WORK PROGRAMME 2010

COOPERATION

THEME 1

HEALTH

(European Commission C(2009) 5893 of 29 July 2009)

Objective: Improving the health of European citizens and increasing the competitiveness and boosting 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 in clinical applications including scientific validation of experimental results), the development and validation of new therapies, methods for health promotion and prevention including promotion of child health, healthy ageing, diagnostic tools and medical technologies, as well as sustainable and efficient healthcare systems.

I CONTEXT

Approach for 2010

This work programme 2010 is to be published in July 2009 for proposals to be selected in 2010. It aims to ensure continuity with the previous work programme and to develop new activities within the budgetary constraints. The estimated total budget allocation for work programme 2010 is EUR 638 238 951 drawing from the 2010 budget[1]. Section II of this document describes the topics for which project proposals can be submitted; sections III and IV describe the modalities for implementation of the different calls[2] and other actions. The estimated budget breakdown for work programme 2010 is provided in section V.

Clinical research will continue to be a main focus in many topics, both in area *'Biotechnology, generic tools and medical technologies for human health'* and in area *'Translating research for human health'*. In addition area *'Optimising the delivery of healthcare'* supports the translation of clinical results into clinical practice. For clinical trials, EC contribution will be limited to phases I and II and only exceptionally to further studies[3]. Projects conducting clinical research must take into account (in the research protocols, methodologies and analysis of results) possible differences in relation to gender and age.

Responding to EU policy needs linked to new legislation: Research and networking will continue to enable support for EU efforts to adapt off-patent medicines to the needs of paediatric populations, to investigate adverse drug reactions at European level and to enable better safety assessments of drugs and cosmetics through the identification of toxicity pathways. Efforts will continue to ensure coherence with the *Innovative Medicines Initiative (IMI)*[4,5] priorities for 2009 and 2010 and complementarity with *EDCTP*[6] to combat poverty-related diseases. In this work programme, the fields of allergies and vector-borne diseases will be the subject of coordination with Themes Environment (including climate change) and Food, Agriculture, Fisheries, and Biotechnology.

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[1] Under the condition that the preliminary draft budget for 2010 is adopted without modifications by the budgetary authority.

[2] FP7-HEALTH-2010-single-stage; FP7-HEALTH-2010-two-stage; FP7-HEALTH-2010-Alternative-Testing; FP7-INFLUENZA-2010; FP7-AFRICA-2010; FP7-ERANET-2010-RTD;

[3] *e.g.* in the topics HEALTH.2010.2.4.1-3: Structuring clinical research in paediatric and adolescent oncology in Europe; HEALTH-2010-2.4.4.-1 "Clinical development of substances with a clear potential as orphan drugs"; HEALTH-2010-4.2-1 "Off-patent medicines for children", consideration may be given to studies including up to Phase III clinical trials.

[4] 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

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

[6] European and Developing Countries Clinical Trials Partnerships

In 2010, the main focus will be on the following three key challenges: *Providing tools for translational research, Structuring translational research in the field of cancer* and *Structuring translational research in the field of neurodegenerative diseases*. In addition, this work programme features a special focus for better health for Africa also in a special call for Africa (see also section II) with Themes Environment (including climate change) and Food, Agriculture and Fisheries, and Biotechnology (details see under 'International Cooperation'). In parallel, a number of actions will be undertaken to strengthen the European Research Area (ERA) in other areas and to support EU policies. A targeted action is launched for the development of safety methods with higher predicted value, faster and cheaper than animal tests. The three ERA-NETs in this work programme will be part of the call FP7-ERANET-2010-RTD.

Providing tools for translational research: Developing tools for translational research is an overarching objective of the Health Theme, which includes the following aspects: ***Systems biology, cell therapy*** **and** ***diagnostics***. Overall this will contribute towards structuring EU efforts and better understanding of disease mechanisms, drug discovery and translational research.

Structuring translational research in the field of cancer: The aim is to develop a structured European approach in both the areas of cancer systems biology and cancer therapy by bringing together resources not available in any single country. The former will facilitate understanding the complex networks of ***genes involved in cancer development***. The latter addresses comprehensively ***new avenues for cure***. Other areas of action include ***survivor studies*** as well as ***patient stratification technologies***.

Structuring translational research in the field of neurodegenerative diseases: ***Neurodegenerative diseases*** and particularly ***dementia*** are becoming a global medical and socio-economic challenge. Only a structured European approach can address this major challenge by pooling and coordinating the efforts of basic and clinical researchers in this field.

- **SME relevant research**

The work programme 2010 will continue to foster SME participation, with a number of topics that are particularly attractive to SMEs. *Nevertheless, for all areas of work programme 2010, 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, toxicology studies) are also eligible to participate.*

- **International Cooperation**

For all areas of the programme, project consortia are encouraged to include also participants from countries, which are neither from EU Member States (MS), nor from countries Associated to FP7 (AC). Organisations established in international cooperation partner countries (ICPC)[7] are eligible for funding. Special international cooperation actions (SICAs) will be particularly targeted for research activities in the areas of infectious diseases, health systems, cancer and reproductive and child health supporting the realisation of the WHO Millennium Development Goals (MDG). Some topics will also be dedicated to participants from regions such as *Asia* and *Latin America*. A particular focus will be on health-related research challenges that are of major concern to *Africa* as set out in the special call for Africa.

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

In recognition of the opening of NIH[8] programmes to European researchers, participants established in the *United States of America* are eligible to participate and to be funded in the context of the topics described in this work programme. Furthermore, coordination of research with certain third countries is set out in specific topics such as the topics coordinated with *China, Egypt* as well as *Russia*.

- **Cross-thematic approaches**

In this work programme, complementarity is ensured with other Themes of the Cooperation Programme. In particular with Themes 'Food, Agriculture and fisheries, and Biotechnology', '*Information & Communication Technologies*'; '*Nanosciences, Nanotechnologies, Materials and new Production Technologies*'; '*Environment (including Climate Change)* and *Socioeconomic Sciences and Humanities*'.

CALL FP7-AFRICA-2010

This call is implemented jointly by Theme 1: 'Health', Theme 2: 'Food, Agriculture and fisheries, and Biotechnology' and Theme 6: 'Environment (including climate change)'. The aim of this call is to address some of the Science & Technology objectives of the "Africa - EU Strategic Partnership" putting emphasis on "Water and Food Security and "Better Health for Africa". This call has a multi-disciplinary approach involving various scientific and technological research fields, such as food, agriculture, health, land and water resources, including their interaction with climate change, which have to be considered within an integrated scheme, and, where appropriate at river basin scale, building on existing knowledge and considering demographic changes, globalisation processes and sustainability. Due consideration should also be given to the various geographical, sectoral and cultural differences which exist within Africa. The integrated approach should also take into account broader socio-economic factors including: migration and resettlements, urbanisation, health care systems and programme interventions, destabilisation of national food reserves, variations of food and oil prices, etc. The various topics called are indicated in the corresponding work programmes.

The call intends principally to strengthen local capacities in the relevant science and technology fields and their applications, also through appropriate training activities and exchange of staff. The final outputs should provide amongst others, innovative management and governance tools and adaptive technologies suitable for the relevant authorities and stakeholders for providing contributions to reduce poverty, increase food security, academic training and health research networks, manage water more efficiently and protect natural ecosystems in Africa.

The participation of local stakeholders, and/or regional actors, and the necessary networking, is considered of paramount importance to achieve the expected impact.

Relevant projects selected from each topic should establish synergies between them to enhance complementarities in the implementation phase. Therefore, a dedicated budget for clustering and coordination activities between the relevant selected projects should be foreseen in the overall budget planning of each proposal. The details of these topic-to-topic coordination activities will be defined during the negotiation phase with the Commission. A further coordinating action promoted by the International Cooperation activities under the "Capacities" specific programme will also help establishing further synergies with other national, regional or international programmes.

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

CALL FP7-INFLUENZA-2010

A special call for Influenza is implemented through cross-thematic collaboration involving Theme1: 'Health' and Theme 2: 'Food, Agriculture and fisheries, and Biotechnology'.

The recent outbreak of a novel human-to-human transmissible A (H1N1) virus, containing human, swine and avian sequences, has raised a number of research questions. Some are directly related to this outbreak and viral strain and are currently being addressed by a number of research groups worldwide. FP7 as well as previous Framework Programmes have supported a large number of research projects on influenza and have led to important results.

This call is meant to complement this portfolio and to address important research priorities that will help Europe and the world to be better prepared for future epidemics. Swine influenza is a highly contagious viral infection of swine caused by influenza A viruses. Swine influenza viruses are some of the most prevalent respiratory viruses of pigs and a cause of acute respiratory disease outbreaks. Pigs are an important host in influenza virus ecology since they are also susceptible to infection with both human and avian influenza A viruses. It is generally accepted that pigs can play a role in the transmission of avian influenza viruses to humans. Unlike for humans and poultry, the surveillance and general knowledge of influenza viruses in swine populations are more limited. A network of laboratories working on swine influenza has been supported in FP5 and FP6 for the surveillance in pigs in Europe and research in swine influenza viruses is partially/marginally addressed within the wider context of influenza.

The emergence of a new H1N1 virus on the American continent in humans, which shares common features with swine influenza viruses, calls for the mobilisation of further research efforts in the pig, complementing current on-going activities in influenza in humans and birds. In humans, vaccination is the cornerstone of prevention, but treatment with antiviral drugs remains an essential element for the treatment of infected individuals as well as for the containment or mitigation of outbreaks. Recently developed neuraminidase inhibitors represent an efficient drug for most viral strains, but the emergence of resistance to these drugs has been observed in other H1N1 strains as well as in some H5N1 strains. Therefore additional treatment strategies for influenza are urgently needed.

- **Dissemination actions**

Coordination and Support Actions will focus on technology transfer, on capacity building and on the dissemination of results. It is important that 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**

With regard to submission, evaluation and selection procedures both, single-stage as well as two-stage submission and evaluation procedures will be used in separate calls. The relevant call is indicated for each topic in section II and the details for the procedures in separate call fiches in section III. 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[9] are described in the Guide for Applicants (Annex 4, section 4).

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

[9] http://cordis.europa.eu/fp7/ethics_en.html

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 relevant research funded by the European Commission.

Funding schemes: The work programme 2010 is implemented through a range of funding schemes. The forms of the grants to be used for the various funding schemes are described in section III and the guides for applicants. For each funding scheme there are limits on the requested EC contribution (see topic description in section II and table 2 in section III for details). **It is important to note that upper and lower funding limits will be applied as eligibility criteria so that proposals that do not respect these limits will be considered ineligible (see section III implementation).** Furthermore, proposals responding to a Specific International Cooperation Actions (SICA) topic must involve at least two participants from different Member States or Associated States plus two from different International Cooperation Partner Countries (ICPC)[10], see details in topic descriptions in section II and any special conditions relating to the topics laid out in the call for Africa.

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 (of 11 point) as set out in the Guide for Applicants. Parts of the proposals extending beyond these limitations will not be considered in the evaluation.

[10] 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 but at least two different participants must come from two different provinces, republics, states oblasts within Brazil, China, India or Russia.

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'.

Note: for the following topics HEALTH.2010.1.1-1, HEALTH.2010.1.1-2 and HEALTH.2010.1.1-3 applicants will have to follow the rules for single-stage submission procedure (see respective call fiche in section III).

HEALTH.2010.1.1-1: Harmonisation of phenotyping and biosampling for human large-scale research biobanks. FP7-HEALTH-2010-single-stage. The project should improve the assessment and classification of multivariate phenotypes associated with complex diseases, including environmental and life style exposures, enabling interoperability of databases of both phenotype and genotype data. The project should also develop evidence-based standards for harmonised quality management and quality control during the collection, transport, processing, storage and retrieval of human biospecimens (tissues, blood, other body fluids). The project is expected to develop effective strategies for optimising the correlation and integration of existing and novel data, maximizing the sharing and exchange of information between population cohorts and clinical research centres/biobanks across Europe. The project should build on pre-existing achievements (where available) and coordinate its activities with similar international efforts. Ethical, social and legal aspects, as well as the relevance to public health, should be tackled appropriately. Active participation of SMEs could lead to an increased impact of the research proposed and this will be considered in the evaluation of the proposal. **Note:** Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria. You must refer to the call fiche for details of these limits.
Funding scheme: Collaborative project (Large-scale integrating project)
EC contribution per project: min. EUR 6 000 000 – max. EUR 12 000 000
Only up to one proposal can be selected.
Expected impact: Biobanks are increasingly seen as an essential tool in translating biomedical research. By addressing some of the today's challenges in the overall field of human biobanks, the project is expected to maximise the potential of both existing and new research biobanks and support multicentric studies for translational health research across Europe.

HEALTH.2010.1.1-2: Genomics and Genetic Epidemiology of Multifactorial Diseases. FP7-ERANET-2010-RTD[11]. The project should bring together national programmes on

[11] Call fiche: see ANNEX 4 to the cooperation work programme

genomics and genetic epidemiology of multifactorial diseases. It should also create synergies by uniting vast amount of data, resources and know-how which exist in different member states. **Note:** Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria. You must refer to the call fiche for details of these limits.
Funding scheme: ERA-NET Coordination and Support Action (Coordinating Action)
EC contribution per ERA-NET: max. EUR 2 000 000
Only up to one proposal can be selected.
Expected impact: This ERA-NET will coordinate national programmes on genomics and genetic epidemiology of multifactorial diseases. It will establish a platform for setting joint priorities and strategies for research programmes, launch joint transnational calls for proposals, and foster collaboration between scientists from different countries and thereby contribute to the creation of the European Research Area.

HEALTH.2010.1.1-3: High-throughput analysis of post-translational modifications of proteins. FP7-HEALTH-2010-single-stage. Research should aim to establish technologies of high-throughput analysis of post-translational modification in clinical samples. Specific classes of modifications should be identified and characterized, and procedures and reagents should be developed to enable analysis of these modifications in clinical samples. The approach should overcome limitations of current techniques and the procedure should be used to address important biomedical problems. The resulting project will be asked to collaborate closely with similar, locally funded projects from China. A part of the budget should be set aside for this cooperation. Active participation of SMEs could lead to an increased impact of the research proposed and this will be considered in the evaluation of the proposal. **Note:** Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria. You must refer to the call fiche for details of these limits.
Funding scheme: Specific International Cooperation Action (**SICA)**, Collaborative Project (Small or medium-scale focused research project). Target Regions: at least two different regions of China.
EC contribution per project: max. EUR 3 000 000.
Only up to one proposal can be selected.
Expected impact: This initiative is expected to lead to a much closer cooperation between Member States, Associated Countries and China than is the case for traditional FP projects. It is expected that the Chinese authorities (Ministry of Science and Technology, MoST) will issue a similar call, within its research programme, to finance Chinese projects in the area and the EC funded project would cooperate closely with that related project.

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. **Note:** For topic HEALTH.2010.1.2-1: applicants will have to follow the rules for two-stage submission procedure (see respective call fiche in section III).

Note: for the following topics HEALTH.2010.1.2-2, HEALTH.2010.1.2-3 and HEALTH.2010.1.2-4 applicants will have to follow the rules for single-stage submission procedure (see respective call fiche in section III).

Topic for two-stage submission and evaluation; deadline 1st stage: 29 October 2009

HEALTH.2010.1.2-1: Tools for the identification and the detection of biomarkers in clinical samples and patients. FP7-HEALTH-2010-two-stage. Research should focus on innovative tools and technologies for the discovery and/or the use of specific biomarkers in clinical samples and patients. A combination of bio-imaging and molecular testing markers could be considered. An open approach is proposed with this broad topic considering a two-stage procedure for submitting proposals. Proposers are invited to consider at least one of the following areas; integration of more than one area could lead to an increased impact of the research proposed, and this will be considered in the evaluation of the proposal. Clinicians should be involved as appropriate. Active participation of SMEs could also lead to an increased impact of the research proposed and this will also be considered in the evaluation of the proposal. **Note:** Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria. You must refer to the call fiche for details of these limits.

- **Multimodality biomarker analysis:** Development of workflows, methods and devices for multiplex analysis of biomarkers (RNA, DNA, proteins or others in parallel) with the potential for analysis in routine diagnostics. The focus should be on analytical tools and methods but not on the search of new biomarkers. Participation of the industry, including SMEs, is expected.
- **Tools for detection, isolation and functional characterisation of complexes of interacting molecules for diagnostic purposes:** Tools for detection, isolation and functional characterisation of complexes and robust methods for isolation and quantification of interacting complexes suitable for detection in patient samples should be developed. Research should focus on interactions among proteins with each other and with other classes of bio-molecules like DNA and coding or non coding RNA molecules in disease states. These complexes could become new classes of biomarkers for diagnostic purposes.
- **Development of new quantitative imaging biomarker(s) for monitoring therapeutic effects and safety in chronic diseases:** The project(s) should develop new quantitative imaging biomarker(s) that should provide surrogates for monitoring treatment response or safety at an early stage. The imaging biomarkers considered here can be newly developed molecules, novel technological approaches, or established imaging technologies with novel applications. They should have the potential to be translated into clinical use. The project(s) should address validation of the biomarkers in major chronic disease.
- **High throughput molecular diagnostic imaging:** Research should develop the integration of high throughput molecular testing with detailed cellular imaging for advanced diagnosis and monitoring of disease. The goal is to integrate sophisticated sample selection and handling technologies (e.g. microfluidics, micro-cell culture, arraying and/or conditioning) with powerful, innovative imaging technologies (e.g. scanning probe, electron or fluorescence microscopies), including advanced image analysis, in a quest for new powerful clinically-relevant biomarkers.
- **Development and implementation of Quantum Imaging of X-rays/γ-rays for Diagnosis:** Research should aim to develop and implement quantum X- or γ-ray detection for a diagnostic imaging setting. Potential implementations of such detectors should include at least one or more of the following: fast, low dose dynamic imaging of

moving tissues or organs; specific, spectrally resolved imaging of patients; high resolution reconstruction of low contrast tissues in minimal radiation dose conditions. Potential applications should concern major chronic disease, such as neurological or cardiovascular disorders, or cancer. The developed method(s) should be tested at least pre-clinically.

Funding scheme: Collaborative Project (Small or medium-scale focused research project)
EC contribution per project: max. EUR 6 000 000
One or more proposals can be selected.
Expected impact: Research should aim to structure the European research in the field of new biomarkers. In some cases, a new innovation step could be achieved by the convergence of medical imaging and in vitro diagnostics approaches. Whatever the approach (in vivo, in vitro or in combination), it should lead to advances over existing tools and technologies for the discovery and/or the use of specific biomarkers. The outcomes should meet bio-medical research or clinical needs and have the potential for clinical validation and exploitation. Research should lead to new non-invasive prediction, diagnosis, monitoring and/or prognosis of disease, in view of a benefit to the patients and, when appropriate, involve the European diagnostics industry, including SMEs.

HEALTH.2010.1.2-2: Stratification approaches and methodologies to select from a wide range of biomarkers relevant candidates for clinical validation. FP7-HEALTH-2010-single-stage. The number of potentially clinically relevant biomarkers is increasing tremendously. There is a need for standardised and superior approaches that would allow discrimination of the best candidates for diagnostic purposes before bringing them to clinical trials. The focus should be on the identification of bottle necks, approaches and technologies. It should help characterising the pipeline problem of diagnostics biomarkers and identifying possible solutions. Specific attention should be paid to standardisation, reproducibility and harmonisation of procedures. The outcome should be recommendations and guidelines for the screening of biomarkers in specific diseases. Participation of the industry is expected. Active participation of SMEs could lead to an increased impact of the research proposed and this will be considered in the evaluation of the proposal. Projects should not exceed 18 months. **Note:** Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria. You must refer to the call fiche for details of these limits.
Funding scheme: Coordination and Support Action (Supporting Action)
EC contribution per project: max. EUR 500 000
Only up to one proposal can be selected.
Expected impact: This action should answer the need for standardised and superior approaches in discriminating the best candidates for the validation of diagnostics biomarkers. It should help the relevant stakeholder defining better strategies. The Support Action should benefit to the European diagnostics industry, including SMEs.

HEALTH.2010.1.2-3: Harmonization, validation and standardisation in genetic testing. FP7-HEALTH-2010-single-stage. This Coordinating Action should promote harmonisation and quality assurance of genetic practice and give consideration to non-invasive prenatal diagnostics. It should contribute to accreditation and certification, and provide quality-assured information, including informatics tools. Outcomes should be validation of methods and technologies, training, counselling, quality procedures and guidelines. **Note:** Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria. You must refer to the call fiche for details of these limits.
Funding scheme: Coordination and Support Action (Coordinating Action)

EC contribution per project: max. EUR 2 000 000
Only up to one proposal can be selected.
Expected impact: The action should lead to harmonisation and quality assurance of genetic practice in Europe. It is expected to help structuring European research and diagnostic services in genetics. Benefits to the patients and the European diagnostics industry are expected.

HEALTH.2010.1.2-4: Early events in acute hepatitis C virus (HCV) infection with the aim to identify new biomarkers. FP7-HEALTH-2010-single-stage. Research should aim to elucidate how a minority of infected individuals clear the virus without therapeutic intervention. Comparison of biological materials from patients with symptomatic acute hepatitis C, resolving infection or progressing into chronic disease, shall be used to search for new biomarkers of events occurring early in infection which could serve as predictors for the evolution of the disease. New viral or host biomarkers could be identified in serum or peripheral blood cells with "-omics" approaches, or by looking for differential expression of micro-RNAs and their targets in liver biopsies. The possible role of host genetic determinants in evolution of acute hepatitis C shall be investigated. Cooperation with other related national and international projects from the Mediterranean Partner Countries (MPC)[12] region should be ensured and a part of the budget should be set aside for this cooperation and for training activities. **Note:** Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria. You must refer to the call fiche for details of these limits.
Funding Scheme: Specific International Cooperation Action (**SICA)** for Mediterranean Partner Countries (MPC). Collaborative Project (Small or medium-scale focused research project)
EC contribution per project: max. EUR 3 000 000
One or more proposals can be selected.
Expected impact: Results are expected to lead to a much closer cooperation between Member States, Associated Countries and countries of the MPC region (in particular Egypt) than is the case for traditional FP projects. It is expected that the Egyptian authorities will issue a complementary call to finance Egyptian projects in this field and that the EC funded project will cooperate closely with those and other related projects.

