 000.
3.2.	HEALTH-2009-3.2-4: Impact of cross border collaboration on health services.	The requested European Community contribution in each project shall not exceed EUR 6 000 000.
4.1.	HEALTH-2009-4.1-1: Monitoring tool and technology transfer analysis for health grants during FP7.	The requested European Community contribution in each project shall not exceed EUR 1 000 000.
4.1.	HEALTH-2009-4.1-2: Dissemination of results from research in Life Sciences and Biotechnology for Health to the general public and/or information multipliers.	The requested European Community contribution in each project shall not exceed EUR 1 000 000. One or more projects can be selected.
4.2.	HEALTH-2009-4.2-1: Adapting off-patent medicines to the specific needs of paediatric populations.	The requested European Community contribution in each project shall not exceed EUR 6 000 000.
4.2.	HEALTH-2009-4.2-2: Study of the Arrhythmogenic potential of different classes of medicines.	The requested European Community contribution in each project shall not exceed EUR 3 000 000.

4.2.	HEALTH-2009-4.2-3: Human Papillomavirus Vaccination (HPV) and cervical cancer screening programmes: estimate of impact of different policy options by way of disease modelling and health economics.	Only up to one project can be selected.
4.3.1.	HEALTH-2009-4.3.1-1: Discovery and development of new vaccines or drugs for helminth infections (SICA).	The requested European Community contribution in each project shall not exceed EUR 6 000 000. SICA – Minimum number of participants: 2 from different Member States or associated countries and 2 from ICPC Countries.
4.3.1.	HEALTH-2009-4.3.1-2: Identification and development of vaccine candidates for neglected bacterial infections (SICA).	The requested European Community contribution in each project shall not exceed EUR 6 000 000. SICA – Minimum number of participants: 2 from different Member States or associated countries and 2 from ICPC Countries.
4.3.1.	HEALTH-2009-4.3.1-3: Human immune responses to co-infections of poverty-related (HIV, malaria, TB) and neglected infectious diseases (SICA).	SICA – Minimum number of participants: 2 from different Member States or associated countries and 2 from ACP Countries.
4.3.2.	HEALTH-2009-4.3.2-1: Strategies and interventions for improving reproductive health (SICA).	SICA – Minimum number of participants: 2 from different Member States or associated countries and 2 from ICPC Countries.
4.3.2.	HEALTH-2009-4.3.2-2: Access to medicines (SICA).	SICA – Minimum number of participants: 2 from different Member States or associated countries and 2 from ICPC Countries.
4.3.2.	HEALTH-2009-4.3.2-3: Integration of Disease Surveillance and Health Systems Response (SICA).	SICA – Minimum number of participants: 2 from different Member States or associated countries and 2 from ACP Countries or Asian Countries.
4.3.3.	HEALTH-2009-4.3.3-1 (SICA): Comparative population genetic studies on multifactorial diseases.	Only up to one project can be selected. SICA – Minimum number of participants: 2 from different Member States or associated countries and 2 from Russia.
4.3.3.	HEALTH-2009-4.3.3-2: Mechanisms of diabetic and weight-related co-morbidity in heart failure (SICA).	Only up to one project can be selected. SICA – Minimum number of participants: 2 from different Member States or associated countries and 2 from Russia.

In line with the objectives of each topic, additional eligibility criteria may be indicated in the work programme

Evaluation procedure: The basic principles of the Evaluation criteria for proposals are described in Annex 2 of the work programme. However, for this call, the priority order for

proposals with the same score will be determined in the manner described under 'Proposal ranking' (see below).
For all proposals submitted to this call the evaluation shall follow a single stage procedure. The proposers are requested to follow the instructions set out in the guide for applicants and in the proposal part B template available through the EPSS, including page number limitations and a minimum font size of 11. The Commission will instruct the experts to disregard any pages in excess of these limits. The proposals will be evaluated by external experts on the basis of three evaluation criteria. The individual evaluation will be carried out remotely and the consensus meetings of evaluators will be held in Brussels.