1.3 SUITABILITY, SAFETY, EFFICACY OF THERAPIES

See: 4.2. RESPONDING TO EU POLICY NEEDS

1.4 INNOVATIVE THERAPEUTIC APPROACHES AND INTERVENTIONS

The focus is on cell-based immunotherapy. This approach offers hope for sufferers of diseases which are currently untreatable and where life is at stake. 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

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

products. Cell-based immunotherapy has possible applications in autoimmune and inflammatory diseases, allergies, infectious diseases, blood disorders (leukaemia, hereditary diseases), cancer, or improvement of engraftment of transplants. To meet the challenges and promise of cell-based immunotherapy, large Collaborative Projects will be supported. In particular they will focus on translational research coupled with supporting research on adapting the treatment to particular needs and on improving understanding of mechanisms.

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

HEALTH.2010.1.4-1: Translational research on cell-based immunotherapy. FP7-HEALTH-2010-single-stage. Research should aim to develop cell-based approaches to modulate (boost or suppress) or rebuild the immune system for therapeutic purposes. This would involve use of immunotherapeutic cells derived from any human source (e.g. cord blood, bone marrow, peripheral blood, stem cells, specialised or modified cells) for haematopoietic and immune reconstitution or for specific targeting. Projects should focus on translational research: rigorous toxicology studies should precede clinical trials. Planning and execution of multi-centre clinical trials should represent a central part of the project design. Clinical experience will provide the basis for the search for refinements to the system and for improving understanding of mechanisms. Proposals may address any justified disease or condition; research on solid tumours is excluded. Research should be multidisciplinary and consortia should be constructed so that results can be exploited by clinical and/or industrial sectors (especially SMEs) as appropriate. Active participation of SMEs could lead to an increased impact of the research proposed and this will be considered in the evaluation of the proposal. **Note:** Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria. You must refer to the call fiche for details of these limits.
Funding scheme: Collaborative Project (Large scale integrating project)
EC contribution per project: min. EUR 6 000 000 – max. EUR 12 000 000
One or more proposals can be selected.
Expected impact per project: The main impact of this work will be developing European capability in cell-based immunotherapy. Projects should carry out translational research involving clinical trials, deliver patient data, expand knowledge of mechanisms of the new therapies and develop supporting technologies. Research will boost the European biotechnology industry, especially the SME sector. New treatment options are expected. Research should also address societal, ethical and intellectual property issues as appropriate.

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.

Note: for both topics applicants will have to follow the rules for single-stage submission procedure (see respective call fiche in section III).

HEALTH.2010.2.1.1-1: Large-scale efforts in mouse functional genomics to determine the functions of genes and their involvement in disease. FP7-HEALTH-2010-single-stage. Research should integrate the European contribution to the International Knockout Mouse Consortium (IKMC) initiative in order to fully valorise the mouse mutant resources and make them available to the biomedical scientific community as a valuable and comprehensive tool to address the role of each gene in development, health and disease. Research might cover one or several of the following aspects: completion of a global resource of ES cells with high quality conditional mutations in all protein coding genes, and possibly in regulatory transcripts and non coding elements; development and characterisation of driver mouse strains for conditional expression of the mutations in each tissue: molecular phenotyping (transcriptome and proteome) at the cellular and organism levels. The project should involve the biomedical community. **Note:** Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria. You must refer to the call fiche for details of these limits.
Funding scheme: Collaborative Project (Large-scale integrating project)
EC contribution per project: min. EUR 6 000 000 – max. EUR 12 000 000
Only up to one proposal can be selected.
Expected impact: The project should integrate the European contribution to the International Knockout Mouse Consortium (IKMC) initiative in order to fully valorise the mouse mutant resources and make them available to the biomedical scientific community as a valuable and comprehensive tool to address the role of each gene in development, health and disease.

HEALTH.2010.2.1.1-2: Coordination action(s) on standards in large scale data gathering. FP7-HEALTH-2010-single-stage. The action(s) should aim at coordination of research activities in genomics, proteomics, and/or other "-omics". The focus should be on developing and implementing standards and/or operating procedures (e.g. standardized data collection, data repositories, data exchange), as well as ensuring the optimal public access and use of data. A strong international aspect should be ensured by inclusion of third country participants. Inclusion of industrial and publishing partners could lead to an increased impact of the research proposed, and this will be considered in the evaluation of the proposal. Active participation of SMEs could lead to an increased impact of the research proposed and this will be considered in the evaluation of the proposal. **Note:** Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria. You must refer to the call fiche for details of these limits.
Funding scheme: Coordination and Support Action (Coordinating Action)
EC contribution per project: max. EUR 2 000 000
One or more proposals can be selected.

Expected impact per project: The action should contribute to more harmonised use of information. Definition of criteria for data quality as well as promotion of open access policy will facilitate the use of results obtained through publically funded studies.

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.

Note: for the following topics HEALTH.2010.2.1.2-1, HEALTH.2010.2.1.2-2 applicants will have to follow the rules for two-stage submission procedure (see respective call fiche in section III). Note for topic HEALTH.2010.2.1.2-3: applicants will have to follow the rules for single-stage submission procedure (see respective call fiche in section III).

Topics for two-stage submission and evaluation; deadline 1st stage: 29 October 2009

HEALTH.2010.2.1.2-1: Tackling Human Diseases through Systems Biology Approaches. FP7-HEALTH-2010-two-stage. Multidisciplinary research that crosses the borders of different disciplines including basic and clinical research, experimental and computational modelling should use the holistic approaches of systems biology to gain knowledge on the mechanisms of diseases. These approaches, based on laboratory generation and integration of large-scale quantitative data sets, should generate reliable and validated disease models. Active participation of SMEs could lead to an increased impact of the research proposed and this will be considered in the evaluation of the proposal. **Note:** Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria. You must refer to the call fiche for details of these limits.
Funding scheme: Collaborative Project (Large-scale integrating project)
EC contribution per project: min. EUR 6 000 000 – max. EUR 12 000 000
One or more proposals can be selected.
Expected impact: These projects are expected to deliver robust models for human diseases that will open new avenues for therapeutic interventions. For many diseases it has been demonstrated that many factors are involved. In certain cancers, like pancreatic cancer (>90 % lethality), more than 50 genes are implicated in at least 10 different pathways. To better understand the complex networks of genes behind such complex diseases the projects will apply systems biology approaches to investigate diseases as complex systems.

HEALTH.2010.2.1.2-2: Establishing the foundations to enable systems biology of complex biological processes relevant to human health. FP7-HEALTH-2010-two-stage. The network(s) should create the necessary common tools, resources and approaches to set-up the foundations in areas of basic biological processes, which currently lack the necessary framework to enable ambitious systems biology approaches. They should gather multidisciplinary expertise (i.e. biology, biochemistry, bioinformatics, computational biology, translational research) and encourage the cross fertilisation between these different disciplines.
The proposed Network of Excellence (NoEs) should provide a rationally organised joint programme of activities to implement common research goals and strategies, common research platforms and technologies, as well as standardised methods and protocols. Integration activities will furthermore comprise joint multidisciplinary training schemes and a

concrete dissemination plan. The NoE(s) should aim to create durable joint structure(s) (e.g. forming part of a virtual European research institute) to promote stronger institutional integration between core partners of the network(s), with the aim of structuring the European Research Area in the field. Active participation of SMEs could lead to an increased impact of the research proposed and this will be considered in the evaluation of the proposal. **Note:** Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria. You must refer to the call fiche for details of these limits.
Funding scheme: Network of Excellence (NoE)
EC contribution per project: max. EUR 12 000 000
One or more projects can be selected.
Expected impact: The NoE(s) will gather around common strategies the necessary expertise, tools and resources to catalyse progress in systems biology relevant to health issues. The NoE(s) will also set up the standards for data quality, for data exchange and storage that are crucial for systems biology

HEALTH.2010.2.1.2-3: Developing new and improving existing mathematical algorithms for systems biology. FP7-HEALTH-2010-single-stage. The research should focus on the design of algorithms for modelling complex biological systems. These algorithms should be of general applicability for the field of systems biology and should be thoroughly tested using suitable health-related models. Cooperation with other related projects from the Eastern Europe/Central Asia (EECA) region should be ensured and a part of the budget should be set aside for this cooperation, in addition to the participation of at least two participants from different countries (or provinces in Russia) in the region.
Funding scheme: Specific International Cooperation Action (**SICA)** Collaborative Project (Small or medium-scaled focused research projects) with focus on EECA
EC contribution per project: max. EUR 3 000 000
Only up to one proposal can be selected.
Expected impact: This initiative is expected to lead to a much closer cooperation between EU, associated countries (AC) and countries of the EECA region (in particular Russia) than is the case for traditional FP projects. The subject was selected at a workshop jointly organised by DG Research (Health Directorate) and the Russian Federal Agency of Science and Innovations (FASI), in St. Petersburg in September 2007. It is expected that FASI would issue a complementary call to finance Russian projects in the area and the EC funded project would cooperate closely with those and other related projects. The initiative represents an important aspect of systems biology and capitalises on the highly developed skills and knowledge in both the EU/AC and EECA countries. The projects will benefit from mutual exchange of information, researchers and a combination of efforts. Active participation of SMEs could lead to an increased impact of the research proposed and this will be considered in the evaluation of the proposal. **Note:** Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria. You must refer to the call fiche for details of these limits.

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

2.2.1. Brain and brain-related diseases

Around 6.2 million people are estimated to suffer from different types of dementia (concentrated on older people), of which Alzheimer's disease (AD) accounts for around three-quarters of cases. Taking into account their careers and families, for whom caring often becomes a heavy personal and financial burden, some 20 million people are affected, i.e. around 4% of the European population. The French Presidency of the Council has identified Alzheimer's disease as a particular priority. The Council adopted on 26 September 2008[13] conclusions on a common commitment by the Member States to combat neurodegenerative diseases, in particular Alzheimer's disease. On 2 December 2008[14] the Council adopted conclusions on "Joint Programming" which also refer to the conclusions adopted on 26 September considering it necessary to launch a pilot "Joint Programming" initiative on combating neurodegenerative diseases, particularly Alzheimer's disease. This concept might well contribute to the implementation of a European Partnership on Alzheimer's disease. The area of Alzheimer's disease is suitable for such a partnership not only because it addresses a major medical and socio-economical issue, but also because there is a real need for pooling and coordinating the efforts of European basic and clinical researchers in this field. Considering that most research on Alzheimer's disease is still at the pre-clinical phase, public research will be instrumental to any breakthrough. The Commission services are currently exploring how best to support such an initiative. Under area 4.2 of the HEALTH-2010 work programme under topic HEALTH-2010.4.2-8 the Commission will support as Coordination action a common research initiative for combating neurodegenerative diseases, in particular Alzheimer's disease, implemented by Joint Programming.

2.2.2. Human development and ageing

Human development and ageing: use of a wide variety of methodologies and tools to better understand the process of life-long development and healthy ageing. The focus will be on the study of human and model systems, including interactions with factors such as environment, genetics, behaviour and gender.

Note: for the following topics HEALTH.2010.2.2.2-1, HEALTH.2010.2.2.2-2, HEALTH.2010.2.2.2-3 and HEALTH.2010.2.2.2-4 applicants will have to follow the rules for two-stage submission procedure (see respective call fiche in section III). Note for topic HEALTH.2010.2.2.2-5: applicants will have to follow the rules for single-stage submission procedure (see respective call fiche in section III).

[13] http://register.consilium.europa.eu/pdf/en/08/st13/st13668.en08.pdf

[14] http://register.consilium.europa.eu/pdf/en/08/st16/st16775.en08.pdf

Topics for two-stage submission and evaluation; deadline 1st stage: 29 October 2009

HEALTH.2010.2.2.2-1: Role of early-life developmental processes in longevity determination. FP7-HEALTH-2010-two-stage. Research should aim to capitalize on knowledge acquired in the fields of biology, in particular developmental biology as well as in gerontology and research on ageing, gathering research groups with the relevant know-how and expertise. Studies of the role of epigenetic mechanisms should be part of the research approach. Other factors, such as socioeconomic, lifestyle or environmental variables could be tackled, if considered relevant to the research. Research will focus on early-life programming, including prenatal phases and will take advantage of the existing data generated by developmental biology studies on cell systems and model organisms to allow translation to humans. Active participation of SMEs could lead to an increased impact of the research proposed and this will be considered in the evaluation of the proposal. **Note:** Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria. You must refer to the call fiche for details of these limits.
Funding scheme: Collaborative project (Large-scale integrating project)
EC contribution per project: min. EUR 6 000 000 – max. EUR 12 000 000
Only up to one proposal can be selected.
Expected impact: Studies are directly aimed at understanding the mechanisms of healthy human ageing and of life extension.

HEALTH.2010.2.2.2-2: Homeostasis in human development and its effects on lifespan. FP7-HEALTH-2010-two-stage. Longevity will be studied in terms of the capacity to ensure and maintain good homeostasis and networking between various body systems and functions, and of the entire organism. In addition to internal control mechanisms of homeostasis, the project should also take into account external influences, as for instance, lifestyle and environmental exposures. **Note:** Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria. You must refer to the call fiche for details of these limits.
Funding scheme: Collaborative project (Small or medium-scale focused research project)
EC contribution per project: max. EUR 6 000 000
Only up to one proposal can be selected.
Expected impact: Maintaining a stable internal environment implies constant monitoring and adjustments as conditions change. Malfunctioning and failures of the homeostatic balance result in cellular malfunctions and disease implying that the well-being of the person depends upon the well-being of all the interacting body systems. Knowledge acquired in this area will pave the way to therapeutic interventions.

HEALTH.2010.2.2.2-3: Integrative systems biology and comparative genomics for studying human ageing. FP7-HEALTH-2010-two-stage. Research should focus on genes and pathways more likely to be involved in ageing, on their interactions and how these give rise to an ageing phenotype. This will enable integrating and making optimal use of resources available for research in bio-gerontology and paving the way to unravelling the genetic and molecular mechanisms of ageing. Comparative genomics and proteomics will be favoured to compare data from humans, to that of other organisms, in order to understand which regions of the genome are involved in ageing. The research intends to study how the genome regulates the rate of ageing and age-related processes in humans, through computational approaches and the use of models. Active participation of SMEs could lead to an increased impact of the research proposed and this will be considered in the evaluation of the proposal.

Note: Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria. You must refer to the call fiche for details of these limits.
Funding scheme: Collaborative Project (Large-scale integrating project)
EC contribution per project: min. EUR 6 000 000 - max. EUR 12 000 000
Only up to one proposal can be selected.
Expected impact: Research will have to accelerate the sharing, integration and analysis of biological data acquired while studying various models, thus contributing to understand the complexity of the relationship between genotype and phenotype in relation to ageing.

HEALTH.2010.2.2.2-4: Markers of cellular senescence for human ageing. FP7-HEALTH-2010-two-stage. The aim of this research is to define robust markers of cellular senescence, and to investigate their role in ageing. **Note:** Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria. You must refer to the call fiche for details of these limits.
Funding scheme: Collaborative Projects (Small or medium-scale focused research project)
EC contribution per project: max. EUR 3 000 000
Only up to one proposal can be selected.
Expected impact: Studies on cellular senescence and in particular telomere biology in animal and human ageing will be reviewed in order to understand their value and potential in elucidating mechanisms of ageing.

HEALTH.2010.2.2.2-5: Frailty and its implications in modern society. FP7-HEALTH-2010-single-stage. Suggested workshop to be carried out through collaboration between clinicians, geriatricians, health care professionals, carers and patients on "frailty": definition, causes, determination and impact in present day societies. The aim will be to establish a common definition of "frailty", taking into account both the geriatric syndrome of frailty and its clinical correlate, to identify specific biomarkers and develop an assay panel for the early diagnosis of frailty to be used in clinical practice, enhance communication between representatives of the various domains and raise awareness of the older population. **Note:** Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria. You must refer to the call fiche for details of these limits.
Funding scheme: Coordination and Support Action (Supporting Action)
EC contribution per project: max. EUR 500 000
Only up to one proposal can be selected.
Expected impact: The expected impact will be a better and common understanding of the concept of "frailty" used to monitor the decline of older people, including the determination of frail phenotype(s) with predictive value. This will be of direct benefit to older patients as well as a tool for health managers and policy makers.

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

2.3.1. Anti-microbial drug resistance

CLOSED in WP 2010

2.3.2. HIV/AIDS, malaria and tuberculosis

The focus will be on developing new therapies, diagnostic tools, and preventive tools such as vaccines. Research efforts will confront the three diseases at global level, but will also address specific European aspects of the three diseases. Preclinical and early clinical research activities will be emphasised, and where relevant collaboration with European and global initiatives is foreseen.

Note: for topics under this area applicants will have to follow the rules for single-stage submission procedure (see respective call fiche in section III).

HEALTH.2010.2.3.2-1: Target characterisation and hit-to-lead progression in tuberculosis (TB) Drug development. **FP7-HEALTH-2010-single-stage.** In this research, genetic and chemical approaches should be utilised to identify and validate TB drug targets in the form of a single collaborative project, which brings together a critical mass of partners from public and private sectors. Research should concentrate on the target-to-hit phase and contribute to filling the pipeline of new TB drug candidates with the potential of shortening treatment and being effective against multidrug-resistant TB. Hit-to-lead progression should be done effectively by academics and partnering industry. Essential elements of the project could include assay development, structural biology, virtual screening, high-throughput screening, fragment-based screening and rational drug design. Participation of partners from Eastern Europe and Central Asia (EECA) could increase the impact of this project and will be considered in the evaluation of the proposal. Active participation of SMEs could lead to an increased impact of the research proposed and this will be considered in the evaluation of the proposal. **Note:** Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria. You must refer to the call fiche for details of these limits.
Funding scheme: Collaborative project (Large-scale integrating project)
EC contribution per project: min. EUR 6 000 000 – max. EUR 12 000 000
Only up to one proposal can be selected.
Expected impact: European scientists have already achieved good results with early discovery of targets for TB drug candidates. Genomic information and structural data banks are available already, but the European know-how could be better integrated to make advances in the field towards new hits and leads. Eastern Europe is particularly strong in this area and their participation will have a structural effect on European TB Drugs field. Preparedness for controlling spreading of the multidrug resistant forms of TB will be increased, since efforts will be made to develop new classes of drugs which have the potential of shortening the current standard treatment and to be effective against multi drug-resistant (MDR-TB) and extensively drug-resistant TB (XDR-TB). Overall strength to the TB drug pipeline will be sought.

HEALTH.2010.2.3.2-2: Lead optimisation and late preclinical development in TB drugs. FP7-HEALTH-2010-single-stage. Preclinical studies in TB drug development are requested. Research should aim at optimising the drug-like properties of lead compounds and generate a pharmacological, safety and biopharmaceutical profile of the compounds. Projects are expected to take at least one lead compound closer to clinical phase. In addition, to lead optimization, the project could contain other elements of late pre-clinical and/or early clinical development, such as manufacturing information and clinical protocols. Active involvement of industry, especially SMEs and/or Product Development Public-Private Partnership organisations, could lead to an increased impact on the research proposed, and this will be considered in the evaluation of the proposal. **Note:** Limits on the EC financial contribution

apply. These are implemented strictly as formal eligibility criteria. You must refer to the call fiche for details of these limits.
Funding scheme: Collaborative project (Small or medium-scale focused research project)
EC contribution per project: max EUR 6 000 000
One or more proposals can be selected.
Expected impact: The expected impact is enhanced output of research results essential for the development of new drugs against tuberculosis. This topic emphasises translational research supporting development of more efficient drugs 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 public and private institutions will be an extra asset in this area, and the involvement of research groups from Eastern Europe will strengthen the impact.

HEALTH.2010.2.3.2-3. European network of cohort studies on HIV/AIDS. FP7-HEALTH-2010-single-stage. The aim is to present an integrated pan-European network of cohort studies involving HIV-infected patients, including migrant populations, injection drug users, and men who have sex with men. Main goals should include improving diagnosis and prognosis of patients infected with HIV, understanding mechanisms of non-progression to disease, advancing understanding of pathogenesis (especially immunopathogenesis) of the HIV infection, studying the epidemiology of different HIV subtypes in Europe (including Eastern Europe), combating mother to child transmission of HIV, and proposing new interventions against the infection. The Network should be able to efficiently coordinate multi-disciplinary efforts to prevent and treat HIV infection in Europe, both in adults and children. The inclusion of cohorts of patients with HIV-related co-infections will be considered as an asset. The proposed Network of Excellence (NoE) should provide a rationally organised joint programme of activities to implement common research goals and strategies, common research platforms and technologies, as well as standardised methods and protocols. Integration activities will furthermore comprise joint multidisciplinary training schemes and a concrete dissemination plan. The NoE should aim to create durable joint structure (e.g. forming part of a virtual European research institute) to promote stronger institutional integration between core partners of the network, with the aim of structuring the European Research Area in the field. Active participation of SMEs and/or Product Development Public-Private Partnership organisations could lead to an increased impact of the research proposed, and this will be considered in the evaluation of the proposal. **Note:** Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria. You must refer to the call fiche for details of these limits.
Funding scheme: Network of Excellence
EC contribution per project: max. EUR 12 000 000
Only up to one proposal can be selected.
Expected impact: Grouping all main European cohorts under a single NoE will allow construction of larger multi-cohort collaborations providing a higher statistical power, and will hence offer more robust prevention and treatment guidelines and a better public health impact. Moreover, the creation of a single network will allow the construction of an amalgamated single dataset to address key questions of direct relevance to infected populations. Finally, from a managerial point of view, a single network will ensure that resources are maximized in comparison to many different small, uncoordinated cohorts.

Changing distribution of vector-borne diseases: Environment, transmission and vector control measures

The distribution, density and ecology of disease-transmitting vectors are particularly sensitive to environmental change caused in part by changing climatic conditions. The resulting spread of human vector-borne diseases will likely have major health impacts on vulnerable populations in Africa as well as – through the spread of vectors beyond their original tropical habitat – also in Europe. In this work programme under the topics 2.3.2-4., 2.3.3-1. and 2.3.3-3. resources are pooled to address in an integrated manner key issues related to the spread of vector-borne infections in Africa and Europe. Please note that another topic related to vectors is published in the work programme 2010 of Theme 'Environment (including climate change)'. The latter together with topic 2.3.2-4 here is published in a separate call for Africa see details in the respective call fiche under section III. The selected projects from Themes 'Health', 'Food, Agriculture and fisheries, and Biotechnology' and 'Environment (including climate change)' are expected to cooperate.

HEALTH.2010.2.3.2-4: Controlling malaria by hitting the vector: New or improved Vector Control Tools. FP7–CALL–FOR-AFRICA-2010. An integrated research effort shall deliver new or improved tools and methods which can contribute to interrupting mosquito-mediated transmission of malaria. The research plan may comprise vector biology, including behavioural and population studies, but it must keep a clear translational focus on generating new or improved measures to prevent malaria infection of human populations through mosquito bites. Research into new or improved, environmentally sustainable insecticides (including larvicides) and repellents is encouraged. The major focus of the project shall be on vector control in Africa, where the disease burden is highest and the need for malaria control most pressing. Inclusion of African research groups is essential to ensure needs and realities of the target countries are met. The aim is to synergistically contribute to on-going European and global research efforts on vector control. Therefore, expertise in supranational coordination of large research consortia must be ensured. The aim is to achieve a balanced level of participation for African countries in collaboration with their European partners and it will be considered in the evaluation. **Note:** Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria. You must refer to the call fiche for details of these limits.
Funding scheme: Specific International Cooperation Action (**SICA)** Collaborative project (large scale integrating project) Target region: International cooperation partner countries (ICPC) from African ACP and the following Mediterranean Partner countries (African MPC), Algeria, Egypt, Libya, Morocco and Tunisia
EC contribution per project: min. EUR 6 000 000 – max. EUR 12 000 000
Only up to one proposal can be selected.
Expected impact: The project should lead to better understanding of the biology and the population dynamics of mosquito vectors transmitting malaria in Africa. New and improved vector control tools will be contributing to reducing the malaria disease burden in Africa. It will increase the European contribution to on-going global efforts to control and eradicate malaria and will strengthen research partnerships and research capacities in Africa.

2.3.3. Potentially new and re-emerging epidemics

The focus will be on confronting emerging pathogens with pandemic potential, including zoonoses. 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.

Note: for topics under this area applicants will have to follow the rules for single-stage submission procedure (see respective call fiche in section III).

HEALTH.2010.2.3.3-1: Biology and control of vector-borne infections in Europe. FP7-HEALTH-2010-single-stage. Research should aim to engage a broad scope of basic and translational biological and health research on vectors of existing or potentially emerging relevant human and veterinary infections in Europe. The emphasis should be on the infection's natural cycle, including basic biology of vectors and diseases reservoirs, and on vector control interventions and their systematic evaluation. Given the distribution of vector-borne diseases, participation of researchers from Eastern Europe and Central Asia (EECA) countries could lead to an increased impact of the research proposed, and this will be considered in the evaluation of the proposal. Public Health actors and decision makers will be important users of the project results and interaction with these stakeholders should be addressed in project proposals. Malaria vectors are not addressed under this topic, since they are covered in other topic of this programme (2.3.2-4.). **Note:** Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria. You must refer to the call fiche for details of these limits.
Funding scheme: Collaborative project (Large scale integrating project)
EC contribution per project: min. EUR 6 000 000 – max. EUR 12 000 000
Only up to one proposal can be selected.
Expected impact: Knowledge on vectors generated under this project is expected to deliver a better understanding of the biology of vectors relevant to human and veterinary diseases. This knew knowledge in turn should help (i) to predict the emergence and spread of new vector-borne diseases, and (ii) to assess the efficacy of different interventions and develop new interventions to interrupt or limit the spread of vector-borne diseases with the goal of protecting European citizens from these threats. A major impact is also expected on strengthen the European research capacity in this field.

HEALTH.2010.2.3.3-2: Drug lead discovery against RNA viruses. FP7-HEALTH-2010-single-stage. Research should aim to develop concepts and methods to discover and design drug leads against various families of human pathogenic RNA viruses responsible for emerging or neglected infections, major viral infections with established antiviral drug discovery programmes, such as HIV, hepatitis C or influenza are not targeted by this topic. The milestone of proof-of-concept in animal studies should be reached during the lifetime of the project. Issues like exploitation plans, route-to-market, intellectual property management and integration of biotechnology SMEs and/or pharmaceutical industry should be explicitly addressed. Active participation of SMEs could lead to an increased impact of the research proposed and this will be considered in the evaluation of the proposal. **Note:** Limits on the EC

financial contribution apply. These are implemented strictly as formal eligibility criteria. You must refer to the call fiche for details of these limits.
Funding scheme: Collaborative project (Large scale Integrating Project)
EC contribution per project: min. EUR 6 000 000 – max. EUR 12 000 000
Only up to one proposal can be selected.
Expected impact: Research is expected to deliver major progress in developing new drugs for RNA viruses responsible for emerging or neglected infections. It will do so through the discovery of new leads as well as by moving leads along the drug development pipeline. Eventually the project is expected to contribute to one of the major defence lines (i.e. drugs) against new and re-emerging infections posing a threat to Europe and worldwide.

HEALTH.2010.2.3.3-3: Integrated disease-specific research on West Nile Virus infections, Chikungunya and/or Crimean Congo Haemorrhagic Fever. FP7-HEALTH-2010-single-stage. The aim is to integrate research on one or more of the above diseases – or other relevant newly emerging human infections in Europe. Research areas such as basic virology, transmission, epidemiology, diagnostic approaches and/or treatment and prevention strategies should contribute to a comprehensive approach towards these diseases. Proposals are expected to be output-oriented and to build on existing basic research results to the extent possible in order to advance to late term pre-clinical studies and deliver tools countering the threat of these infections. **Note:** Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria. You must refer to the call fiche for details of these limits.
Funding scheme: Collaborative projects (Small or medium-scale focused research project)
EC contribution per project: max. EUR 3 000 000
One or more proposals can be selected.
Expected impact: Projects in this field are expected to create an integrated European research capacity on diseases, which are among the prime threats of vector-borne emerging diseases in Europe. In case of a significant new unforeseen threat before the time of the call closure, research on this should be included. Significant synergy is expected from uniting researchers from different fields around the common goal of generating new knowledge on these diseases, and delivering improved ways to monitor its spread, diagnose, prevent, control and treat it. The ultimate impact is to enhance Europe's preparedness for these new diseases.

HEALTH.2010.2.3.3-4: Novel therapeutics against influenza. FP7-INFLUENZA-2010. Research should address the need for novel therapeutic options against influenza. This could encompass the development of drugs against viral targets as well as drugs interfering with host-response pathways that play a role in the development of the disease. Passive immunotherapy or combination therapy could also be considered under this topic. One or several of these different approaches could be envisaged in each proposal. During project duration, the stages of proof-of-concept in animal models, safety and toxicology profiles and possibly first clinical studies should be reached. Active participation of SMEs could lead to an increased impact of the research proposed and will be considered in the evaluation of the proposal. The essential integration of SMEs in view of route-to-market considerations and the relevant intellectual property management needs to be clearly addressed in the proposal. **Note:** Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria. You must refer to the call fiche for details of these limits.
Funding scheme: Collaborative projects (Small or medium-scale focused research project)
EC contribution per project: max. EUR 6 000 000
One or more proposals can be selected.

Expected impact: Projects are expected to pave the way for the development of new and alternative treatment options, with the aim of reinforcing the necessary therapeutic arsenal for control of influenza outbreaks. This will improve the protection of populations in Europe (and worldwide) against potential new pandemics as well as offer alternative treatment options for patients vulnerable to seasonal influenza. The results of these projects will in particular provide alternative management options for viral strains resistant to currently available anti-influenza drugs. The project will also contribute to increasing European competitiveness in the pharmaceutical sector.

2.3.4. Neglected infectious diseases

The aim of this area is to establish an integrated approach for the development of preventive, therapeutic and diagnostic, tools for neglected infectious diseases. Activities will address, but not be limited to, parasitic diseases caused by Trypanosomatidae species (Trypanosomiasis, Chagas Disease, Leishmaniasis), bacterial diseases such as Buruli ulcer, leprosy and trachoma, helminth diseases such as schistosomiasis, as well as health conditions that can be caused by several pathogens, such as childhood diarrhoea. Projects should address preclinical and early clinical activities, as well as the particular public 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 could lead to an increased impact of the research proposed, and this will be considered in the evaluation of the proposal. Where applicable, technology transfer, training activities and human capacity building should also be part of the projects.

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

HEALTH.2010.2.3.4-1: Vaccines for childhood bacterial diarrhoeal diseases. FP7-HEALTH-2010-single-stage. Research should be focused on accelerating the development of vaccine candidates to clinical testing. Testing in vitro and in vivo should form part of the project, which may also include early clinical trials. Priority will be given to projects on multivalent vaccines that aim to work across different strains of either Enterotoxigenic Escherichia coli (ETEC) or Shigella. Vaccines should be suitable for use in endemic regions, and involvement of partners from International Cooperation Partner Countries (ICPC) countries as well as partners with expertise in industrial vaccine production could lead to an increased impact of the research proposed and this will be considered in the evaluation of the proposal. Active participation of SMEs could lead to an increased impact of the proposed research and this will be considered in the evaluation of the proposal. **Note:** Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria. You must refer to the call fiche for details of these limits.
Funding scheme: Specific International Cooperation Action (**SICA)** Collaborative Project (Large scale integrating project) Target Region: all ICPC
EC contribution per project: min. EUR 6 000 000 – max. EUR 12 000 000
Only up to one proposal can be selected.
Expected impact: Research shall gather a multi-disciplinary team of vaccinologists from Europe, disease-endemic countries and elsewhere and establish a comprehensive pipeline of candidate vaccines against one of the major enteric bacterial pathogens causing childhood diarrhoea. The consortium shall have the capacity to undertake the full pre-clinical

development of vaccine candidates, safety and toxicology studies, and have the ambition to advance the most promising candidate(s) into early clinical testing (phase I/IIa).

HEALTH.2010.2.3.4-2: Comprehensive control of Neglected Infectious Diseases (NID). FP7-HEALTH-2010-single-stage. Research should aim at developing an improved system for delivering primary health care in resource poor settings. This project should aim to overcome the vertical approach of many disease-specific control programmes, and develop methods that are more adapted to a primary health care setting. The proposed research should address several of the NID priority diseases, while not necessarily be limited to these. The project should aim at integrating existing prevention methods with new diagnostic methodology and diagnosis-treatment algorithms adapted to resource-poor settings. The project can include the development of new or optimized diagnostic platform for multiple infectious diseases, but the proposed prevention and treatment options should be based on existing and affordable tools, vaccines and medication. Innovative research on intervention delivery may be included. Finally, the project should also aim to develop primary health care recommendations for use by policy makers and health care managers in disease endemic countries. Active participation of SMEs could lead to an increased impact of the research proposed and this will be considered in the evaluation of the proposal. **Note:** Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria. You must refer to the call fiche for details of these limits.
Funding scheme: Specific International Cooperation Action (**SICA)** Collaborative Project (Small- or medium scale focused research project) Target Region: all International Cooperation Partner Countries (ICPC)
EC contribution per project: max. EUR 6 000 000
One or more proposals can be selected.
Expected impact: Research must bridge vertical, disease-specific approaches and must use state-of-the-art epidemiological and diagnostic knowledge and technology to develop 1) a single comprehensive, low-cost diagnostic system that is suitable for use in resource poor settings and 2) diagnosis-treatment algorithms on the basis of existing prophylactics and medication, and 3) document the cost-savings and increased efficacy of a comprehensive, horizontal approach to NID, and develop recommendations for broad implementation to policy makers, relevant international organisations, and health care managers.

HEALTH.2010.2.3.4-3: Next generation of researchers for Neglected Infectious Diseases. FP7-HEALTH-2010-single-stage. Coordination is requested for targeted measures aiming at improving the career prospects for young researches in neglected infectious diseases. The activities should comprise training of young scientists, and support young researchers to establish independent research activities in disease-endemic countries. High quality science contents, demonstrated organisation and management abilities and clear indications of sustainability and impact will be prerequisites of selected actions. Coordination with ongoing EC activities to support training of researchers in poverty-related diseases (PRD) is encouraged. **Note:** Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria. You must refer to the call fiche for details of these limits.
Funding scheme: Coordination and Support Action (Coordinating action)
EC contribution per project: max. EUR 2 000 000
One or more proposals can be selected.
Expected impact: The Coordination Action is expected to establish a long-term training programme that is open to promising young scientists in neglected infectious diseases. It should further manage a career development programme to support young researchers in establishing themselves with independent research in disease-endemic countries. The action

should establish collaboration with ongoing training and career development activities in poverty-related diseases with an aim to establish a joint, coordinated programme.

2.4. TRANSLATIONAL RESEARCH IN OTHER MAJOR DISEASES

2.4.1. Cancer

With an estimated 3.2 million new cases and 1.7 million deaths each year, cancer remains an important public health problem in Europe for cancer patients, their family as well as health care systems across Europe[15]. With the ageing of the European population these numbers are predicted to steadily increase. Research in this policy area will focus on disease aetiology, identification and validation of drug targets and prevention, early diagnosis and treatment biomarkers as well as on assessment of preventive, diagnostic, prognostic, and therapeutic interventions. In the long term, this area will contribute to reducing cancer incidence and mortality and to improving quality of life and care with fewer side-effects to patients.

Note: For topic HEALTH.2010.2.4.1-1: applicants have to follow the rules of the FP7-ERANET-2010-RTD Call[16]; for topics HEALTH.2010.2.4.1-2 and HEALTH.2010.2.4.1-3 applicants have to follow the rules for single-stage submission procedure (see respective call fiche in section III). For topic HEALTH.2010.2.4.1-4: applicants have to follow the rules of the FP7-CALL FOR AFRICA-2010. (see section III).For topics HEALTH.2010.2.4.1-5; HEALTH.2010.2.4.1-6; HEALTH.2010.2.4.1-7; HEALTH.2010.2.4.1-8 and HEALTH.2010.2.4.1-9: applicants have to follow the rules for two-stage submission procedure (see respective call fiche in section III).

HEALTH.2010.2.4.1-1: ERA-NET on translational cancer research in Europe. FP7-ERANET-2010-RTD[17]. ERA-NET to coordinate national and regional translational cancer research funding organisations' activities, aiming at the integration of basic, clinical and epidemiological cancer research and facilitation of coordinated, transnational cancer funding in Europe with the ultimate aim to streamline EU-wide cancer screening, early diagnosis, prognosis, treatment and care. **Note:** Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria. You must refer to the call fiche for details of these limits.
Funding scheme: Coordination and Support Action (Coordinating Action)
EC contribution per ERA-NET: max. EUR 2 000 000
Only up to one proposal can be selected.
Expected impact: The results of this ERA-NET will contribute to the creation of the European Research Area by facilitating and coordinating regional, national and European cancer research funding programmes between member states. The ERA-NET will structure human resources and allow synergy rather than competition for and dispersion of many different sources of funding improving both the strategic planning and efficient management of translational cancer research efforts in the EU-27 and associated countries.

HEALTH.2010.2.4.1-2: Structuring translational cancer research between cancer research centres in Europe. FP7-HEALTH-2010-single-stage. The aim is to integrate joint

[15] Ferlay J et al. (2007) Ann. Oncol. 18(3):581-92
[16] Call fiche: see ANNEX 4 to the cooperation work programme
[17] Call fiche: see ANNEX 4 to the cooperation work programme

translational research amongst cancer research centres and dedicated cancer hospitals by careful prioritisation of investigator-driven, patient-directed joint translational research, including clinical research on promising cancer prevention, early cancer detection and/or therapeutic anti-cancer strategies. At the same time, this network should further define and complement ongoing translational research efforts on cancer in Europe, design effective joint training/education and coordinate strategic efforts towards long-term sustainability, taking into account and linking ongoing transnational cancer research and partnering activities. The proposed Network of Excellence (NoE) should provide a rationally organised **joint programme of activities** to implement common research goals and strategies, common research platforms and technologies, as well as standardised methods and protocols. Integration activities will furthermore comprise joint multidisciplinary training schemes and a concrete dissemination plan. The NoE should aim to create a durable joint structure (e.g. forming part of a virtual European research institute) to promote stronger institutional integration between core partners of the network, with the aim of structuring the European Research Area in the field. Active participation of SMEs could lead to an increased impact of the research proposed and this will be considered in the evaluation of the proposal. **Note:** Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria. You must refer to the call fiche for details of these limits.
Funding scheme: Network of Excellence
EC contribution per project: max. EUR 12 000 000
Only up to one proposal can be selected.
Expected impact: This Network of Excellence will accelerate the development of promising screening, diagnostic and therapeutic strategies by integrating and structuring translational cancer research in Europe.

HEALTH.2010.2.4.1-3: Structuring clinical research in paediatric and adolescent oncology in Europe. FP7-HEALTH-2010-single-stage. The network should aim to integrate and formalise translational, clinical research (up to Phase III clinical trials) amongst institutions at the forefront of research on paediatric and adolescent oncology, including furthering joint research on (1) harmonised therapy strategies, including targeted therapies, that increase cancer cure, improve the quality-of-life of children and adolescents with cancer and reduce long-term side effects; (2) clinical epidemiology that will improve early diagnosis and prognosis; (3) development and/or effective sharing of standardised data centres, standardised methodology, tools, technology and equipment. In addition, it should (4) design and deploy effective joint training/education and (5) referral schemes and (6) coordinate strategic efforts towards long-term sustainability, taking into account ongoing transnational partnering activities. The proposed Network of Excellence (NoE) should provide a rationally organised joint programme of activities to implement common research goals and strategies, common research platforms and technologies, as well as standardised methods and protocols. Integration activities will furthermore comprise joint multidisciplinary training schemes and a concrete dissemination plan. The NoE should aim to create a durable joint structure (e.g. forming part of a virtual European research institute) to promote stronger institutional integration between core partners of the network, with the aim of structuring the European Research Area in the field. Active participation of SMEs could lead to an increased impact of the research proposed and this will be considered in the evaluation of the proposal. **Note:** Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria. You must refer to the call fiche for details of these limits.
Funding scheme: Network of Excellence
EC contribution per project: max. EUR 12 000 000
Only up to one proposal can be selected.

Expected impact: The results of research in this area will integrate a large number of informal, investigator-driven research networks in paediatric and adolescent oncology currently active in Europe, improve patient care and access to tailored medicine as well as structure European scientific excellence in paediatric and adolescent oncology.

HEALTH.2010.2.4.1-4. Infectious agents and cancer in Africa. FP7-CALL-FOR-AFRICA-2010. Translational and multidisciplinary research is requested to address the aetiology and epidemiology of cancers caused by infectious agents, i.e. Kaposi's sarcoma, cervical cancer, liver cancer, stomach cancer, non-Hodgkin lymphoma or bladder cancer, in the African population, with the purpose of identifying high-risk factors, including environmental exposure, genetic predisposition and key steps in tumour pathogenesis. Research will have to design novel point-of-care diagnostics and therapies adapted to local necessities and geographical requirements. Active participation of SMEs could lead to an increased impact of the research proposed and this will be considered in the evaluation of the proposal. The aim is to achieve a balanced level of participation for African countries in collaboration with their European partners and it will be considered in the evaluation. **Note:** Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria. You must refer to the call fiche for details of these limits.
Funding scheme: Specific International Cooperation Action (**SICA)** Collaborative Project (Small or medium-scale focused research project) Target Region: International cooperation partner countries (ICPC) from African ACP and the following Mediterranean Partner countries (African MPC), Algeria, Egypt, Libya, Morocco and Tunisia
EC contribution per project: max. EUR 3 000 000
One or more proposals can be selected.
Expected impact: The results of research in this area will improve early diagnosis and treatment of the most frequent, infection-related cancers in Africa and promote lasting partnerships between Europe and Africa.

Topic for two-stage submission and evaluation; deadline 1st stage: 29 October 2009

HEALTH.2010.2.4.1-5: Structuring clinical research on rare cancers in adults. **FP7-HEALTH-2010-two-stage.** Collaborative research should aim to integrate and formalise translational, clinical research (up to phase III clinical trials) amongst institutions at the forefront of research on rare cancers in adults, including furthering joint clinical research on harmonised and, evidence-based therapeutic strategies, including targeted therapies which increase cancer cure or improve the quality-of-life of rare cancer patients. Rare cancers are defined as cancers affecting not more than five in ten thousand persons in the Community[18].
Note: Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria. You must refer to the call fiche for details of these limits.
Funding scheme: Collaborative Project (Small or medium-scale focused research project)
EC contribution per project: max EUR 6 000 000
One or more proposals can be selected.
Expected impact: The results of research in this area will integrate informal investigator-driven research networks on rare cancers in adults currently active in Europe, improve patient care and access to tailored medicine as well as structure European scientific excellence on rare cancers.

[18] http://ec.europa.eu/enterprise/pharmaceuticals/orphanmp/doc/141_2000/141_2000_en.pdf

HEALTH.2010.2.4.1-6: Translational research on cancers with poor prognosis. FP7-HEALTH-2010-two-stage. Research must focus on either cancers of the pancreas, liver, lung, or oesophagus. The successful consortium will reverse-translate clinical observations concerning treatment failure into innovative cancer models closely mimicking the disease while validating better therapeutic strategies that increase patient survival. Consortia should include clinical expertise to guarantee a clinical proof-of-principle. Active participation of SMEs could lead to an increased impact of the research proposed and this will be considered in the evaluation of the proposal. **Note:** Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria. You must refer to the call fiche for details of these limits.
Funding scheme: Collaborative Project (Small or medium-scale focused research project)
EC contribution per project: max EUR 3 000 000
One or more proposals can be selected.
Expected impact: The results of research in this area will contribute to ultimately reducing patient mortality for a number of difficult-to-treat cancers with dismal survival rates and integrate basic-clinical European scientific excellence.