Evaluation criteria and thresholds: For this call the following criteria and thresholds are applied. For each criterion marks from 0 to 5 will be given, with the possibility of half point scores. For proposals failing to achieve a threshold for a criterion, the evaluation of the proposal will be stopped at the first criterion failing a threshold. Therefore for such proposals the ESR (evaluation summary report) will not contain marks and comments for the remaining criteria. Successful proposals must pass the following minimum thresholds:

Table 5: Thresholds for evaluation criteria

Criterion	Minimum threshold
S/T quality	**3/5**
Implementation	**3/5**
Impact	**3/5**
Overall threshold	**10/15**

In line with the objectives of each topic, additional evaluation criteria may be indicated in the work programme.

Proposal ranking: The series of priority lists will be prepared by the panels of external experts, per indicative sub-budget line as set out in this call fiche. The aspects taken into account for establishing a priority order for ranking of proposals are as follows:

- First by overall score;
- Second, proposals with the same overall score will be ranked based on the score for the Science and Technology (S/T) quality criterion;
- To avoid prioritising any proposals of similar content to those proposals with higher scores already on the list
- Then also to be taken into account: coverage of the work programme (the overall balance of proposals to be funded), provided proposals of sufficient quality have been submitted, and any strategic objectives and/or community policies specified in the work programme.

There will be differing numbers of proposals short-listed according to the funding scheme and topic. However, there may be topics for which no proposals are of sufficient quality to be

selected for funding, as there will be competition within topics and between topics on the basis of the quality of the proposals.

- For Large-scale Integrating Projects, Networks of Excellence, Coordination and Support Actions, **up to one proposal** can be funded per topic, unless otherwise stated in the topic description in the topic description in table 4 (particular requirements for specific topics).
- For small and medium-scale Focused Research Projects, **one or more proposals** can be funded per topic, unless otherwise stated in the table.

The Commission ranked lists of proposals to be retained for negotiation will be based on the priority list established by the panel of external experts taking into account the budget available for each budget line (as indicated in this call for proposals). For each budget line, a number of proposals below the indicative budget cut-off line on the Commission ranked list may be kept on a reserve list to allow for eventualities such as the failure of negotiations on grant agreements, the withdrawal of proposals, budget savings agreed during negotiation, or the availability of additional budget from other sources.

Indicative evaluation and contractual timetable: The first stage evaluation should be finalised in February/March 2009. Overall evaluation results are estimated to be available within 4 months after the closure date for the call. It is expected that contract negotiations for short-listed proposals would begin in May/June 2009.

Consortium agreements: Participants in large-scale integrating projects are required to conclude a consortium agreement.

The forms of grants and maximum reimbursement rates which will be offered are specified in Annex 3 to the Cooperation work programme.

Call identifier: FP7-Health-2009-two-stage

Proposal submission and evaluation: two-stage procedure. Collaborative Projects (large-scale integrating projects)

Date of publication: 3 September 2008[22]

Deadline for stage 1 proposals: 3 December 2008 at 17.00.00 (Brussels local time)[23]

Indicative budget: EUR 115 million from the 2009 budget[24]

- The budget for this call is indicative. The final budget awarded to this call, following the evaluation of proposals, may vary by up to 10% of the total value of the call.

Table 1

ACTIVITY/AREA	FUNDING SCHEME	Indicative budget (EUR million)
1. BIOTECHNOLOGY, GENERIC TOOLS AND MEDICAL TECHNOLOGIES FOR HUMAN HEALTH 1.1. HIGH-THROUGHPUT RESEARCH 2. TRANSLATING RESEARCH FOR HUMAN HEALTH 2.1. LARGE-SCALE DATA GATHERING AND SYSTEMS BIOLOGY	*Collaborative Project (Large-scale integrating project)*	**115**

Table 2: Topics called:

Area	Topics called	Funding Scheme
1.1 High-Throughput Research	HEALTH-2009-1.1-1: Computational tools for genome annotation and genotype/phenotype data integration	Collaborative project (Large-scale integrating project)
1.1 High-Throughput Research	HEALTH-2009-1.1-2: High throughput tools and technologies to analyse samples in large-scale human biobanks	
1.1 High-Throughput Research	HEALTH-2009-1.1-3: Tools, technologies and resources for the characterisation of protein functions	
2.1.1 Large-scale data gathering	HEALTH-2009-2.1.1-1: Large-scale functional genomics effort in multi-cellular organisms to elucidate the function of human genes products	
2.1.1 Large-scale data gathering	HEALTH-2009-2.1.1-2: Large-scale functional genomics efforts to identify molecular determinants of cancer	

[22] The Director-General responsible for the call may publish it up to one month prior or after the envisaged date of publication.

[23] At the time of the publication of the call, the Director-General responsible may delay this deadline by up to two months.

[24] Under the condition that the preliminary draft budget for 2009 is adopted without modifications by the budgetary authority.

2.1.1 Large-scale data gathering	HEALTH-2009-2.1.1-3: Characterisation of human genetic variation in Europe	
2.1.2 Systems Biology	HEALTH-2009-2.1.2-1: Systems biology approaches for basic biological processes relevant to health and disease	

Eligibility conditions (stage 1 and stage 2):

The general eligibility criteria are set out in Annex 2 of the work programme. In addition, specific criteria apply to this call as set out below.

Eligibility criteria for each proposal are checked by Commission staff before the evaluation begins. Proposals which do not fulfil these criteria will not be included in the evaluation. For this call a proposal will only be considered eligible if it meets all of the following conditions:

- It is received by the Commission via the electronic proposal submission system respecting the deadline (date and time) as set out above.
- It is complete (i.e. both the requested administrative forms and the proposal description are present)
- The content of the proposal relates to the topic(s) and funding scheme(s), including any special conditions set out in the relevant parts of the work programme
- It involves at least the minimum number of participants as set out in the table below.

It is important to note that the following upper and lower limits for the EU contribution will be applied as an additional eligibility criterion and that proposals (stage 1 and stage 2) which do not respect these limits will be considered as ineligible:

- For large-scale integrating projects the requested EC contribution **shall be over EUR 6 million and not exceed EUR 12 million.**

The minimum number and type of participating legal entities for all funding schemes is set out in the FP7 Rules for Participation and summarised in the following table for the funding scheme used in this call.

Table 3: Eligibility conditions

Funding scheme	Minimum participation conditions
Collaborative project	At least 3 independent legal entities, each of which is established in a MS or AC, and no two of which are established in the same MS or AC.

Evaluation procedure:

The basic principles of the Evaluation criteria for proposals are described in Annex 2 of the work programme. However, for this call, the priority order for proposals with the same score will be determined in the manner described under 'Proposal ranking" (see below).

For all proposals submitted to this call the evaluation shall follow a two-stage procedure. The proposals will be evaluated by external experts.

Stage 1 proposals

Stage 1 proposals must be submitted by the deadline mentioned above.

Stage 1 proposals should follow the instructions set out in the Guide for Applicants and in the proposal part B template available through EPSS. Proposals should focus on the overall scientific and technological content and on clear identification of the milestones to be reached (intended results), their intended use and the expected impact (scientific, economic, social, environmental, etc.) in a maximum of 5 pages (excluding the cover page and the required tables). Applicants may also provide an additional 1 page (maximum)to describe the consortium and the estimated financial resources involved. The maximum page limits of each section must be respected. The Commission will instruct the experts to disregard any pages in excess of these limits. A minimum font size of 11 is required.

Stage 1 proposals will be evaluated remotely and at consensus meetings of evaluators in Brussels.

Stage 1 proposals will be evaluated on the basis of the following two criteria: **Scientific/technological quality** and **Impact**. For each criterion, marks from 0 to 5 will be given, with the possibility of half-point scores. Proposals must pass the minimum thresholds as follows:

Table 3: Thresholds for evaluation criteria for first stage

Criterion	Minimum threshold
S/T quality	**4/5**
Impact	**3/5**
Overall threshold	**8/10**

Coordinators of proposals retained at stage 1 (proposals passing the evaluation thresholds) will be invited to submit a complete proposal (stage 2 proposal) that will then be evaluated against the entire set of evaluation criteria.