HEALTH.2010.2.4.1-7: Predicting long-term side effects to cancer therapy. FP7-HEALTH-2010-two-stage. Research should aim to systematically collect and register data on the incidence, prevalence, causes, and risk factors of late adverse effects to treatment of cancer patients, such as organ toxicity/failure, secondary cancers, (co)morbidity, mortality, and gender and country-specific issues correlated to treatment-related parameters from radiotherapy and/or chemotherapy and/or surgery and/or targeted therapy. It will translate these findings into harmonised guidelines on long-term prevention, health promotion, risk prediction, training of health care professionals and better health care management of adverse effects from therapy in cancer survivors. **Note:** Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria. You must refer to the call fiche for details of these limits.
Funding scheme: Collaborative Project (Small or medium-scale focused research project).
EC contribution per project: max. EUR 6 000 000
One or more proposals can be selected.
Expected impact: The results of research in this area will promote cancer therapies with fewer side effects, better care of cancer survivors and integrate European scientific excellence.

HEALTH.2010.2.4.1-8: Predicting individual response and resistance to cancer therapy. FP7-HEALTH-2010-two-stage. Research should aim to integrate relevant clinical data obtained through standardised methodologies, such as pharmacogenetics / genomics, proteomics, comparative genomic hybridisation, SNP mapping, copy number variation, from clinical research on (epi)genetic variation of cellular response and resistance to treatment both in the host and the tumour as well as on clinical observation data of cancer patients to improve our understanding of the critical molecular and resistance pathways involved, including drug metabolism and transport. The successful project will achieve validated risk stratification criteria to be used in personalised, early and innovative patient screening methodologies, prediction of individual therapy response and resistance and monitoring successful treatment outcome. Active participation of SMEs could lead to an increased impact of the research proposed and this will be considered in the evaluation of the proposal. **Note:** Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria. You must refer to the call fiche for details of these limits.
Funding scheme: Collaborative Project (Small or medium-scale focused research project).

EC contribution per project: max. EUR 6 000 000
One or more proposals can be selected.
Expected impact: The results of research in this area will ultimately benefit survival and quality-of-life of cancer patients by providing more cost effective personalised therapies with a higher therapeutic index and integrate European scientific excellence.

HEALTH.2010.2.4.1-9. Optimising the delivery of (chemo)radiotherapy and/or surgery to cancer patients. FP7-HEALTH-2010-two-stage. Research with a strong clinical component should optimise the delivery of (chemo)radiotherapy and/or surgery to patients suffering from solid cancers, carefully aiming at optimising treatment efficacy and controlling treatment quality while diminishing/limiting undesired effects. Active participation of SMEs could lead to an increased impact of the research proposed and this will be considered in the evaluation of the proposal. **Note:** Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria. You must refer to the call fiche for details of these limits.
Funding scheme: Collaborative Project (Small or medium-scale focused research project)
EC contribution per project: max. EUR 6 000 000
One or more proposals can be selected.
Expected impact: The results of research in this area will integrate European scientific excellence and lead to better therapy regimens for and cancer care of patients.

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. 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 worldwide.

Note: for topics under this area applicants will have to follow the rules for single-stage submission procedure (see respective call fiche in section III).

HEALTH.2010.2.4.2-1: Reducing in-stent thrombosis. FP7-HEALTH-2010-single-stage. Research should aim to develop new strategies to prevent late in-stent thrombosis in the treatment of ischemic heart disease combining mechanistic research in platelet biology and coagulation in relevant model studies, with clinical studies using novel imaging technology. Active participation of SMEs could lead to an increased impact of the research proposed and this will be considered in the evaluation of the proposal. **Note:** Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria. You must refer to the call fiche for details of these limits.
Funding scheme: Collaborative Project (Small or medium-scale focused research project)
EC contribution per project: max. EUR 6 000 000
Only up to one proposal can be selected.
Expected impact: Research is expected to integrate in a multidisciplinary approach researchers tackling different aspects of the in-stent thrombosis problem and to reduce a burden of this complication.

HEALTH.2010.2.4.2-2: New approaches to reduce ischemic damage to the heart. FP7-HEALTH-2010-single-stage. Research should aim to implement and evaluate recently developed methods in a medium-scale patient study with extensive sampling for biomarker and annotation of disease variables in order to explore patient-related confounders. Evaluation of the efficacy of pharmacological treatments in patients undergoing non-cardiac surgery may also be considered. **Note:** Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria. You must refer to the call fiche for details of these limits.
Funding scheme: Collaborative Project (Small or medium-scale focused research project)
EC contribution per project: max. EUR 6 000 000
Only up to one proposal can be selected.
Expected impact: The results of research through a novel focus on complementary therapies that reduce infarct size are expected to contribute to the reduction of the evolution to heart failure and the need for regenerative medicine.

HEALTH.2010.2.4.2-3: Identifying new therapeutic targets in atrial fibrillation. FP7-HEALTH-2010-single-stage. Research should aim to identify molecular markers that better explain the mechanisms causing persistent atrial fibrillation and to identify and validate the potential of new diagnostic biomarkers and therapeutic targets. The project should take advantage of large-scale patient data and bio sampling, computational biology (including modelling and simulations), the potential of animal models for preclinical testing and of small proof-of-concept patient studies. Active participation of SMEs could lead to an increased impact of the research proposed and this will be considered in the evaluation of the proposal. **Note:** Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria. You must refer to the call fiche for details of these limits.
Funding scheme: Collaborative Project (Large scale integrating project)
EC contribution per project: min. EUR 6 000 000 – max. EUR 12 000 000
Only up to one proposal can be selected.
Expected impact: Research is expected to provide new insights in the cardiac remodelling processes that lead to refractory atrial fibrillation and to form the basis of novel, cost effective therapies.

HEALTH.2010.2.4.2-4: Diastolic heart failure. FP7-HEALTH-2010-single-stage. Research should aim to define and explore the molecular mechanisms underlying diastolic heart failure with the aim to develop specific therapies and algorithms for diagnosis and treatment. A multidisciplinary approach is needed, including molecular marker, tissues, genetic studies, animal models, imaging, cell and systems biology, and including the use of patient data to generate hypotheses to be validated in the experimental setting. Active participation of SMEs could lead to an increased impact of the research proposed and this will be considered in the evaluation of the proposal. **Note:** Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria. You must refer to the call fiche for details of these limits.
Funding scheme: Collaborative Project (Large scale integrating project)
EC contribution per project: min. EUR 6 000 000 – max. EUR 12 000 000
Only up to one proposal can be selected.
Expected impact: The results of research in this area should lead to better understanding of a diastolic heart failure development. New diagnostic and treatment options will contribute to reducing the burden of this pathology.

2.4.3. Diabetes and obesity

CLOSED for WP 2010

2.4.4. Rare diseases

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

Note: for topic HEALTH.2010.2.4.4-1 applicants will have to follow the rules for single-stage submission procedure (see respective call fiche in section III). Applicants for topic HEALTH.2010.2.4.4-2 have to follow the rules of the FP7-ERANET-2010-RTD.

HEALTH.2010.2.4.4-1: Clinical development of substances with a clear potential as orphan drugs. FP7-HEALTH-2010-single-stage. Support will be provided to clinical studies (including Phase III clinical trials) of EU designated orphan medicinal products[19]. Clinical studies should focus on biopharmaceutic studies (incl. bioavailability, bioequivalence, in-vitro in-vivo correlation), human pharmacokinetic and pharmacodynamic studies, human efficacy and safety studies. Involvement of industry, in particular SMEs, is strongly recommended. Cancer diagnostics/therapies will not be considered[20]. The orphan medicinal product will need to be granted the EU orphan designation at the latest on the date of the call closure. **Note:** Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria. You must refer to the call fiche for details of these limits.
Funding scheme: Collaborative Project (Small or medium-scale focused research project)
EC contribution per project: max. EUR 6 000 000
One or more proposals can be selected.
Expected impact: The selected projects should mobilise the critical mass of expertise in order to test diagnostic and/or therapeutic approaches to rare diseases. The acquired knowledge should bring valuable information for the care of rare diseases patients.

HEALTH.2010.2.4.4-2: ERA-Net on rare diseases. FP7-ERANET-2010-RTD[21]. This action should improve the linking and efficient integration and coordination of national/regional programmes for rare diseases research, building on previous activities in this field. The action should include a strategy leading to the mutual opening of national/regional programmes to the participants and to the implementation of joint transnational calls, as well

[19] The European register of designated Orphan Medicinal Products is available from http://ec.europa.eu/enterprise/pharmaceuticals/register/orphreg.htm
[20] Topics on 'Structuring clinical trials on rare cancers in adults' and' Structuring clinical research in paediatric and adolescent oncology in Europe' are included in section 2.4.1
[21] Call fiche: see ANNEX 4 to the cooperation work programme

as activities aimed at fostering the development of rare diseases research programmes in non-participant Member States and Associated States. The action will also help identifying priorities for research on rare diseases, based on regional/national/European information. Due consideration should be given to the enlarged European Research Area. **Note:** Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria. You must refer to the call fiche for details of these limits.
Funding scheme: Coordination and Support Action (Coordinating Action)
EC contribution per ERA-NET: max. EUR 2 000 000
Only up to one proposal can be selected.
Expected impact: This action should deepen and extend the coordination of European research in the field of rare diseases.

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

Note: for topics under this area applicants will have to follow the rules for single-stage submission procedure (see respective call fiche in section III).

HEALTH.2010.2.4.5-1: Investigation of the mechanisms of initiation of allergic response, genetic predisposition, biomarkers and identification of targets for therapy. FP7-HEALTH-2010-single-stage. Research should represent a joint effort of clinicians (allergologists and epidemiologists), geneticists, immunologists, molecular biologists and biochemists with a strong clinical research component and applying experimental and animal models. The approach should contribute to the elucidation of the mechanisms of allergy-associated diseases using cross-sectional and longitudinal approaches including a study of genetic predisposition, characterization of the risk groups among the population, in particular children, definition of environmental protective and susceptibility factors, characterization of potential inhalant and food allergens throughout Europe, as well as methodology to establish suitable biomarkers for early diagnosis and prevention of allergy-associated diseases such as asthma and atopic dermatitis. Active participation of SMEs could lead to an increased impact of the research proposed and this will be considered in the evaluation of the proposal. **Note:** Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria. You must refer to the call fiche for details of these limits.
Funding scheme: Collaborative Project (Large-scale integrating research project)
EC contribution per project: min EUR 6 000 000 - max. EUR 12 000 000
Only up to one proposal can be selected.
Expected impact: The results of research in this area will integrate European scientific excellence in the area of study and treatment of allergic diseases that is currently fragmented because no concerted action in this area has as yet been undertaken.

HEALTH.2010.2.4.5-2: Infection and dysbiosis as the triggers of the development of inflammatory processes in allergies and autoimmune diseases. FP7-HEALTH-2010-single-stage. Research should focus on the triggering mechanism induced by various

pathogens, leading to an inflammatory reaction which, under the influence of a persistent – subclinical – stimulus becomes chronic and may trigger an allergic or autoimmune reaction. It should include investigation of the potential lack of the resolution as a cause for the chronic nature of the inflammatory response. Translational research to identify infectious agents involved, the role of specific pathogens (bacterial, viral, fungal, etc.) and the mechanisms underlying altered host-pathogen interactions in the establishment and persistence of allergic and autoimmune diseases should apply a multidisciplinary approach involving allergologists, clinical immunologists, virologists, bacteriologists, geneticists, molecular biologists, bio-informaticians and the use of animal models and clinical data. Active participation of SMEs could lead to an increased impact of the research proposed and this will be considered in the evaluation of the proposal. **Note:** Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria. You must refer to the call fiche for details of these limits.
Funding scheme: Collaborative Project (Small or medium-scale focused research project)
EC contribution per project: max. EUR 6 000 000
One or more proposals can be selected.
Expected impact: The results of research in this area will integrate European scientific excellence and make it more competitive at international level.

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

To optimise health care delivery it is necessary to understand how to create the best interventions, but also how to best ensure that they are effectively delivered in clinical practice to get the best return on decades of investment in biomedical research. Recent literature has underscored the importance of understanding the many factors that affect whether the clinicians will use a given intervention. Invited research on dissemination will address how information about health care interventions are created, packaged, transmitted, and interpreted among a variety of important stakeholder groups. Research on implementation will address the level to which health interventions can fit within real-world clinical service systems. This distinction needs to be made because interventions developed in the context of efficacy and effectiveness trials are rarely transferable without adaptations to specific settings.
Note: applicants will have to follow the rules for two-stage submission procedure (see respective call fiche in section III).

Topic for two-stage submission and evaluation; deadline 1st stage: 29 October 2009

HEALTH.2010.3.1-1: Better understanding of dissemination and implementation strategies. FP7-HEALTH-2010-two-stage. Research should aim to bridge the know-do gap between clinical research and everyday clinical practice by building a knowledge base on how health information, interventions and new clinical practices are translated into health service provision in specific settings. Such research could address the processes (development and testing of theoretical models for dissemination and implementation processes), methodologies and measures for investigating such processes, the capacity of specific settings to incorporate

dissemination and implementation processes within the current organisational arrangement, and the sustainability of effective dissemination and implementation processes.
This research could either address the dissemination process, i.e. the targeted distribution of information and intervention materials to a specific clinical practice audience with the intent to spread knowledge and the associated evidence-based interventions. This will require the identification of mechanisms and approaches to effectively package and convey the evidence-based information to the identified target groups.
The research could also address the implementation process, i.e. how to adopt and integrate evidence-based health interventions and change health service delivery patterns in specific settings. This research should help to assess how interventions are transferred into everyday clinical practice and whether the eventual implementation remained faithful to the original conceptualisation and intent of the intervention. **Note:** Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria. You must refer to the call fiche for details of these limits.
Funding scheme: Collaborative Project (small or medium-scale focused research project)
EC contribution per project: max. EUR 3 000 000
One or more proposals can be selected.
Expected impact: This research should establish the empirically tested theoretical basis for better understanding which factors influence the effectiveness of dissemination and implementation strategies of new knowledge (e.g. clinical guidelines), products, or interventions. The conceptual models that are developed and/or tested here should be applicable across diverse health care settings and allow the design of research that will be able to rigorously assess the effectiveness of dissemination and implementation strategies. The cooperation between researchers in Europe and other geographic regions should be enhanced to promote integration and excellence of European research in the area.

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. **Note**: for both topics applicants will have to follow the rules for single-stage submission procedure (see respective call fiche in section III).

HEALTH.2010.3.2-1: Financing systems' effect on quality of healthcare. FP7-HEALTH-2010-single-stage. Research should aim to develop models that take into account the needs of different patient groups in relation to how healthcare is financed in different settings of the health systems in Europe. The incentive mechanisms effect on quality of care need to be explored. Issues such as cost control, equity and efficiency should also be addressed. **Note:** Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria. You must refer to the call fiche for details of these limits.
Funding scheme: Collaborative Project (Small or medium-scale focused research project)

EC contribution per project: max. EUR 3 000 000
One or more proposals can be selected.
Expected impact: The knowledge gained from the research should provide support for Member States to choose the right financing mechanisms in the different areas of the health care system according to their need. Addressing different aspects of the financial incentives' effect on quality of care should advance the knowledge base on sustainability of the health systems further.

HEALTH.2010.3.2-2: Risk adjustment algorithms for better health insurance coverage. FP7-HEALTH-2010-single-stage. Research should aim to develop risk adjustment models to better share risks between providers of social health insurance and reduction of the asymmetric information in health insurance. Also the relationship between patients and insurers, insurers and providers, and patients and providers should be investigated. This research should build up the evidence base for setting up mechanisms to ensure efficiency in the financing of social insurance based healthcare in both new and old Member States. Active participation of SMEs could lead to an increased impact of the research proposed and this will be considered in the evaluation of the proposal. **Note:** Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria. You must refer to the call fiche for details of these limits.
Funding scheme: Collaborative Project (Small or medium-scale focused research project)
EC contribution per project: max. EUR 3 000 000
One or more proposals can be selected.
Expected impact: This research should provide evidence for setting up mechanisms to ensure efficiency in the financing of social insurance based health care, aim to prevent risk adjustment by the insurers and secure equal access to healthcare for the population.

3.3. ENHANCED HEALTH PROMOTION AND DISEASE PREVENTION

CLOSED for WP 2010

3.4. INTERNATIONAL PUBLIC HEALTH & HEALTH SYSTEMS

This 4th Call foresees an emphasis on collaborative health research with Africa entitled "Better health for Africa". Research activities foreseen in this area is the result of extensive consultations and interaction with stakeholders, in particular WHO for example the 2008 World Health Report on Primary Health Care, the World Health Assembly Resolution WHA61.21 on a 'Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property' 24th May 2008 (the 'IGWG Process') a special session hosted in the 2008 Ministerial Forum on Research for Health in Bamako, Mali, the November 2008 EC Conference on poverty-related diseases and other international fora such as the Africa, Caribbean and the Pacific (ACP). Furthermore Cluster 6 of the EU-Africa partnership foresees S&T collaboration with an emphasis on capacity building. The lack of reliable evidence on the overall impact and the cost-effectiveness of major health programmes and the need for more impact research has been one of the main conclusions from the Ministerial Summit in Bamako 2008. There is a need to provide evidence on the effectiveness of new strategies and interventions to improve maternal and newborn health and to contribute directly to the Millennium Development Goals (MDGs) N°5 - maternal health and N°4 - child health,

as about one third of all under-five mortality is related to perinatal causes. At the same time opportunities have to be created to promote evidence-based policy making by involving stakeholders and policy makers, contributing to better access to essential health care and contributing to achieving the health related MDGs.

Note: for the following topics HEALTH.2010.3.4-5 and HEALTH.2010.3.4-6 applicants will have to follow the rules for single-stage submission procedure (see respective call fiche in section III). Applicants for topics HEALTH.2010.3.4-1; HEALTH.2010.3.4-2; HEALTH.2010.3.4-3 and HEALTH.2010.3.4-4 have to follow the rules of the FP7-CALL-FOR-AFRICA-2010 (see section III).

HEALTH.2010.3.4-1: Develop and assess key interventions and policies to address the human resource crisis in the health sector. FP7-CALL-FOR-AFRICA-2010. Research should aim to assess the scope of the deficit in human resources for health and identify and analyse the main causes as well as the effects of related interventions and policies. Aspects to be considered may include – among others - training capacity, inappropriate task allocations, brain drain, maldistribution and working conditions. Based on this situation analyses, improved or new interventions and/or policies should be developed and tested in terms of effectiveness, costs, feasibility and potential acceptance by policy makers in close cooperation with stakeholders. The aim is to achieve a balanced level of participation for African countries in collaboration with their European partners and it will be considered in the evaluation.
Note: Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria. You must refer to the call fiche for details of these limits.
Funding scheme: Specific International Cooperation Action (**SICA)** Collaborative Project (Small or medium-scale focused research project) Target Region: International cooperation partner countries (ICPC) from African ACP and the following Mediterranean Partner countries (African MPC), Algeria, Egypt, Libya, Morocco and Tunisia
EC contribution per project: max. EUR 3 000 000
One or more proposals can be selected.
Expected impact: Results are expected to provide evidence on effective interventions and policies for improving the availability of a sufficient number of competent human resources for health and thus contribute to better access to essential health care and achieving the health related WHO Millennium Development Goals (MDGs).

HEALTH.2010.3.4-2: Feasibility and community effectiveness of innovative intervention packages for maternal and new-born health in Africa. FP7-CALL-FOR-AFRICA-2010. Research should focus on impact-oriented research on the effectiveness and feasibility of strategies and related interventions to promote the health of mothers and their new-borns. Such strategies and interventions may cover areas and links ranging across the health system from the community level, to the first level and the hospital-based referral level of care and may address all pregnancy-related services from pre-conception, to antenatal, to delivery and to postnatal care. Interventions to be considered could range from systemic and managerial interventions such as continuity of care, quality of care, patient safety, to interventions focusing on human resources, social and educational interventions to specific innovations in prevention, medical treatment and diagnostics. The project should aim at providing evidence on new strategies and interventions that are relevant and applicable in local socioeconomic and cultural contexts. The aim is to achieve a balanced level of participation for African countries in collaboration with their European partners and it will be considered in the

evaluation. **Note:** Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria. You must refer to the call fiche for details of these limits.
Funding scheme: Specific International Cooperation Action (**SICA)** Collaborative Project (Small or medium-scale focused research project) Target Region: International cooperation partner countries (ICPC) from African ACP and the following Mediterranean Partner countries (African MPC), Algeria, Egypt, Libya, Morocco and Tunisia
EC contribution per project: max. EUR 3 000 000
One or more proposals can be selected.
Expected impact: Results are expected to provide evidence on the effectiveness of new strategies and interventions to improve maternal and newborn health and will contribute directly to the WHO Millennium Development Goals (MDGs) 5 (maternal health) and 4 (child health) and as about one third of all under-five mortality is related to perinatal causes.

HEALTH.2010.3.4-3: Building sustainable capacity for research for health in Africa. FP7-CALL-FOR-AFRICA-2010. The Coordination Action should develop and implement a concept for the sustainable development of capacity for health research in Africa in close collaboration with African research institutions and a substantial element of South-South cooperation. Topical areas to be covered should be identified through a training needs assessment with all stakeholders as part of the project and may include – among others – epidemiology and demography, health economics, environmental health, evaluation sciences, medical anthropology, and community-based health care. Interdisciplinary courses may also be considered. The format of the training interventions should be adjusted to the needs of the African partner countries; in case of formal training programmes, joint degrees or degrees from the African partner institutions should be preferred. Emphasis should be given to establishing and supporting excellent academic teaching and research networks. Active participation of young African researchers in regional and international fora as well as exchange within African research institutions and between European and African institutions could be considered. The aim is to achieve a balanced level of participation for African countries in collaboration with their European partners and it will be considered in the evaluation. **Note:** Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria. You must refer to the call fiche for details of these limits.
Funding scheme: Coordination and Support Action (Coordinating Action). Target Region: International cooperation partner countries (ICPC) from African ACP and the following Mediterranean Partner countries (African MPC), Algeria, Egypt, Libya, Morocco and Tunisia
EC contribution per project: max. EUR 2 000 000
One or more proposals can be selected.
Expected impact: The action is expected to promote African health scientists along with their institutions and research networks in order to create a sustainable and attractive research landscape for health research in Africa.