Proposals will be retained at stage 1 (proposals passing the evaluation thresholds) to a total budgetary value of maximum 3 times the indicative budget for this call.

Stage 2 proposals

The proposers are requested to follow the page limitation instructions as set out in the Guide for Applicants and in the proposal part B template available through the EPSS, respecting page number limitations and a minimum font size of 11. The Commission will instruct the experts to disregard any pages in excess of these limits.

The deadline for submission for stage 2 proposals will be specified in the invitation to submit. The **indicative deadline** for stage 2 proposals is: 22 April 2009.

Stage 2 proposals will be evaluated remotely and at consensus meetings of evaluators in Brussels.

Stage 2 proposals are evaluated on the basis of the following three criteria: **Scientific/technological quality** and **Implementation** and **Impact**. For each criterion, marks from 0 to 5 will be given, with the possibility of half-point scores. Proposals must pass the minimum thresholds as follows:

Table 4: Thresholds for evaluation criteria for second stage

Criterion	Minimum threshold
S/T quality	**4/5**
Implementation	**3/5**
Impact	**3/5**
Overall threshold	**12/15**

Proposal ranking at stage 2: A priority list will be prepared by the panel of external experts. The aspects taken into account for establishing a priority order for ranking of proposals will be as follows:

- First, overall score;
- Second, proposals with the same overall score will be ranked based on the score for the Science and Technology (S/T) quality criterion;
- To avoid prioritising any proposals of similar content to those proposals with higher scores already on the list
- Then also to be taken into account: coverage of the work programme (the overall balance of proposals to be funded), provided proposals of sufficient quality have been submitted, and any strategic objectives and/or community policies specified in the work programme.
- For the topics of this call, which are all for Large-scale Integrating Projects, **one or more proposals** can be selected for funding for any given topic.

However, there may be topics for which no proposals are of sufficient quality to be selected for funding, as there will be competition within topics and between topics on the basis of the quality of the proposals

The Commission ranked list of proposals to be retained for negotiation will be based on the priority list established by the panel of external experts taking into account the budget available (as indicated in this call for proposals). A number of proposals below the indicative budget cut-off line on the Commission ranked list may be kept on a Commission reserve list to allow for eventualities such as the failure of negotiations on grant agreements, the withdrawal of proposals, budget savings agreed during negotiation, or the availability of additional budget from other sources.

Indicative evaluation and contractual timetable: The first stage evaluation should be finalised at the end of January 2009. The evaluation of the second stage is expected to take place in May 2009. Overall evaluation results: estimated to be available within 3 months after the closure date for stage 2 proposals. It is expected that contract negotiations for short-listed proposals would begin in July 2009**.**

Consortium agreements: Participants in large-scale integrating projects are required to conclude a consortium agreement.

Forms of grant and maximum reimbursement rates for projects funded through the Cooperation work programme are given in Annex 3.

IV OTHER ACTIONS

Human Frontier Science Programme Organisation

An annual subscription to the international Human Frontier Science Programme Organisation (HFSPO)[25] will be made jointly with the Information and Communication Technologies (ICT) Theme. This will allow EU non-G8 Member States to fully benefit from the Human Frontier Science Programme (HFSP) and provide increased visibility for European research. Out of the total Community subscription of EUR 3 981 000 for 2009, EUR 2 388 600 will be paid from this Theme, and the remainder from the ICT Theme. **Funding scheme:** CSA – subscription.[26]

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

[26] In accordance with Article 14(d) of Regulation (EC) No 1906/2006 of 18 December 2006 laying down the rules for the participation of undertakings, research centres and universities in actions under the Seventh Framework Programme and for the dissemination of research results (2007-2013).
In accordance with Article 108(2)(d) of the Financial Regulation and Article 160a of the detailed rules of the implementation of the Financial Regulation.

V BUDGET

All budgetary figures given in this work programme are indicative. Following the evaluation of proposals the final budget awarded to actions implemented through calls for proposals may vary:

- by up to 10% of the total value of the indicated budget for each call; and
- any repartition of the call budget may also vary by up to 10% of the total value of the indicated budget for the call.

The final budgets for evaluation, monitoring and review may vary by up to 20% of the indicated budgets for these actions. The final budgets for all other actions not implemented through calls for proposals may vary by up to 10% of the indicated budget for these actions.

	2009[27] EUR million
CALL FP7-HEALTH-2009-single-stage	476.000
CALL FP7-HEALTH-2009-two-stage	115.000
CALL FP7-ERANET-2009-RTD (Annex 4)	2.000
GENERAL ACTIVITIES	8.319
OTHER ACTIVITIES: Evaluations: HFSP: Call for tender	 5.800 2.388 0.200
ESTIMATED TOTAL BUDGET ALLOCATION	609.707

Indicative budget General Activities

	2009 EUR million
CORDIS	2.161
Eureka/Research organisations	0.066
COST	6.055
ERA-NET	0.038
Total	**8.319**

[27] Under the condition that the preliminary draft budget for 2009 is adopted without modifications by the budgetary authority.

Indicative budget breakdown Call FP7-HEALTH-2009-single-stage

ACTIVITY/AREA		Indicative budget[28] (EUR million)
1. BIOTECHNOLOGY, GENERIC TOOLS AND MEDICAL TECHNOLOGIES FOR HUMAN HEALTH		
1.2 DETECTION, DIAGNOSIS AND MONITORING 1.3 SUITABILITY, SAFETY, EFFICACY OF THERAPIES 1.4 INNOVATIVE THERAPEUTIC APPROACHES AND INTERVENTIONS		120
2. TRANSLATING RESEARCH FOR HUMAN HEALTH		
2.2 RESEARCH ON THE BRAIN AND RELATED DISEASES, HUMAN DEVELOPMENT AND AGEING		41
2.3. TRANSLATIONAL RESEARCH IN MAJOR INFECTIOUS DISEASES: TO CONFRONT MAJOR THREATS TO PUBLIC HEALTH		75
2.4. TRANSLATIONAL RESEARCH IN OTHER MAJOR DISEASES		95
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 MEDICINES, AND APPROPRIATE USE OF BEHAVIOURAL AND ORGANISATIONAL INTERVENTIONS AND NEW HEALTH THERAPIES AND TECHNOLOGIES 3.2. QUALITY, EFFICIENCY AND SOLIDARITY OF HEALTHCARE SYSTEMS INCLUDING TRANSITIONAL HEALTH SYSTEMS 3.3. ENHANCED HEALTH PROMOTION AND DISEASE PREVENTION		64
4. OTHER ACTIONS ACROSS THE HEALTH THEME		
4.1. COORDINATION AND SUPPORT ACTIONS ACROSS THE THEME		3
4.2. RESPONDING TO EU POLICY NEEDS		33
4.3. SPECIFIC INTERNATIONAL COOPERATION ACTIONS (SICA)	4.3.1. Neglected infectious diseases	27
	4.3.2. International Public Health and Health Systems	12
	4.3.3. Coordinated topics with Russia	6

[28] Under the condition that the preliminary draft budget for 2009 is adopted without modifications by the budgetary authority.

Indicative budget breakdown Call FP7-HEALTH-2009-two-stage

ACTIVITY/AREA	Indicative budget (EUR million)[29]
1. BIOTECHNOLOGY, GENERIC TOOLS AND MEDICAL TECHNOLOGIES FOR HUMAN HEALTH 1.1. HIGH-THROUGHPUT RESEARCH 2. TRANSLATING RESEARCH FOR HUMAN HEALTH 2.1. LARGE-SCALE DATA GATHERING AND SYSTEMS BIOLOGY	**115**

[29] Under the condition that the preliminary draft budget for 2009 is adopted without modifications by the budgetary authority.