HEALTH.2010.3.4-4: Assessment of migrants' health, disease patterns and impact on health systems. FP7-CALL-FOR-AFRICA-2010. Coordination in this field is expected to look at the full migration cycle, including effects in the countries of origin, the host countries, and re-migration. Aspects to be covered should include accessibility and appropriateness of health services, health status and health differentials compared to the resident populations, health effects of migration on resident populations, and health events as a potential cause for migration or re-migration. Further aspects may include policy analysis and effects of migration of health workers. Several International Cooperation Partner Countries as well as European countries should be studied for comparison purposes. The aim is to achieve a balanced level of participation for African countries in collaboration with their European

partners and it will be considered in the evaluation. **Note:** Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria. You must refer to the call fiche for details of these limits.
Funding scheme: Coordination and Support Action (Coordinating Action) Target Region: International cooperation partner countries (ICPC) from African ACP and the following Mediterranean Partner countries (African MPC), Algeria, Egypt, Libya, Morocco and Tunisia
EC contribution per project: max. EUR 2 000 000
Only up to one proposal can be selected.
Expected impact: Migration has a profound effect on health and health systems in the countries of origin as well as in host countries. Health systems are often not well prepared to adequately address the health needs of migrants as well as the migration-related health challenges for the resident population. This research should inform policy, civil society and the scientific community by establishing region-specific evidence on the scope and magnitude of the problem, on options for interventions, and on further research needs.

HEALTH.2010.3.4-5: Assessment of migrants' health, disease patterns and impact on health systems. FP7-HEALTH-2010-single-stage. Coordination in this field is expected to look at the full migration cycle, including effects in the countries of origin, the host countries, and re-migration. Aspects to be covered should include accessibility and appropriateness of health services, health status and health differentials compared to the resident populations, health effects of migration on resident populations, and health events as a potential cause for migration or re-migration. Further aspects may include policy analysis and effects of migration of health workers. Several International Cooperation Partner Countries as well as European countries should be studied for comparison purposes. **Note:** Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria. You must refer to the call fiche for details of these limits.
Funding scheme: Coordination and Support Action (Coordinating Action) (Target Regions: countries from Latin America and Mediterranean partner countries (MPC). At least 6 independent legal entities, of which, 3 must be established in different MS or AC and the other 3 must be established in different international cooperation partner countries (ICPC) from the above mentioned target regions (LA, MPC).
EC contribution per project: max. EUR 2 000 000
Only up to one proposal from each target region can be selected.
Expected impact: Migration has a profound effect on health and health systems in the countries of origin as well as in host countries. Health systems are often not well prepared to adequately address the health needs of migrants as well as the migration-related health challenges for the resident population. This research should inform policy, civil society and the scientific community by establishing region-specific evidence on the scope and magnitude of the problem, on options for interventions, and on further research needs.

HEALTH.2010.3.4-6: Impact and cost-effectiveness of existing major health programmes. FP7-HEALTH-2010-single-stage. Research should aim to develop and validate an appropriate methodology and apply it to one or more existing major health programmes or models of service provision addressing priority health issues, such as child health, reproductive health, mental health, patient safety, and/or specific disease control programmes. The methodology should aim at producing relevant comparable outcome parameters, including possible unintended positive or negative health side-effects on individuals and health systems beyond the immediate target condition. The methodology should also be adaptable to a wider range of health programmes. Involvement of stakeholders and dissemination of results to policy makers, civil society and the scientific community

should be incorporated. While methodologies for assessing specific single interventions are well established, the assessment of the impact of large scale health programmes, being rolled out on regional, national, or even international level, is more complex. **Note:** Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria. You must refer to the call fiche for details of these limits.
Funding scheme: Specific International Cooperation Action (**SICA)** Collaborative Project (Small or medium-scale focused research project) Target Regions: all International Cooperation Partner Countries (ICPC)
EC contribution per project: max. EUR 3 000 000
One or more proposals can be selected.
Expected impact: Results are expected to provide evidence on the effectiveness, cost-effectiveness and appropriateness of major health programmes and thus provide scientific evidence for rational decision making on national and international level. Beyond that the development of an improved methodology for research on programme impact could help include mechanisms for better impact assessment in revised or new future programme designs. As many of the programmes in question are related to the WHO Millennium Development Goals (MDGs), the project will contribute to achieving the MDGs through more effective and targeted programme implementation.

HEALTH.2010.3.4-7: Financing models for accessible health care. FP7-HEALTH-2010-single-stage. Research should develop and assess equitable health care financing models that aim at universal coverage and sustainability of quality healthcare in low and middle-income countries. These models could incorporate a mix of financing mechanisms and should take national contexts and existing financing systems into account. Such research should serve to prevent catastrophic expenditures for users of health services, be appropriate for use in low and middle-income countries and implementation at the national level. Incentive mechanisms to deliver health services to the poor must be taken into account. **Note:** Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria. You must refer to the call fiche for details of these limits.
Funding scheme: Specific International Cooperation Action (**SICA)** Collaborative Project (Small or medium-scale focused research project) Target Regions: all International Cooperation Partner Countries (ICPC).
EC contribution per project: max. EUR 3 000 000
One or more proposals can be selected.
Expected impact: This research is expected to provide the necessary evidence for national decision makers in low and middle-income countries when they reform their existing financing systems for healthcare. It should also contribute to the global debate on how to achieve universal coverage of quality healthcare

Please see also **HEALTH.2010.4.2-5. Methodology to evaluate and monitor health policy implementation and performance of EU funded interventions in developing countries. FP7-HEALTH-2010-single-stage.**

4. OTHER ACTIONS ACROSS THE HEALTH THEME

4.1. COORDINATION AND SUPPORT ACTIONS ACROSS THE THEME

The objective of these actions is to contribute to the implementation of the Framework Programmes and the preparation of future Community research and technological development policy. The focus of this area will be on facilitating SME participation.

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

HEALTH.2010.4.1-1: Promoting participation of high-technology research-intensive SMEs, operating in the Health sector. FP7-HEALTH-2010-single-stage. The objectives are: *(i)* to promote participation of SMEs with the focus on high-technology, research intensive SMEs in the calls of the FP7 Health theme. The promotional activity should include participation in relevant events and organisation of workshops, as appropriate, with special attention to the enlarged Europe, acceding and candidate countries; *(ii)* to assist SMEs in participating into EU-funded research proposals in the Health thematic priority of FP7, with training activities and tools; *(iii)* to encourage cooperation between SMEs and Academia; *(iv)* to provide support for consortium building and matchmaking for SMEs and Academia in preparing EU project proposals with the help of a matchmaking database*; (v)* to provide tools and advice for improving the quality of research proposals submitted in the Health thematic priority of FP7 and increase the participation rate of SMEs*. (vi)* For the participants of health theme proposals in negotiation, to provide support, tools and training to facilitate a successful negotiation of grant agreements*; (vii)* to provide support on IPR issues that may rise during negotiation or during funded projects' lifetime; *(viii)* to assist SMEs participating into EU-funded research projects in the Health thematic priority of FP7, with training activities and tools; *(ix)* to provide advise/information/training on valorisation of project results in view of future commercialization covering for example business management, innovation financing sources, organisation of partnering events. The project should collaborate, complement and develop synergistic approach with existing support structures like National Contact Points and already funded support projects relevant for SMEs working in health sector, like the IPR help-desk. **Note:** Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria. You must refer to the call fiche for details of these limits.
Funding scheme: Coordination Action or Support Action (Coordinating Action)
EC contribution per project: max. EUR 2 000 000
Only up to one proposal can be selected.
Expected impact: The promotional activity is expected to support the increase of high-tech SMEs participation in the Health Theme, enhancing Lisbon objective for contributing to technological evolution, competitiveness of European industry, economic growth and employment. Participation of industry and SMEs in particular in FP7 health projects, will enhance the dissemination and exploitation of research results generated in the activities funded by this Theme, which has the political objective of giving to SMEs 15% of the EU contribution. The project is expected to help SMEs in successfully participating into framework projects.

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.

Note: for topics under area 4.2 applicants will have to follow the rules for single-stage submission procedure (see respective call fiche in section III). For thematic and organisational reasons topics are grouped into three groups: 4.2a, 4.2b and 4.2c, which represents an extra call.

4.2a

HEALTH.2010.4.2-1.: Off-patent medicines for children. FP7-HEALTH-2010-single-stage. Research should aim to increase the availability of medicines duly authorised for children as well as to increase the information available on the use of medicinal products in the paediatric population. Project(s) will need to develop and test new paediatric medicine formulations in children from older off-patent medicines. The Paediatric Medicines Priority List of Off-Patent Products, available at the following address: http://www.emea.europa.eu/htms/human/paediatrics/prioritylist.htm reflects a longer list than before of needs which can be broken down into:

- new formulations, for example oral presentations for existing products (oncology, pain relief, etc.),
- the needs of neonates (in infectious diseases, neurology, analgesia, intensive care),
- age-appropriate formulations and
- new conditions (rheumatology, etc).

New data on efficacy, safety and the pharmacokinetic profiles are required. In view of many facilities offered by the European Medicines' Agency (EMEA), such as fee reductions, exemptions and deferrals for advice obtained in the context of Marketing Authorisation Applications (MAAs), including PUMAs (Paediatric Use Marketing Authorisation). Active participation of SMEs could lead to an increased impact of the research proposed and this will be considered in the evaluation of the proposal. **Note:** Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria. You must refer to the call fiche for details of these limits.
Funding scheme: Collaborative Project (Small or medium-scale focused research project)
EC contribution per project: max. EUR 6 000 000
One or more proposals can be selected.
Expected impact: The expected result should be a Paediatric Use Marketing Authorisation (PUMA) application.

HEALTH.2010.4.2-2: International paediatric initiative. FP7-HEALTH-2010-single-stage. The initiative is expected to bring together European and US stakeholders, as well as other third countries as appropriate, which are involved in the joint development and testing of medicines for children. It should demonstrate a rationally structured joint programme of activities aimed at integrating research efforts in different multidisciplinary fields (trial methodology, ethics, pharmaco-epidemiology, new formulations and drug safety). The overall objective is to enhance the availability of medicines for children in Europe and in the USA. An expected deliverable will be the successful development of a joint paediatric clinical pharmacology training programme. Others include jointly executed EU/US paediatric

medicine research activities in support of the joint programme of activities, mutually agreeable standards for clinical trials, quality assurance, development of integrated tools (e.g. databases) for pharmaco-epidemiological studies etc. Areas of clinical interest should include, but not exclusively, new formulations, the needs of neonates, paediatric gastroenterology, cardiology, neonatology, neuropsychiatric, infectious and rare paediatric diseases. A concrete dissemination plan should be included. The initiative should also establish a joint structure to enhance and consolidate durable integration, with the possibility of adding new groups via competitive Calls for Proposals as necessary. Active participation of SMEs could lead to an increased impact of the research proposed and this will be considered in the evaluation of the proposal. **Note:** Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria. You must refer to the call fiche for details of these limits.
Funding scheme: Network of Excellence
EC contribution per project: max. EUR 12 000 000
Only up to one proposal can be selected.
Expected impact: To integrate European research programmes in paediatrics. To foster a closer interaction with those in the USA and third countries in order to accelerate the accessibility to new medicines for children. A wide range of stakeholders, including especially patient organisations, should be represented.

HEALTH.2010.4.2-3: Adverse drug reaction research. FP7-HEALTH-2010-single-stage.
The safe use of medicines maintains an even higher profile than before, with often serious adverse events becoming apparent many years after products have been launched and because such events may not be limited to one molecule alone, but to whole classes of products, with similar physiochemical characteristics. Such issues are a matter of grave public concern and the research of selected proposal(s) should generate new knowledge on potentially life-threatening drug adverse events that affect different body systems. Although more than one proposal can be selected from each of the following themes, research in each of the proposals should focus on only one:

- Long-term effects in children and in young adults of methylphenidate in the treatment of attention deficit hyperactivity disorder (ADHD)
- Long-term adverse effects of immunomodulators (monoclonal antibodies)
- Long-term adverse skeletal effects of bisphosphonates.
- Medicine use in pregnancy (design of effective pregnancy prevention programmes, recommendations for safe use in pregnancy)
- Suicidal behaviour in relation to certain drug use (antidepressants, antipsychotics, varenicline, montelukast).
- Safety aspects of antipsychotics in demented patients.

Note: Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria. You must refer to the call fiche for details of these limits.
Funding scheme: Collaborative Project (Small or medium-scale focused research projects)
EC contribution per project: max. EUR 3 000 000
One or more proposals can be selected.
Expected impact: Project results should lead to new knowledge on important adverse drug reactions that constitute major public health concerns i.e. those impacting on the balance of benefits and risks of medicinal products. This new knowledge will support regulatory decisions on marketing authorisations for medicinal products including the warnings in product information for doctors and patients. Public health will be promoted and protected through more effective and safer use of medicines.

4.2b

HEALTH.2010.4.2-4: International pluripotent stem cell registry. FP7-HEALTH-2010-single-stage. Coordination should develop an online platform that provides a freely accessible database of human pluripotent cell lines that are available for research in Europe, including adult and embryonic stem cells (hESC) lines and established induced pluripotent cells (iPS) lines. This registry should provide detailed information on these cell lines including molecular, genetic, phenotypic and functional data. It should network with other stem cell registries established elsewhere in the world with the aim to standardise the available information on these lines. **Note:** Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria. You must refer to the call fiche for details of these limits.
Funding scheme: Coordination and Support Action (Coordinating Action)
EC contribution per project: max. EUR 2 000 000
Only up to one proposal can be selected.
Expected impact: Such a registry in place should ensure a better monitoring of the use of different type of pluripotent cells in Europe. In addition, by providing detailed information on all the stem cell lines available, the registry should contribute to maximise the use of existing hESC and may help to avoid unnecessary derivations of new hESC lines. By networking with other registries in the world, this action should also contribute to generate standardised information on these lines.

HEALTH.2010.4.2-5: Methodology and tools to evaluate and monitor implementation and performance of EU funded interventions in developing countries. FP7-HEALTH-2010-single-stage. Research should aim to develop a sound methodological model for use by EC services and low and middle income countries, accompanied by evaluation and monitoring tools (indicators), to best assess the health impact and wider policy implementation and performance of EU-funded project interventions in developing countries. Models and experiences from other donors and agencies should also be taken into account. Case studies should illustrate possible scenarios. International cooperation partner countries' participation is required. **Note:** Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria. You must refer to the call fiche for details of these limits.
Funding scheme: Specific International Cooperation Action (SICA) Collaborative Project (Small or medium-scale focused research project) Target Regions: all International Cooperation Partner Countries (ICPC)
EC contribution per project: max. EUR 3 000 000
Only up to one proposal can be selected.
Expected impact: This research should serve decision makers in the EU and the development partner countries to strengthen monitoring and evaluation of EU-funded projects and consequently base their decisions on the best scientific advice available when they decide on the use of EU development funds. The collaboration between researchers in Europe and the respective development partner countries should be enhanced to promote integration and excellence of EU-funded research in the area.

HEALTH.2010.4.2-6: Impact of EU legislation on health research. **FP7-HEALTH-2010-single-stage.** The action should aim to evaluate the impact of specific EU legislation and related guidelines, including where applicable the way they are applied at national level, on research activities within the Health theme, including related developments and applications. Each action is expected to address a specific issue relating to an EU legislation of major importance for the research and outcome performed within this theme. Such EU legislation

includes the regulation on advanced therapies, the data protection directive, the regulation on orphan medicinal products, the directive on clinical trials, or the protection of vertebrate animals used for experimental and other scientific purposes. **Note:** Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria. You must refer to the call fiche for details of these limits.
Funding scheme: Coordination Action or Support Action (Supporting Action)
EC contribution per project: max. EUR 500 000
One or more proposals can be selected.
Expected impact: to better assess the consequences of EU legislation on research activities and related developments supported within this theme using scientific analysis based on facts and figures. In particular, such projects are expected to constitute the evidence base that will help the European Commission to anticipate the needs for eventual revision of current EU legislation or elaboration of new legislation.

HEALTH.2010.4.2-7: International forum for European life sciences funders and performers. FP7-HEALTH-2010-single-stage. The coordination action should aim to organise conferences during which scientists and policy makers would debating strategy to be put in place for addressing large-scale research initiatives in Europe. **Note:** Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria. You must refer to the call fiche for details of these limits.
Funding scheme: Coordination and Support Action (Coordinating Action)
EC contribution per project: max. EUR 2 000 000
Only up to one proposal can be selected.
Expected impact: This international forum should help fostering the ERA in life sciences research. It may be the first towards the identification and establishment of large scale research effort in Europe that may suited for ERA-NET, ERA-NET+ or joint programming.

HEALTH-2010.4.2-8: Coordination action in support of the implementation by participating States of a Joint Programming Initiative for combating neurodegenerative diseases, in particular Alzheimer's disease. FP7-HEALTH-2010-single-stage. Following the Commission's Communication on Joint Programming to tackle Europe's major societal challenges, the Competitiveness Council' called for a common commitment of EU Member States (MS) to fight Alzheimer's disease and other neurodegenerative diseases. The successful coordination action must support the implementation of a pilot Joint Programming Initiative by proposing innovative ways of pooling national expertise and resources and establishing closer and robust collaborations among the participating States in the field of neurodegenerative diseases, in particular Alzheimer's disease. Applicants must be national/regional agencies and/or ministries funding activities related to neurodegenerative diseases. **Note:** Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria. You must refer to the call fiche for details of these limits.
Funding scheme: Coordination and Support Action (Coordinating Action).
EC contribution per project: max. EUR 2 000 000
Only up to one proposal can be selected.
Expected impact: This topic will help build ERA by fighting fragmentation, and improve integration and coordination on national research programmes in the field of neurodegenerative diseases.

4.2c (Alternative testing strategies)
Topics for call of alternative testing strategies; deadline: 3 February 2010

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HEALTH.2010.4.2-9: Towards the replacement of repeated dose systemic toxicity testing in human safety assessment.

Call identifier: FP7-HEALTH-2010-Alternative-Testing.

The full replacement of animals in safety testing is a very challenging long-term target in the implementation of the Three Rs principle (Replacement, Reduction, Refinement). Relevant legislation, regulations and directives require urgently a phasing out of animal tests thus putting a high pressure on research, validation and regulatory acceptance. The present call focuses on the construction of a solid foundation of this long term task. It reflects the research strategy for the next years aimed at the development of 'human safety assessment strategies'. The research plan for the first phase will include the specific building blocks: development and use of functional human-based target cells, identification of intermediate biomarkers and endpoints with clinical relevance, construction of advanced organ-simulating devices, the development of biological models with emphasis on systems biology, Quantitative Structure Activity Relationships (QSARs), Physiologically Based Pharmacokinetic Modeling (PBPK), and Threshold of Toxicological Concern (TTC), and integrated data analysis and servicing. Applicants are strongly encouraged to examine how new scientific disciplines could be included in project proposals in order to develop truly novel approaches towards human safety assessment. R&D results should be disseminated broadly to the public domain for the benefit of science and society as a whole. Where appropriate, active participation of small and medium-sized enterprises (SMEs) is strongly recommended in order to increase the impact of the research proposed.

Funding schemes: Six collaborative Projects (Large-scale integrating project; duration: up to five years) and one coordinating action (duration: six years). Up to one project per topic can be selected for funding. Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria. You must refer to the call fiche for details of these limits.

Expected overall impact: Significant contribution to the development of safety testing methods with higher predictive value, faster and cheaper than animal tests; significant reduction of animals currently used in safety testing.

EC financial contribution: The research area "Alternative Testing Strategies" will be implemented with a maximum financial EC contribution of EUR 25 000 000. Contrary to other research topics of the programme the maximum EC financial contribution will be 50 % of the eligible cost of the projects independent on the applicable funding scheme (e.g. co-ordinating action, large scale integrating project). Applicants are encouraged to seek for additional financial support from third parties[22].
The budget foreseen for this topic (Alternative Testing Strategies) will be available exclusively for this area of the call. It can be transferred neither partially nor as a whole to other areas or to other calls for proposals.

[22] The cosmetics industry has announced its commitment to provide additional funding, equal to the contribution of the EC (see COLIPA website www.colipa.eu).

Specific Conditions
It should be noted that this specific research initiative focuses on human safety and that only proposals not involving tests on living animals are eligible for funding. The selection of test chemicals should be made on the basis of existing high-quality datasets from human and animal toxicity studies.

Research work concerning the effects of nanoparticles is excluded from the present call.

Each proposal submitted in one of the topic areas has to clearly describe the interconnections and interfaces with the five other research areas. This is essential in order to optimise the co-operation between the projects and ensure an optimum of synergies. The partners in all research projects selected for funding should agree to an integrated data analysis concept (see 4.2.9.6).

HEALTH.2010.4.2.9-1: Optimisation of current methodologies and development of novel methods to achieve functional differentiation of human-based target cells *in vitro.*
FP7-HEALTH-2010-Alternative-Testing

The following underlined items (a), b),…) should be integrated in the project. However, a successful proposal does not necessarily have to cover all the different issues described in the detailed text of the items.

a) Optimisation of stem cell technology as a source for human-based target cells for toxicological purposes

Stem cells foresee a virtual unlimited source of different cell types. In recent years, many efforts have been focussed on the *in vitro* differentiation of stem cells into cells that are of toxicological relevance, e.g. hepatic cells. There are, however, still a number of hurdles to be overcome. These include the difficulty of reproducibly generating organ-specific cells, as well as the challenge of scalably producing the quantities of such cells needed for high-throughput analysis. Current methods for generating early somatic tissue lineages from stem cells can efficiently yield progenitor cell types expressing biomarkers that are shared with their *in vivo* counterparts. However, efficiency declines as these progenitor populations are driven further towards mature differentiated cells. Therefore, improvements will be needed, especially at intermediate stages of differentiation between stem cell and mature cell states, to increase final yields of mature, organ-specific cells. Likewise, marked improvements are called for maintaining the *in vitro* proliferative status in such intermediate cell types (transit-amplifying cells) as a means of obtaining sufficient cells for large-scale analyses. In particular, the recently introduced strategy to achieve differentiated (organ-specific) cells by sequential exposure of stem cells to a series of growth factors, reflecting (*in vivo*) embryogenesis, seems promising and deserves further attention. Stability of the differentiated state and maintenance of a relevant phenotype, i.e. for toxicity testing, are clearly necessary for successful delivery of both target and metabolically active cell types**.** The overall target is to develop human stable cell lines and stem cells originating from toxicologically relevant target organs.

b) Refinement of cell culture systems for long-term toxicity testing

The maintenance of the differentiated phenotype of cells in culture, both at the morphological level and at the functional level, is key for the development of cell culture systems that can be used for long-term toxicity testing. Current strategies to favour cellular differentiation or to

counteract cellular dedifferentiation *in vitro* are mainly based on mimicking the physiological *in vivo* situation. Typical examples, especially for human primary cells and cell lines, include culture on extracellular matrix proteins (restoration of cell-extracellular matrix contacts), co-cultivation with another cell type (re-introduction of cell-cell interactions), and addition of physiologically relevant chemical compounds to the cell culture medium. In addition, tissue slices offer the advantage that they keep the original cellular architecture, but they also suffer from dedifferentiation and can thus only be used for short-term purposes. The target here thus is to develop cell culture systems in which the differentiated phenotype, in particular the toxicologically relevant functionality of the target organ, can be maintained for at least two weeks.

c) Exploitation of emerging mechanistically-driven methods controlling cellular differentiation

The target of this topic is to carry out basic research to clarify the molecular mechanisms that drive cellular (de)differentiation, which in turn could open new perspectives for the development of innovative methods to induce and/or maintain differentiation of cells in culture. For instance, interfering with posttranslational protein modifications may substantially enhance functional differentiation over the long-term. Genetic and epigenetic approaches, including the introduction of differentiation-promoting genes into the genome and the modification of the chromatin structure in favour of differentiation-promoting transcriptional activity, respectively, allow the direction of the differentiation process at the most upstream regulatory level. It is evident that "-omics" technology in all its aspects plays a key role in these new strategies. Another major challenge lies in altering the expression profile of microRNA species, which are essential determinants of cellular differentiation. Such innovative "cellular differentiation therapies" are still in their infancy, and need to be further exploited before they can be optimally used in (long-term) *in vitro* modelling.

Funding scheme: Collaborative project (Large-scale integrating project)
EC contribution per project: min. EUR 4 000 000 – max. EUR 5 000 000
Only up to one proposal can be selected.
Expected Impact: Development of in vitro systems with toxicological in vivo-like function and phenotype, which can be maintained stable over extended periods and are ready to enter pre-validation (as defined by ECVAM[23]).

HEALTH.2010.4.2.9-2: Exploitation of organ-simulating cellular devices as alternatives for long-term toxicity testing. FP7-HEALTH-2010-Alternative-Testing

The following underlined items (a), b),…) should be integrated in the project. However, a successful proposal does not necessarily have to cover all the different issues described in the detailed text of the items.

a) Integration of target and metabolising cells to simulate multi-organ-related toxicity in vitro

One potential approach to replace or at least reduce animal experimentation in repeated dose systemic toxicity testing is the use of organ-simulating devices. These may be based directly on complex three-dimensional architectures of cultured human-based target cells in a

[23] R. D. Curren, J.A. Southee, H. Spielmann, M. Liebsch, J.H. Fentem, M. Balls The role of prevalidation in the development, validation and acceptance of alternative methods; ATLA 23, 211 – 217, 1995

bioreactor designed to reproduce *in vivo*-like functional activity over extended periods. Bioreactors need to be designed to support both assembly and homeostasis of a complex architecture within an affordable framework. The system must include facilities for drug application and for read-out of the assay. A correlated requirement is for appropriate human cells preferably differentiated *in situ* to represent a particular phenotype. More detailed understanding and control of the chemical composition of the culture media is required in order to maintain all parameters within a specific range of action. Miniaturisation should be employed both to emulate substructures in human organs and to facilitate high-throughput test designs. An alternative approach is the use of organ-simulating devices based on robust monocultures or supracellular structures designed to mimic the essential molecular interactions in a biochemical simulator that can feed information to an *in silico* model. Despite rapid advances in the individual technical fields required to assemble such devices, predictive procedures for assessing human exposure based on such technologies remain rudimentary and restricted to the research level. A concerted interdisciplinary effort is required to elevate these methodologies to a level suitable for practical application. The general target is thus to develop at least one organ-simulating cellular device at the proof-of-principle level.

b) Utilisation of scaffolds and microstructures to optimise the cellular microenvironment

An alternative approach to organ-simulating devices is to reduce the complexity of the bio-assembly in the device by substituting this with artificial microstructures and scaffolds. Two- or three-dimensional arrays of monocultures connected chemically using fluidics could deliver more robust systems designed to mimic functionality rather than to mimic morphology. Nanostructured materials, synthetic and natural polymer technology, or self-assembled systems may provide the basis for the three-dimensional structures required to support cell proliferation while oxygen and nutrient supply are delivered using artificial microsystems or fluidic transfers. Likewise, the metabolic interactions may be effected by engineered microfluidic connections rather than depending on wholly natural assemblies to deliver complex structural interactions. Research is needed into appropriate structures to support sustainable cell growth in an artificial environment where the demands of biocompatibility are ameliorated compared to the restrictions placed on implantable systems. These then need to be integrated into functional systems designed using novel methods for the construction of three-dimensional fluidic architectures to produce an integrated system with the potential to meet industrial needs for an inexpensive test facility. The target is thus to develop stable cell culture systems that are supported by scaffolds and microstructures that mimic the natural microenvironment.

c) Development of novel cellular barrier models relevant to systemic exposure

For the assessment of topical applications, a number of cellular barrier models are currently available used as well in research as for commercial purposes. No comparable system, however, seems to be available for systemic exposure. *In vitro* models are required for detecting damage to various cellular barriers such as the renal epithelium, the intestinal barrier and the blood-brain barrier, after acute and chronic exposure to chemicals and products of various kinds. Measurement of transport or leakage of indicator compounds, direct non-invasive monitoring of the intact tissue or measurement of indirect effects correlating to barrier effects, could provide viable routes forward. Appropriate culture techniques coupled with advanced sensing technologies are required to furnish a cost-effective solution. The target is therefore to develop appropriate cellular barrier models for systemic exposure to measure the bioavailability of chemicals in the target cells.

d) Optimisation of microsensors to monitor tissue responses in organ-simulating devices

Bioreactors need to be designed to support homeostasis of complex tissue architectures by incorporating appropriate ways to monitor the response of the system using, e.g. non-invasive sensors, in-built microsensors or molecular signalling. Work is required to create sensing strategies or structures that can probe the three-dimensional complexity of cultured material with sufficient resolution and accuracy to support both homeostasis and/or the acquisition of transitional changes that can be more rapidly correlated to toxic responses than can be achieved using conventional outcomes. This output could usefully be multifactorial in order to furnish richer information about the status and response of the artificial organ. A further progression would be to reduce the organ-simulating device to representative arrays of supramolecular structures designed to mimic selected elements of cell susceptibility and to supplement this chemical information with computational modelling. This latter approach may be considered as a hybrid, which supplements computer modelling with new real-time data on actual biochemical interactions generated by the target compound. The target is thus to develop detecting tools for non-invasive monitoring of functional behaviour of cells whether or not treated with chemicals.

Funding scheme: Collaborative project (Large-scale integrating project)
EC contribution per project: min. EUR 4 000 000 – max. EUR 5 000 000
Only up to one proposal can be selected.
Expected Impact: Advanced co-culture devices in a multi-organ setting that includes the most relevant human tissues for repeated dose toxicity testing and aimed at entering pre-validation (as defined by ECVAM).

HEALTH.2010.4.2.9-3: Establishment of endpoints and intermediate markers in human-based target cells with relevance for repeated dose systemic toxicity testing. FP7-HEALTH-2010-Alternative-Testing

The following underlined items (a), b),…) should be integrated in the project. However, a successful proposal does not necessarily have to cover all the different issues described in the detailed text of the items.

a) Functional parameters as predictive signals of human long-term toxicity

Functional endpoints are regarded as the most relevant parameters of the physiological *in vivo* situation of the organism. Therefore they are highly relevant to assess the toxicological effects and should be regarded as refinement of the "-omics"-based markers (see HEALTH.2010.4.2.9-3 b). The target is to identify functional organotypic parameters of human long-term toxicity at the cellular level.

b) Establishment of "-omics"-based markers as predictive signals of human long-term toxicity

Besides aspects of target cells, the determination and evaluation of genomic, proteomic, metabonomic and system biological markers with strong relevance for human toxicity should be included. The markers have to be tested for their predictive capacity for systemic and long-term toxicity. The target is therefore to identify relevant "-omics"-based markers of human long-term toxicity.

c) Integration of markers for enhancement of human long-term predictive capacity

A valid test battery must include more than one parameter. Therefore efforts should be made to examine combinations of "-omics"-based and functional parameters in order to enhance the predictive capacity of the screening systems. Hence, the target is to integrate functional and "-omics"-based markers as a screening system for human long-term toxicity.

Funding scheme: Collaborative project (Large-scale integrating project)
EC contribution per project: min. EUR 3 500 000 – max. EUR 4 500 000
Only up to one proposal can be selected.
Expected Impact: Molecular profiling of combinations of relevant/predictive organ specific biomarkers and –omics-based endpoints for repeated dose toxicity that will allow to develop robust in vitro systems aimed at pre-validation procedures (as defined by ECVAM).

HEALTH.2010.4.2.9-4: Computational modelling and estimation techniques. FP7-HEALTH-2010--Alternative-Testing

The following underlined items (a), b),…) should be integrated in the project. However, a successful proposal does not necessarily have to cover all the different issues described in the detailed text of the items.

a) Threshold of toxicological concern approach for the safety assessment of cosmetic ingredients

The threshold of toxicological concern (TTC) concept is based upon the evidence that potent toxic chemicals would not be expected to cause harm to humans if the exposure is below a defined threshold. Separate evaluations done by industry and by independent experts at the European level came to the conclusion that improvement and adaptation of the concept seems necessary before it could be applied to cosmetic ingredients. Further efforts in this direction should be focussed on the development and validation of toxicological (e.g. carcinogenicity) databases, since the actually existing carcinogenicity database is 25 years old and was expanded about 10 years ago only to a limited extent. New databases should be established, e.g. for carcinogenicity, based on substances classified as human carcinogens, probably or likely human carcinogens, and for non-cancer toxicological endpoints focus should be in particular on the inclusion of recent toxicity data. The following aspects with regard to data entry in the toxicological databases need to be addressed: (*i*) Presence of up-to-date and peer-reviewed data. (*ii*) Display of data under the same focus as existing data. (*iii*) Consideration of correction factors (e.g. allometry, study duration, study outcome) (*iv*) Inclusion of sufficient structure analogues to cosmetic ingredients. The overall target is thus to appropriately apply the TTC approach to the cosmetic field through improvement and development of the respective toxicological databases. The inclusion on how different exposure routes might affect the TTC could also be considered.

b) Innovative computational chemistry approaches in the safety assessment of cosmetic ingredients

Existing approaches such as (Q)SAR and read-across methods need to be refined and overall strategies devised incorporating kinetic and metabolic studies to permit quantitative interpretation of results in terms of consumer risk. If *in silico* approaches are used routinely in the cosmetics industry, it will be important to identify reliable packages that can be supported over the long-term. Grouping approaches, e.g. known now for the evaluation of flavourings,

could be potentially considered for ingredients of cosmetics. The target thus is to optimise (Q)SAR and read-across approaches for the purpose of long-term toxicity prediction of cosmetic ingredients.

c) Predicting the dose at the target level upon long-term exposure

Tools for kinetic modelling should be developed to predict target organ concentrations and the accumulation of chemicals and their metabolites in the context of exposure. Actual concentrations should take into account potential variables such as binding to proteins and specific components of *in vitro* systems, e.g. plastics of the culture dish, three-dimensional networks and scaffolds. The target here thus is to develop kinetic modelling that allows the effective *in vitro* concentration to the target organ level *in vivo* to be extrapolated.

d) PBPK modelling in the safety assessment of cosmetic ingredients

PBPK modelling should be applied to integrate *in vitro* and *in silico* data in order to develop complete absorption, distribution, metabolism and excretion (ADME) models for decision making and risk assessment. This approach represents a way of integrating physicochemical, *in vitro*, human and animal data and computational methods in order to develop a complete model of ADME for a particular compound. No observable (adverse) effect concentration (NO(A)EC) as a measure of toxicity should be derived from *in vitro* repeated dose systems and PBPK should allow to predict a corresponding *in vivo* concentration-dose. One may also integrate other parameters, e.g. an improved exposure assessment using markers to support the application of the TTC. The target is thus to apply PBPK modelling for the purpose of long-term toxicity prediction of cosmetic ingredients.

Funding scheme: Collaborative project (Large-scale integrating project)
EC contribution per project: min. EUR 2 500 000 – max. EUR 3 500 000
Only up to one proposal can be selected.
Expected Impact: Availability of an integrated set of in silico modules and estimation techniques covering the major metabolic pathways of human repeated dose toxicity that will allow the prediction of long term toxicity without the use of animals.

HEALTH.2010.4.2.9-5: Systems biology for the development of predictive causal computer models. FP7-HEALTH 2010-Alternative-Testing

The following underlined items (a), b),…) should be integrated in the project. However, a successful proposal does not necessarily have to cover all the different issues described in the detailed text of the items.

a) Identification and analysis of pathways relevant to long-term toxicity by genetic tools

The general target is to replace current animal testing procedures by a battery of genetic tools that are more selective and, thus, more predictive for long-term toxicity. These genetic tools should be "across species" in order to comprehensively cover the possible target and response pathways of the molecules, they should be highly reproducible and selective (inbred strains, deletion strains) and should be easily accessible for the "-omics"-based technologies described in HEALTH.2010.4.2.9-5 b). Genetic tools under analysis should include relatively simple systems such as yeast, cells/cell lines of animal or human origin and well-characterised human cell lines that are much closer to the human pharmacokinetic profile.0 Experimental

designs should include a panel of selective compounds and the challenge of the different systems with different dosages of these compounds. The outcome of this multi-species analysis should be the identification of conserved (and non-conserved) target pathways along with the long-term toxicity endpoints for the compounds (and compound classes) under analysis.

b) Use of "-omics"- based techniques to identify mechanistic pathways involved in long-term toxicity effects

The target here is to measure and integrate changes upon compound treatment on a global scale with respect to essential biological activities (e.g. transcriptome, epigenome, proteome, metabolome) in the different model systems described in sub-topic HEALTH.2010.4.2.9-6 a) in order to identify mechanistic pathways involved in long-term toxicity effects. "-Omics"-based technology should be based on cutting edge technology such as next-generation sequencing (RNA-Seq, MEDIP-Seq), quantitative proteomics and NMR/MS technology. Additionally, experimental validation technologies such as RNAi screens, ChIP-Seq and protein over- and under-expression of selected compound targets should be applied. The experimental work should be accompanied by the development and application of data integration tools and high-performance computational analysis methods for the different technologies. The outcome of the genome-wide and validation screens should be the identification of response pathways for the long-term toxicity effects of the different compounds.

c) Development of causal predictive computer models for long-term toxicity effects

The target here is the development of modelling systems capable of predicting the response to repeated dose systemic toxicity of chemical compounds. Specific tissues, specific developmental stages or, ultimately, the entire organism should be addressed. Model systems should be able to integrate experimental data on different levels of cellular information generated in sub-topic HEALTH.2010.4.2.9-5 b) and the selective information of the genetic systems proposed in sub-topic HEALTH.2010.4.2.9-5 a). Modelling methodology can include quantitative and qualitative methods. The approaches should be highly automated and should be able to access large collections of network information. Models are typically of large-scale, so the modelling strategy should incorporate computational solutions for performing computing intensive simulations, for example grid computing.

Funding scheme: Collaborative project (Large-scale integrating project)
EC contribution per project: min. EUR 4 000 000 – max. EUR 5 000 000
Only up to one proposal can be selected.
Expected Impact: Molecular profiling using "-omics-based" endpoints of human repeated dose toxicity to identify predictive endpoints that can be used to develop predictive causal computer models aimed at entering pre-validation (as defined by ECVAM).

HEALTH.2010.4.2.9-6: Integrated data analysis and servicing. FP7-HEALTH-2010-Alternative-Testing

The target of the infrastructure research and service project is the establishment of a dedicated web-based 'warehouse', a database and a depository of selected model compounds, a bank for the cells, cell lines and tissues of relevance for *in vitro* toxicity testing within the context of this topic. Besides the research activities, the project should also include specific infrastructural and service functions.

The following underlined items (a), b),…) should be integrated in the project. However, a successful proposal does not necessarily have to cover all the different issues described in the detailed text of the items.

a) Establishment of a dedicated web-based 'data warehouse'

The "data warehouse" is necessary for the centralised compilation of information and data. Links need to be established with relevant public databases. All projects under the topic "alternative testing strategies" need to upload their raw and processed data into this data warehouse as soon as these become available. Data generated will be analysed and the outcome integrated whenever possible into computerised models capable of predicting repeated dose toxicity. Results will be fed back into the projects involved in order to further steer experiments accordingly, which will allow improvement in an iterative way. Overall, this data warehouse should be organised in a way that it provides a sustainable source of information for toxicological research going beyond the lifetime of the projects.

b) Establishment of a database of selected model compounds

The database, to be used also in future studies must meet the highest quality standards. Chemicals in this database should be backed up by high-quality repeated-dose toxicity *in vivo* data from animal studies and, whenever available, experience in humans. The database should not only cover cosmetic ingredients, but could also include industrial chemicals, pharmaceuticals, plant protection products and biocides that meet the same high-quality criteria. In addition, a list of selected model compounds, standard operating procedures for data quality control, processing and analyses should be provided. Whenever compounds are needed for training or validation purposes, these should be selected from this toxicological database in correspondence with their targeted mode of action in chronic toxicity and in collaboration with the cosmetic industry.

c) Establishment of a repository for the selected model compounds

The availability of test chemicals was sometimes a crucial limitation in previous research projects; therefore, the chemicals repository must be established and maintained beyond the end of the projects and measures should be taken to ensure the continuation of this service.

d) Setting up a cell and tissue bank for in vitro *toxicity testing*

An important service to European scientists would be the establishment of a bank of cells, cell lines (including stem cells and stem cell lines) and tissues to be used in the projects.

Funding scheme: Collaborative project (Large-scale integrating project)
EC contribution per project: min. EUR 2 000 000 – max. EUR 3 000 000
Only up to one proposal can be selected.
Expected Impact: Establishment of a centralised and standardised compilation and statistical analysis of the data generated in the participating laboratories in repeated dose toxicity studies to support a flexible, continuous data analysis and discussion early on and to improve the communication among partners of individual projects.

HEALTH.2010.4.2.9-7: Coordination action. FP7-HEALTH-2010-Alternative-Testing

The task of the coordination project is to provide tailor-made progress reporting towards the major stakeholder groups. This will be done through the organization of experts meetings and workshops, exchange of information between the projects and progress monitoring on an

annual basis. In addition, the experience gained throughout the research topic should be made available to scientists in the European Union. In order to fulfil this task the duration of the coordination action shall be 6 years.

Issues to be addressed by the Coordination Action:

a) Tailor-made progress monitoring and reporting towards the major stakeholder groups
The goal is to coordinate and to ensure monitoring and annual reporting of the progress of the projects to selected stakeholder groups and in particular to the Commission and other funding bodies. Furthermore, knowledge gaps will have to be identified and respective research priorities to be defined. This work should be done by the scientific secretariat together with the project coordinators and, whenever necessary, with the assistance of external experts.

b) Organisation of meetings and workshops
Organisation of meetings and workshops should be managed by the scientific secretariat together with an organising committee and a scientific committee with representatives from the relevant stakeholder groups and with the scientific coordinators of the individual projects

c) Facilitating information exchange among members of the participating institutions
This activity should be organised and managed by the scientific secretariat together with the scientific coordinators and the major 'work package' leaders of the projects.

Funding scheme: Collaborative project (Co-ordinating Action)
EC contribution per project: max. EUR 1 500 000
Only up to one proposal can be selected.
Expected Impact: Tailor-made scientific/technical progress monitoring and reporting. Monitoring and communication of the state-of-the art and identification of future RTD priorities in the topic area.

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III IMPLEMENTATION OF CALLS

Call fiche

Call title: HEALTH-2010-single-stage

Call identifier: FP7-HEALTH-2010-single-stage

Proposal submission and evaluation: Single-stage procedure

Date of publication: 30 July 2009[24].

Deadline: 19 November 2009 at 17:00:00 (Brussels local time).[25]

Indicative budget: EUR 333.5 million from the 2010 budget[26]

The budget for this call is indicative. The final budget awarded to actions implemented through calls for proposals may vary:

- *The final budget of the call 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.*

Table 1

ACTIVITY/AREA	Indicative budget (EUR million)
1. BIOTECHNOLOGY, GENERIC TOOLS AND MEDICAL TECHNOLOGIES FOR HUMAN HEALTH	
1.1. HIGH-THROUGHPUT RESEARCH 1.2 DETECTION, DIAGNOSIS AND MONITORING 1.3 SUITABILITY, SAFETY, EFFICACY OF THERAPIES 1.4 INNOVATIVE THERAPEUTIC APPROACHES AND INTERVENTIONS	49
2. TRANSLATING RESEARCH FOR HUMAN HEALTH	
2.1. LARGE-SCALE DATE GATHERING AND SYSTEMS BIOLOGY	16
2.2 RESEARCH ON THE BRAIN AND RELATED DISEASES, HUMAN DEVELOPMENT AND AGEING	0.5
2.3. TRANSLATIONAL RESEARCH IN MAJOR INFECTIOUS DISEASES: TO CONFRONT	78

[24] The Director-General responsible for this call may publish it up to one month prior or after the envisaged date of publication.
[25] The Director-General responsible for this call may delay this deadline by up to two months.
[26] Under the condition that the preliminary draft budget for 2010 is adopted without modifications by the budgetary authority.

MAJOR THREATS TO PUBLIC HEALTH	
2.4. TRANSLATIONAL RESEARCH IN OTHER MAJOR DISEASES	112
3. OPTIMISING THE DELIVERY OF HEALTHCARE TO EUROPEAN CITIZENS	
3.2 QUALITY, EFFICIENCY AND SOLIDARITY OF HEALTH CARE SYSTEMS	14
3.4 INTERNATIONAL PUBLIC HEALTH AND HEALTH SYSTEMS	14
4. OTHER ACTIONS ACROSS THE HEALTH THEME	
4.1. COORDINATION AND SUPPORT ACTIONS ACROSS THE THEME	2
4.2. RESPONDING TO EU POLICY NEEDS	
4.2a	40
4.2b	8

Table 2: Topics called:

Activity/Area	Topics called	Funding Schemes and particular requirements
1.BIOTECHNOLOGY, GENERIC TOOLS AND MEDICAL TECHNOLOGIES FOR HUMAN HEALTH		
1.1 HIGH-THROUGHPUT RESEARCH		
1.1	HEALTH.2010.1.1-1: Harmonisation of phenotyping and biosampling for human large-scale research biobanks.	*Collaborative project (Large-scale integrating project). EC contribution per project: min. EUR 6 000 000 – max. EUR 12 000 000. Only up to one proposal can be selected.*
1.1	HEALTH.2010.1.1-3: High-throughput analysis of post-translational modifications of proteins.	*SICA, Collaborative Project (Small or medium-scale focused research project). Target Region: China. EC contribution per project: max. EUR 3 000 000. Only up to one proposal can be selected.*
1.2 DETECTION, DIAGNOSIS AND MONITORING		
1.2	HEALTH.2010.1.2-2: Stratification approaches and methodologies to select from a wide range of biomarkers relevant candidates for clinical validation.	*Coordination and Support Action (Supporting Action). EC contribution per project: max. EUR 500 000. Only up to one proposal can be selected.*
1.2	HEALTH.2010.1.2-3: Harmonization, validation and standardisation in genetic testing.	*Coordination and Support Action (Coordinating Action). EC contribution per project: max. EUR 2 000 000. Only up to one proposal can be selected.*
1.2	HEALTH.2010.1.2-4: Early events in acute hepatitis C virus (HCV) infection with the aim to identify new biomarkers.	*SICA for Mediterranean Partner Countries Collaborative Project (Small or medium-scale focused*

		research project). EC contribution per project: max. EUR 3 000 000. One or more proposals can be selected.
1.4 INNOVATIVE THERAPEUTIC APPROACHES AND INTERVENTIONS		
1.4	HEALTH.2010.1.4-1: Translational research on cell-based immunotherapy.	*Collaborative Project (Large scale integrating project). EC contribution per project: min. EUR 6 000 000 – max. EUR 12 000 000. One or more proposals can be selected.*
2. TRANSLATING RESEARCH FOR HUMAN HEALTH		
2.1. INTEGRATING BIOLOGICAL DATA AND PROCESSES: LARGE-SCALE DATA GATHERING, SYSTEMS BIOLOGY		
2.1.1. Large-Scale Data Gathering		
2.1.1.	HEALTH.2010.2.1.1-1: Large-scale efforts in mouse functional genomics to determine the functions of genes and their involvement in disease.	*Collaborative Project (Large-Scale integrating project). EC contribution per project: min. EUR 6 000 000 – max. EUR 12 000 000 Only up to one proposal can be selected.*
2.1.1.	HEALTH.2010.2.1.1-2: Coordination action(s) on standards in large scale data gathering.	*Coordination and Support Action (Coordinating Action). EC contribution per project: max. EUR 2 000 000. One or more proposals can be selected.*
2.1.2. Systems Biology		
2.1.2.	HEALTH.2010.2.1.2-3: Developing new and improving existing mathematical algorithms for systems biology.	*SICA Collaborative Project (Small or medium-scaled focused research projects) with focus on EECA. EC contribution per project: max. EUR 3 000 000. Only up to one proposal can be selected.*
2.2. RESEARCH ON THE BRAIN AND RELATED DISEASES, HUMAN DEVELOPMENT AND AGEING		
2.2.2. Human development and ageing		
2.2.2.	HEALTH.2010.2.2.2-5: Frailty and its implications in modern society.	*Coordination and Support Action (Supporting Action). EC contribution per project: max. EUR 500 000. Only up to one proposal can be selected.*
2.3. TRANSLATIONAL RESEARCH IN MAJOR INFECTIOUS DISEASES: TO CONFRONT MAJOR THREATS TO PUBLIC HEALTH		
2.3.2. HIV/AIDS, malaria and tuberculosis		
2.3.2.	HEALTH.2010.2.3.2-1: Target characterisation and hit-to-lead progression in tuberculosis (TB) drug development.	*Collaborative project (Large-scale integrating project). EC contribution per project: min.*

		EUR 6 000 000 – max.EUR 12 000 000. Only up to one proposal can be selected.
2.3.2.	HEALTH.2010.2.3.2-2: Lead optimisation and late preclinical development in tuberculosis (TB) drugs.	*Collaborative project (Small or medium-scale focused research project). EC contribution per project: max EUR 6 000 000. One or more proposals can be selected.*
2.3.2.	HEALTH.2010.2.3.2-3. European network of cohort studies on HIV/AIDS.	*Network of Excellence. EC contribution per project: max. EUR 12 000 000. Only up to one proposal can be selected.*
2.3.3. Potentially new and re-emerging epidemics		
2.3.3.	HEALTH.2010.2.3.3-1: Biology and control of vector-borne infections in Europe.	*Collaborative project (Large scale integrating project). EC contribution per project: min. EUR 6 000 000 – max. EUR 12 000 000. Only up to one proposal can be selected.*
2.3.3.	HEALTH.2010.2.3.3-2: Drug lead discovery against RNA viruses.	*Collaborative project (Large scale Integrating Project). EC contribution per project: min. EUR 6 000 000 – max. EUR 12 000 000. Only up to one proposal can be selected.*
2.3.3.	HEALTH.2010.2.3.3-3: Integrated disease-specific research on West Nile Virus infections, Chikungunya and/or Crimean Congo Haemorrhagic Fever.	*Collaborative projects (Small or medium-scale focused research project). EC contribution per project: max. EUR 3 000 000. One or more proposals can be selected.*
2.3.4 Neglected infectious diseases		
2.3.4.	HEALTH.2010.2.3.4-1: Vaccines for childhood bacterial diarrhoeal diseases.	*SICA Collaborative Project (Large scale integrating project) Target Region: all ICPC. EC contribution per project: min. EUR 6 000 000 – max. EUR 12 000 000. Only up to one proposal can be selected.*
2.3.4.	HEALTH.2010.2.3.4-2: Comprehensive control of Neglected Infectious Diseases.	*SICA Collaborative Project (Small- or medium scale focused research project) Target Region: all ICPC. EC contribution per project: max. EUR 6 000 000. One or more proposals can be selected.*
2.3.4.	HEALTH.2010.2.3.4-3: Next generation of researchers for Neglected Infectious Diseases.	*Coordination and Support Action (Coordinating action). EC contribution per project:*

		max. EUR 2 000 000. One or more proposals can be selected.
2.4. TRANSLATIONAL RESEARCH IN OTHER MAJOR DISEASES		
2.4.1. Cancer		
2.4.1.	HEALTH.2010.2.4.1-2: Structuring translational cancer research between cancer research centres in Europe.	*Network of Excellence. EC contribution per project: max. EUR 12 000 000. Only up to one proposal can be selected.*
2.4.1.	HEALTH.2010.2.4.1-3: Structuring clinical research in paediatric and adolescent oncology in Europe.	*Network of Excellence. EC contribution per project: max. EUR 12 000 000. Only up to one proposal can be selected.*
2.4.2. Cardiovascular diseases		
2.4.2.	HEALTH.2010.2.4.2-1: Reducing in-stent thrombosis.	*Collaborative Project (Small or medium-scale focused research project). EC contribution per project: max. EUR 6 000 000. Only up to one proposal can be selected.*
2.4.2.	HEALTH.2010.2.4.2-2: New approaches to reduce ischemic damage to the heart.	*Collaborative Project (Small or medium-scale focused research project). EC contribution per project: max. EUR 6 000 000. Only up to one proposal can be selected.*
2.4.2.	HEALTH.2010.2.4.2-3: Identifying new therapeutic targets in atrial fibrillation.	*Collaborative Project (Large scale integrating project). EC contribution per project: min. EUR 6 000 000 – max. EUR 12 000 000. Only up to one proposal can be selected.*
2.4.2.	HEALTH.2010.2.4.2-4: Diastolic heart failure.	*Collaborative Project (Large scale integrating project). EC contribution per project: min. EUR 6 000 000 – max. EUR 12 000 000. Only up to one proposal can be selected.*
2.4.4. Rare diseases		
2.4.4.	HEALTH.2010.2.4.4-1: Clinical development of substances with a clear potential as orphan drugs.	*Collaborative Project (Small or medium-scale focused research project). EC contribution per project: max. EUR 6 000 000. One or more proposals can be selected.*
2.4.5. Other chronic diseases		
2.4.5.	HEALTH.2010.2.4.5-1: Investigation of the mechanisms of initiation of allergic response, genetic predisposition, biomarkers and identification of targets for therapy.	*Collaborative Project (Large-scale integrating research project. EC contribution per project: min EUR 6 000 000 -*

		max. EUR 12 000 000. Only up to one proposal can be selected.
2.4.5.	HEALTH.2010.2.4.5-2: Infection and dysbiosis as the triggers of the development of inflammatory processes in allergies and autoimmune diseases.	*Collaborative Project (Small or medium-scale focused research project). EC contribution per project: max. EUR 6 000 000. One or more proposals can be selected.*
3. OPTIMISING THE DELIVERY OF HEALTHCARE TO EUROPEAN CITIZENS		
3.2. QUALITY, EFFICIENCY AND SOLIDARITY OF HEALTHCARE SYSTEMS INCLUDING TRANSITIONAL HEALTH SYSTEMS		
3.2.	HEALTH.2010.3.2-1: Financing systems' effect on quality of healthcare.	*Collaborative Project (Small or medium-scale focused research project). EC contribution per project: max. EUR 3 000 000. One or more proposals can be selected.*
3.2.	HEALTH.2010.3.2-2: Risk adjustment algorithms for better health insurance coverage.	*Collaborative Project (Small or medium-scale focused research project). EC contribution per project: max. EUR 3 000 000. One or more proposals can be selected.*
3.4. INTERNATIONAL PUBLIC HEALTH & HEALTH SYSTEMS		
3.4	HEALTH.2010.3.4-5: Assessment of migrants' health, disease patterns and impact on health systems	*Coordination and Support Action (Coordinating Action) (Target Regions: countries from Latin America and Mediterranean partner countries (MPC). At least 6 independent legal entities, of which, 3 must be established in different MS or AC and the other 3 must be established in different international cooperation partner countries (ICPC) from the above mentioned target regions (LA, MPC).Max. EC contribution/proposal: EUR 2 000 000.Only up to one proposal can be selected per region for this topic*
3.4.	HEALTH.2010.3.4-6: Impact and cost-effectiveness of existing major health programmes.	*SICA Collaborative Project (Small or medium-scale focused research project) Target Regions: all ICPC. EC contribution per project: max. EUR 3 000 000. One or more proposals can be selected.*
3.4.	HEALTH.2010.3.4-7: Financing models for accessible health care.	*SICA Collaborative Project (Small or medium-scale*

		focused research project) Target Regions: all ICPC. EC contribution per project: max. EUR 3 000 000. One or more proposals can be selected.
4. OTHER ACTIONS ACROSS THE HEALTH THEME		
4.1. COORDINATION AND SUPPORT ACTIONS ACROSS THE THEME		
4.1.	HEALTH.2010.4.1-1: Promoting participation of high-technology research-intensive SMEs, operating in the Health sector.	*Coordination Action or Support Action (Coordinating Action). EC contribution per project: max. EUR 2 000 000. Only up to one proposal can be selected.*
4.2. RESPONDING TO EU POLICY NEEDS		
4.2a		
4.2.	HEALTH.2010.4.2-1: Off-patent medicines for children.	*Collaborative Project (Small or medium-scale focused research project). EC contribution per project: max. EUR 6 000 000. One or more proposals can be selected.*
4.2.	HEALTH.2010.4.2-2: International paediatric initiative.	*Network of Excellence. EC contribution per project: max. EUR 12 000 000. Only up to one proposal can be selected.*
4.2.	HEALTH.2010.4.2-3: Adverse drug reaction research.	*Collaborative Project (Small or medium-scale focused research projects). EC contribution per project: max. EUR 3 000 000. One or more proposals can be selected.*
4.2b		
4.2.	HEALTH.2010.4.2-4: International pluripotent stem cell registry.	*Coordination and Support Action (Coordinating Action). EC contribution per project: max. EUR 2 000 000. Only up to one proposal can be selected.*
4.2.	HEALTH.2010.4.2-5: Methodology to evaluate and monitor health policy implementation and performance of EU funded interventions in developing countries.	*SICA Collaborative Project (Small or medium-scale focused research project) Target Regions: all ICPC. EC contribution per project: max. EUR 3 000 000. Only up to one proposal can be selected.*
4.2.	HEALTH.2010.4.2-6: Impact of EU legislation on health research.	*Coordination Action or Support Action (Supporting Action). EC contribution per project: max. EUR 500 000. One or more proposals can be*

		selected.
4.2.	HEALTH.2010.4.2-7: International forum for European life sciences funders and performers.	*Coordination and Support Action (Coordinating Action). EC contribution per project: max. EUR 2 000 000. Only up to one proposal can be selected.*
4.2.	HEALTH-2010.4.2-8: Coordination action in support of the implementation by participating States of a Joint Programming Initiative for combating neurodegenerative diseases, in particular Alzheimer's disease.	*Coordination and Support Action (Coordinating Action). EC contribution per project: max. EUR 2 000 000. Only up to one proposal can be selected.*

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.

Eligibility conditions:

- The general eligibility criteria are set out in Annex 2 of the work programme, and in the guide for applicants for each funding scheme.

In addition, specific eligibility criteria apply to this call as set out below:

- Only information provided in part A of the proposal will be used to determine whether the proposal is eligible with respect to budget thresholds and/or minimum number of eligible participants.
- Please note that the completeness criterion also includes that part B of the proposal shall be readable, accessible and printable
- It is important to note that the upper and lower limits for the EU contribution given per topic in table 2 of this call fiche, will be applied as an additional eligibility criterion and that proposals which do not respect these limits will be considered as ineligible.
- 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 schemes used in this call. There may be exceptions to the minimum number and participant type, which are specified in the topic description in the work programme.

Table 3: Eligibility conditions for participation

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.

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 for the appropriate funding scheme 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 independent external experts to disregard any pages in excess of these limits. The proposals will be evaluated by independent 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 4: 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 set out in annex 2 of the work programme.

There will be differing numbers of proposals short-listed according to the funding scheme and 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 the topic description in the topic description in table 2 (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 table2.

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 lists of proposals to be retained for negotiation will be based on the priority list established by the panel of independent 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 evaluation should be finalised in February/March 2010. Overall evaluation results are estimated to be available within 4 months after the closure date for the call. It is expected that grant agreement negotiations for short-listed proposals would begin in May/June 2010.

Consortium agreements: Participants in large-scale integrating collaborative projects or networks of excellence are required to conclude a consortium agreement. For small- and medium scale collaborative projects a consortium agreement is not mandatory but recommended. For coordination and support actions a consortium agreement is not required. **The forms of grants and maximum reimbursement rates** which will be offered are specified in Annex 3 to the Cooperation work programme.

Flat rates to cover subsistence costs: In accordance with Annex 3 of this work programme, this call provides for the possibility to use flat rates to cover subsistence costs incurred by beneficiaries during travel carried out within grants for indirect actions. For further information, see the relevant guides for applicants for this call. The applicable flat rates are available at the following website: http://cordis.europa.eu/fp7/find-doc_en.html under 'Guidance documents/Flat rates for daily allowances'.

Call fiche

Call title: HEALTH-2010-two-stage

Call identifier: FP7-HEALTH-2010-two-stage

Proposal submission and evaluation: two-stage procedure.

Date of publication: 30 July 2009[27]

Deadline for stage 1 proposals: 29 October 2009 at 17:00:00 (Brussels local time)[28]

Indicative budget: EUR 205 million from the 2010 budget[29]

The budget for this call is indicative. The final budget awarded to actions implemented through calls for proposals may vary:

- *The final budget of the call 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.*

Table 1

ACTIVITY/AREA	Indicative budget (EUR million)
1. BIOTECHNOLOGY, GENERIC TOOLS AND MEDICAL TECHNOLOGIES FOR HUMAN HEALTH	
1.2 DETECTION, DIAGNOSIS AND MONITORING	25
2. TRANSLATING RESEARCH FOR HUMAN HEALTH	
2.1. LARGE-SCALE DATE GATHERING AND SYSTEMS BIOLOGY	64
2.2 RESEARCH ON THE BRAIN AND RELATED DISEASES, HUMAN DEVELOPMENT AND AGEING	32
2.4. TRANSLATIONAL RESEARCH IN OTHER MAJOR DISEASES	66
3. OPTIMISING THE DELIVERY OF HEALTHCARE TO EUROPEAN CITIZENS	18

[27] The Director-General responsible for this call may publish it up to one month prior or after the envisaged date of publication.
[28] The Director-General responsible for this call may delay this deadline by up to two months.
[29] Under the condition that the preliminary draft budget for 2010 is adopted without modifications by the budgetary authority.

Table 2: Topics called:

Activity/Area	Topics called	Funding Schemes and particular requirements
1.BIOTECHNOLOGY, GENERIC TOOLS AND MEDICAL TECHNOLOGIES FOR HUMAN HEALTH		
1.2 DETECTION, DIAGNOSIS AND MONITORING		
1.2	HEALTH.2010.1.2-1: Tools for the identification and the detection of biomarkers in clinical samples and patients.	*Collaborative Project (Small or medium-scale focused research project). EC contribution per project: max. EUR 6 000 000. One or more proposals can be selected.*
2. TRANSLATING RESEARCH FOR HUMAN HEALTH		
2.1. INTEGRATING BIOLOGICAL DATA AND PROCESSES: LARGE-SCALE DATA GATHERING, SYSTEMS BIOLOGY		
2.1.2. Systems Biology		
2.1.2.	HEALTH.2010.2.1.2-1: Tackling Human Diseases through Systems Biology Approaches.	*Collaborative Project (Large-Scale integrating project). EC contribution per project: min. EUR 6 000 000 – max. EUR 12 000 000. One or more proposals can be selected.*
2.1.2.	HEALTH.2010.2.1.2-2: Establishing the foundations to enable systems biology of complex biological processes relevant to human health.	*Network of Excellence. EC contribution per project: max. EUR 12 000 000. One or more projects can be selected.*
2.2. RESEARCH ON THE BRAIN AND RELATED DISEASES, HUMAN DEVELOPMENT AND AGEING		
2.2.2. Human development and ageing		
2.2.2.	HEALTH.2010.2.2.2-1: Role of early-life developmental processes in longevity determination.	*Collaborative project (Large-scale integrating project). EC contribution per project: min. EUR 6 000 000 – max. EUR 12 000 000. Only up to one proposal can be selected.*
2.2.2.	HEALTH.2010.2.2.2-2: Homeostasis in human development and its effects on lifespan.	*Collaborative project (Small or medium-scale focused research project). EC contribution per project: max. EUR 6 000 000. Only up to one proposal can be selected.*
2.2.2.	HEALTH.2010.2.2.2-3: Integrative systems biology and comparative genomics for studying human ageing.	*Collaborative Project (Large-Scale integrating project). EC contribution per project: min. EUR 6 000 000 - max. EUR 12 000 000. Only up to one proposal can be selected.*
2.2.2.	HEALTH.2010.2.2.2-4: Markers of cellular senescence for human ageing	*Collaborative Projects (Small or medium-scale focused research project). EC*

		contribution per project: max. EUR 3 000 000. Only up to one proposal can be selected.
2.4. TRANSLATIONAL RESEARCH IN OTHER MAJOR DISEASES		
2.4.1. Cancer		
2.4.1.	HEALTH.2010.2.4.1-5: Structuring clinical research on rare cancers in adults.	*Collaborative Project (Small or medium-scale focused research project). EC contribution per project: max EUR 6 000 000. One or more proposals can be selected.*
2.4.1.	HEALTH.2010.2.4.1-6: Translational research on cancers with poor prognosis.	*Collaborative Project (Small or medium-scale focused research project). EC contribution per project: max. EUR 3 000 000. One or more proposals can be selected.*
2.4.1.	HEALTH.2010.2.4.1-7: Predicting long-term side effects to cancer therapy.	*Collaborative Project (Small or medium-scale focused research project). EC contribution per project: max. EUR 6 000 000. One or more proposals can be selected.*
2.4.1.	HEALTH.2010.2.4.1-8: Predicting individual response and resistance to cancer therapy.	*Collaborative Project (Small or medium-scale focused research project). EC contribution per project: max. EUR 6 000 000. One or more proposals can be selected.*
2.4.1.	HEALTH.2010.2.4.1-9. Optimising the delivery of (chemo)radiotherapy and/or surgery to cancer patients.	*Collaborative Project (Small or medium-scale focused research project). EC contribution per project: max. EUR 6 000 000. One or more proposals can be selected.*
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.2010.3.1-1: Better understanding of dissemination and implementation strategies.	*Collaborative Project (small or medium-scale focused research project). EC contribution per project: max. EUR 3 000 000. One or more proposals can be selected.*

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.

Eligibility conditions (stage 1 and stage 2):

The general eligibility criteria are set out in Annex 2 of this work programme, and in the guide for applicants for each funding scheme.

In addition, specific eligibility criteria apply to this call as set out below:

- Please note that the completeness criterion also includes that part B of the proposal shall be readable, accessible and printable.
- Proposals must be received by the Commission via the electronic proposal submission system respecting the deadline (date and time) as set out above.
- It is important to note that the upper and lower limits for the EU contribution given per topic in table 2 of this call fiche, 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.
- 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 schemes used in this call at stage 2, unless otherwise specified in the topic description.
- At stage 2, only information provided in part A of the proposal will be used to determine whether the proposal is eligible with respect to budget thresholds and/or minimum number of eligible participants.

Table 3: Eligibility conditions for participation

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.
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

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 total 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 independent 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 should 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 independent external experts to disregard any pages in excess of these limits. A minimum font size of 11 is required.

Stage 1 proposals will be individually evaluated remotely by independent external experts and discussed in consensus meetings.

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

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: March 2010.

Stage 2 proposals will be individually evaluated remotely by external experts and discussed in consensus meetings.

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 5: 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:** Priority lists will be prepared per indicative budget (see table 1 of this call fiche) by the panels of external experts. The aspects taken into account for establishing a priority order for ranking of proposals are set out in Annex 2 of this work programme.

There will be differing numbers of proposals short-listed according to the funding scheme and 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 the topic description in the topic description in table 2 (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 table2.

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 lists of proposals to be retained for negotiation will be based on the priority lists established by the panels 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 lists may be kept on a Commission reserve lists 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 2010. The evaluation of the second stage is expected to take place in May 2010. Overall evaluation results: estimated to be available within 3 months after

the closure date for stage 2 proposals. It is expected that grant agreement negotiations for short-listed proposals would begin in July 2010**.**

Consortium agreements: Participants in all types of collaborative projects or networks of excellence 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.

Flat rates to cover subsistence costs: In accordance with Annex 3 of this work programme, this call provides for the possibility to use flat rates to cover subsistence costs incurred by beneficiaries during travel carried out within grants for indirect actions. For further information, see the relevant guides for applicants for this call. The applicable flat rates are available at the following website: http://cordis.europa.eu/fp7/find-doc_en.html under 'Guidance documents/Flat rates for daily allowances'.

Call fiche

Call title: Call for Africa

Call identifier: FP7-AFRICA-2010

Date of publication: 30 July 2009[30]

Deadline: 14 January 2010 at 17.00.00, Brussels local time[31]

Indicative budget[32] : Total call budget EUR 63 000 000, of which:

- EUR 39 000 000 from Theme 1 - Health
- EUR 6 500 000 from Theme 2 - Food, Agriculture and fisheries, and Biotechnology
- EUR 17 500 000 from Theme 6 - Environment (including climate change)

The budget for this call is indicative.

- The final budget of the call may vary by up to 10% of the total value of the indicative budget for the call;
- 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 aim of this Call is to address some of the Science & Technology objectives of the "Africa - EU Strategic Partnership" putting emphasis on 'Water and Food Security' and 'Better Health for Africa '.

The topics of this call are implemented jointly by Theme 1, 2 and 6 as mentioned above. When applying for this call, please choose the relevant topic codes below.

Topics called

Theme/Activity	**Topics called**	**Funding Schemes**
Theme 1: HEALTH		
Activity 1.2 Translating research for human health	HEALTH.2010.2.3.2-4: Controlling malaria by hitting the vector: New or improved –	*Collaborative Project (large scale integrating project) for specific cooperation actions (SICA) dedicated to international collaboration partner*

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

[31] The Director-General responsible for this call may delay this deadline by up to two months.

[32] Under the condition that the preliminary draft budget for 2010 is adopted without modification by the budgetary authority.

	Vector Control Tools	*countries. EC contribution per project: min. EUR 6 000 000* *EC contribution per project: max. EUR 12 000 000. Only up to one proposal can be selected*
Activity 1.2 Translating research for human health	HEALTH.2010.2.4.1-4: Infectious agents and cancer in Africa	*Collaborative Project (small or medium-scale focused research project) for specific cooperation actions (SICA) dedicated to international collaboration partner countries EC contribution per project: max. EUR 3 000 000. One or more proposals can be selected*
Activity 1.3 International public health and health systems	HEALTH.2010.3.4-1: Develop and assess key interventions and policies to address the human resource crisis in the health sector	*Collaborative Project (small or medium-scale focused research project) for specific cooperation actions (SICA) dedicated to international collaboration partner countries. EC contribution per project: max. EUR 3 000 000. One or more proposals can be selected*
Activity 1.3 International public health and health systems	HEALTH.2010.3.4-2: Feasibility and community effectiveness of innovative intervention packages for maternal and new-born health in Africa	*Collaborative Project (small or medium-scale focused research project) for specific cooperation actions (SICA) dedicated to international collaboration partner countries. EC contribution per project: max. EUR 3 000 000. One or more proposals can be selected*
Activity 1.3 International public health and health systems	HEALTH.2010.3.4-3: Building sustainable capacity for research for health in Africa	*Coordination and Support Action (coordinating action). EC contribution per project: max. EUR 2 000 000. One or more proposals can be selected*
Activity 1.3 International public health and health systems	HEALTH.2010.3.4-4: Assessment of migrants' health, disease patterns and impact on health systems	*Coordination and Support Action (coordinating action). EC contribution per project: max. EUR 2 000 000. Only up to one proposal can be selected*
Theme 2: FOOD, AGRICULTURE, AND FISHERIES, AND BIOTECHNOLOGY		
Activity 2.1: Sustainable production and management of biological resources from land, forest and aquatic environment	*KBBE.-2010.1.-2-03:* Sustainable water resources management (WRM) and soil fertility conservation for food production in Africa - SICA (Africa)	*Collaborative Project (large scale integrating project) for specific cooperation actions (SICA) dedicated to international collaboration partner countries EC contribution per project: max. EUR 4 000 000. Maximum one proposal can be selected*
Activity 2.2 Fork to farm: Food (including seafood), health and well being	KBBE.2010.2.2-03: Identifying research needs on malnutrition in Africa – (Mandatory Africa)	*Coordination and Support Action (supporting action). EC contribution per project: max. EUR 1 000 000. Maximum one proposal can be selected*

Activity 2.3 Life sciences, biotechnology and biochemistry for sustainable non-food products and processes	KBBE.2010.3.5-02: Coping with water scarcity in developing countries: Role of biotechnology in water treatment – mandatory ICPC (Africa)	*Coordination and Support Action (coordinating action). EC contribution per projectl: max.EUR 1 000 000. Maximum one proposal can be selected*
Activity 2.4 Other Activities	KBBE.2010.4-02: Networking of non-governmental organisations involved in agricultural research for development	*Coordination and Support Action (coordinating action). EC contribution per project: max. EUR 500 000. Maximum one proposal can be selected*
Theme 6: ENVIRONMENT (INCLUDING CLIMATE CHANGE)		
Activity 6.1 Climate Change, pollution and risks	ENV.2010.1.2.1-1: The effect of environmental change on the occurrence and distribution of water related vector-borne diseases in Africa	*Collaborative Project (small or medium-scale focused research project) for specific cooperation actions (SICA) dedicated to international collaboration partner countries. EC contribution per project: max. EUR 3 500 000. Maximum one proposal can be selected*
Activity 6.1 Climate Change, pollution and risks	ENV.2010.1.3.3-1: Early warning and forecasting systems to predict climate related drought vulnerability and risks in Africa	*Collaborative Project (small or medium-scale focused research project) for specific cooperation actions (SICA) dedicated to international collaboration partner countries. EC contribution per project: max. EUR 3 500 000. Maximum one proposal can be selected*
Activity 6.2 Sustainable management of resources	ENV.2010.2.1.1-1: Integrated management of water and natural resources in Africa	*Collaborative Project (small or medium-scale focused research project) for specific cooperation actions (SICA) dedicated to international collaboration partner countries. EC contribution per project: max. EUR 3 500 000. Maximum one proposal can be selected*
Activity 6.3 Environmental technologies	ENV.2010.3.1.1-3: Decentralised water supply and sanitation technologies and systems for small communities and peri-urban areas	*Collaborative Project (small or medium-scale focused research project) for specific cooperation actions (SICA) dedicated to international collaboration partner countries. EC contribution per project: max. EUR 2 000 000. Maximum two proposals can be selected*
6.3 Environmental technologies	ENV.2010.3.1.1-4: Water harvesting technologies in Africa	*Collaborative Project (small or medium-scale focused research project) for specific cooperation actions (SICA) dedicated to international collaboration partner countries. EC contribution per project: max. EUR 2 000 000. Maximum two proposals can be selected*

- **Eligibility conditions**

  – The general eligibility criteria are set out in Annex 2 of this work programme, and in the guide for applicants for each funding scheme. Please note that the completeness criterion also includes that part B of the proposal shall be readable, accessible and printable.

  – The following additional eligibility criteria apply to the following funding schemes in this call[33]:

Funding scheme	**Minimum conditions**
Collaborative Project for specific cooperation actions (SICA) dedicated to international cooperation partner countries	At least 4 independent legal entities, of which, 2 must be established in different MS or AC and the other 2 must be established in different international cooperation partner countries (ICPC) from African ACP and the following Mediterranean Partner Countries (African MPC), Algeria, Egypt, Libya, Morocco, and Tunisia
Coordination and Support Action (coordinating action) Coordination and Support Action (supporting action)	At least 6 independent legal entities, of which, 3 must be established different MS or AC, 2 of which are not established in the same MS or AC, and the other 3 must be established in different international cooperation partner countries (ICPC) from African ACP and the following Mediterranean Partner Countries (African MPC), Algeria, Egypt, Libya, Morocco, and Tunisia

  The budget limits shown in the above table are eligibility criteria.

  – Only information provided in part A of the proposal will be used to determine whether the proposal is eligible with respect to budget thresholds and/or minimum number of eligible participants.

- **Evaluation procedure**

  – The evaluation criteria and scoring scheme are set out in annex 2 of the work programme.

    Proposal page limits: Applicants must ensure that proposals conform to the page limits and layout given in the guide for applicants for the appropriate funding scheme, and in the proposal part B template available through the EPSS.

[33] MS = Member States of the EU; AC = Associated country; ACP = African Caribbean and Pacific Countries; MPC = Mediterranean Partner Countries, African MPC countries = Algeria, Egypt, Libya, Morocco, Tunisia.

The Commission will instruct the experts to disregard any pages exceeding these limits.

The minimum font size allowed is 11 points. The page size is A4, and all margins (top, bottom, left and right) should be at least 15 mm (not including any footers or headers).

- The evaluation shall follow a single stage evaluation procedure. Proposals are evaluated on the basis of the following three criteria: 1. S/T quality; 2. Implementation; 3. Impact. For each criterion marks will be given, with the possibility of 0.5 point scores. Successful proposals must pass the minimum thresholds as follows:

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

The result of the evaluation will be one ranked list per Theme. Only the most highly ranked proposal(s) above the minimum threshold per topic will be recommended for funding. Reserve lists of projects will be established per Theme to be used in case the negotiation for entering into a grant agreement fails.

The following points will be reflected in the evaluation: A multi-disciplinary and integrated approach, taking into consideration broader socio-economic factors, and the participation of appropriate stakeholders and local and/or regional actors are considered essential to achieving the expected impacts. The aim is to achieve a balanced level of participation for African countries in collaboration with their European partners. The evaluators will take into account the various geographical, sectoral and cultural differences which exist within Africa. A dedicated budget for clustering and coordination should be foreseen in the overall budget planning of each proposal.

- Independent external experts will carry out the individual evaluation of proposals remotely with the consensus meetings being held in Brussels.
- The procedure for prioritising proposals with equal scores is described below:

At the Panel stage, according to Annex 2 to the Cooperation work programme, proposals with equal overall scores will be prioritised according to their scores for the S/T quality criterion. If they are still tied, they will be prioritised according to their scores for the Impact criterion.

- The number of proposals that can be funded per topic is indicated in the above 'Topics called' table.

- **Indicative timetable**

Evaluations are expected to be carried out during the months of February-March 2010. The evaluation results will be available within four months after the call deadline mentioned above. The grant agreement negotiations for the shortlisted proposals are expected to be opened in June 2010. It is estimated that the first grants related to this call will come into force at the end of 2010.

- **Consortia agreements**

Participants are encouraged to conclude a consortium agreement prior to grant agreement.

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

- **Additional Information**

In addition to this call, the International Cooperation activities of the Capacities Programme publish an INCO-NET - call (call identifier FP7-INCO-2010-1) aimed at expanding the geographical coverage and deepening the coordination and structuring activities of the CAAST-NET project[34]. This project was launched in January 2008 to increase the bi-regional S&T cooperation between European and the Sub-Saharan African Countries. The new INCO-NET call will offer the opportunity for the CAAST-NET project to support the interaction between the national and international programmes relevant to the topics covered by the call for Africa.

Flat rates to cover subsistence costs: In accordance with Annex 3 of this work programme, this call provides for the possibility to use flat rates to cover subsistence costs incurred by beneficiaries during travel carried out within grants for indirect actions. For further information, see the relevant guides for applicants for this call. The applicable flat rates are available at the following website: http://cordis.europa.eu/fp7/find-doc_en.html under 'Guidance documents/Flat rates for daily allowances'.

[34] www.caast-net.org.

Call fiche

Call title: Call for Alternative Testing Strategies

Call identifier: FP7-HEALTH-2010-Alternative-Testing

Proposal submission and evaluation: Single-stage procedure

- **Date of publication**: 30 July 2009[35].
- **Deadline:** 3 February 2010 at 17:00:00 (Brussels local time).[36]
- **Indicative budget**: EUR 25 million from the 2010 budget[37] [38]

The budget foreseen for this topic will be available exclusively for this area of the call. It can be transferred neither partially nor as a whole to other areas or to other calls for proposals.

ACTIVITY/AREA		**Indicative budget**[3] [4] **(EUR million)**
4. OTHER ACTIONS ACROSS THE HEALTH THEME	4.2. RESPONDING TO EU POLICY NEEDS 4.2c Alternative Testing	
	4.2.9 Towards the replacement of repeated dose systemic toxicity testing in human safety assessment	25

Table 1: Topics called:

Activity/Area	**Topics called**	**Funding Schemes and particular requirements**[39]
HEALTH.2010.4.2-9: Towards the replacement of repeated dose systemic toxicity testing in human safety assessment.		
4.2.9.1	Optimisation of current methodologies and development of novel methods to achieve functional differentiation of human-based target cells in vitro	*Collaborative project (Large-scale integrating project). EC contribution per project: min. EUR 4 000 000 – max. EUR 5 000 000. Only up to one*

[35] The Director-General responsible for this call may publish it up to one month prior or after the envisaged date of publication.
[36] The Director-General responsible for this call may delay this deadline by up to two months.
[37] Under the condition that the preliminary draft budget for 2010 is adopted without modifications by the budgetary authority.
[38] This budget of EUR 25 million only relates to the contribution to be paid by the EC. The cosmetics industry has announced its commitment to provide additional funding equal to the contribution of the EC (see COLIPA website www.colipa.eu).
[39] For each of the topics, the minimum and maximum amounts mentioned hereby only relate to the EC contribution. As stated in footnote 4, the cosmetics industry has announced it will provide additional funding for the proposals selected by the EC, equal in each case to the EC contribution (see COLIPA website www.colipa.eu).

		proposal can be selected.
4.2.9.2	Exploitation of organ-simulating cellular devices as alternatives for long-term toxicity testing	*Collaborative project (Large-scale integrating project). EC contribution per project: min. EUR 4 000 000 – max. EUR 5 000 000. Only up to one proposal can be selected*
4.2.9.3	Establishment of endpoints and intermediate markers in human-based target cells with relevance for repeated dose systemic toxicity testing	*Collaborative project (Large-scale integrating project). EC contribution per project: min. EUR 3 500 000 – max. EUR 4 500 000. Only up to one proposal can be selected*
4.2.9.4	Computational modelling and estimation techniques	*Collaborative project (Large-scale integrating project). EC contribution per project: min. EUR 2 500 000 – max. EUR 3 500 000. Only up to one proposal can be selected*
4.2.9.5	Systems biology for the development of predictive causal computer models	*Collaborative project (Large-scale integrating project). EC contribution per project: min. EUR 4 000 000 – max. EUR 5 000 000. Only up to one proposal can be selected.*
4.2.9.6	Integrated data analysis and servicing	*Collaborative project (Large-scale integrating project). EC contribution per project: min. EUR 2 000 000 – max. EUR 3 000 000. Only up to one proposal can be selected.*
4.2.9.7	Coordination project	*Coordination and Support Action (Coordinating Action). EC contribution per project: max. EUR 1 500 000. Only up to one proposal can be selected.*

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.

Eligibility conditions:

- The general eligibility criteria are set out in Annex 2 of the work programme, and in the guide for applicants for each funding scheme.

Specific eligibility criteria apply to this call as set out below:

- Only information provided in part A of the proposal will be used to determine whether the proposal is eligible with respect to budget thresholds and/or minimum number of eligible participants.
- Please note that the completeness criterion also includes that part B of the proposal shall be readable, accessible and printable.
- It is important to note that the upper and lower limits for the EU contribution given per topic in table 1 of this call fiche, will be applied as an additional eligibility criterion and that proposals which do not respect these limits will be considered as ineligible.
- 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 schemes used in this call.
- In line with the objectives of each topic, additional eligibility criteria are indicated in the work programme.

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.

Table 2: Eligibility conditions for participation

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.
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.

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 for the appropriate funding scheme 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 independent 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 3: 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:** A priority list will be prepared by the panel of independent external experts for the indicative budget line as set out in this call fiche. The aspects taken into account for establishing a priority order for ranking of proposals are set out in Annex 2 of the work programme.

There will be only one proposal short-listed per topic according to the funding scheme and topic. However, there may be topics for which no proposal is of sufficient quality to be selected for funding.

The Commission ranked list of proposals to be retained for negotiation will be based on the priority list established by the panel of independent 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 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 evaluation should be finalised in March/April 2010. 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 2010.

– **Consortium agreements:** Participants in large-scale integrating collaborative projects are required to conclude a consortium agreement. For small- and medium scale collaborative projects a consortium agreement is not mandatory but recommended. For coordination and support actions a consortium agreement is not required.

– **The forms of grants and maximum reimbursement rates** which will be offered are specified in Annex 3 to the Cooperation work programme. For projects selected in this specific call 50% of the total eligible cost will be paid by the European Commission independent from the funding schemes, the activities and type of organisations involved. Participants are encouraged to seek for complementary funding from third parties, e.g. industry [40].

Flat rates to cover subsistence costs: In accordance with Annex 3 of this work programme, this call provides for the possibility to use flat rates to cover subsistence costs incurred by beneficiaries during travel carried out within grants for indirect actions. For further information, see the relevant Guides for Applicants for this call. The applicable flat rates are available at the following website: http://cordis.europa.eu/fp7/find-doc_en.html under 'Guidance documents/Flat rates for daily allowances'.

[40] The cosmetics industry has announced its commitment to provide additional funding, equal to the contribution of the EC (see COLIPA website www.colipa.eu).

Call fiche

Call title: Call for INFLUENZA

Call identifier: FP7-INFLUENZA-2010

Date of publication[41]: 30 July 2009

Deadline[42]: 29 October 2009 at 17.00.00 (Brussels local time)

Indicative budget[43]: EUR 18 million from 2010 Budget of which:

- EUR 12 000 000 from Theme 1 - Health
- EUR 6 000 000 from Theme 2 - Food, Agriculture and Fisheries, and Biotechnology

The budget for this call is indicative. The final budget awarded to actions implemented through calls for proposals may vary:

- The final budget of the call 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 aim of this Call is to address research needs in human and animal influenza in view of the recent outbreak of a novel human influenza virus containing swine and avian gene sequences, and taking into account the existing portfolio of FP-funded influenza projects.

The topics of this call are implemented jointly by Theme 1 and Theme 2. When applying for this call, please choose the relevant topic codes below.

Topics called:

Theme/Activity	Topics called	Funding Schemes
Theme 1: HEALTH		
Activity 2.3.3: Potentially new and re-emerging epidemics	HEALTH.2010.2.3.3-4: Novel therapeutics against influenza.	*Collaborative project (Small or medium-scale focused research project[44]) EC contribution per projectl: max. EUR 6 000 000. One or more proposals can be selected.*

[41] The Director General responsible for this call may publish it up to one month prior to or after the envisaged date of publication.
[42] The Director General responsible for this call may delay this deadline by up to two months.
[43] Under the condition that the preliminary draft budget for 2010 is adopted without modifications by the budget authority.
[44] Please note that budget limits for "small or medium-scale" and "large scale integrating" collaborative projects may vary between themes.

Theme 2: FOOD, AGRICULTURE, AND FISHERIES, AND BIOTECHNOLOGY		
Activity 2.1: Sustainable production and management of biological resources from land, forest and aquatic environment	KBBE.2010.1.3-05*:* Swine influenza surveillance network	*Coordination and support action (coordinating action). EC contribution per project: max. EUR 1 000 000. Maximum one proposal can be selected.*
Activity 2.1: Sustainable production and management of biological resources from land, forest and aquatic environment	KBBE.2010.1.3-06: Pathogenesis and transmission of influenza in pigs (CP-IP)	*Collaborative project (large scale integrating project[45]) EC contribution per project: max. EUR 5 000 000 Maximum one proposal can be selected.*

- **Eligibility conditions**

- The general eligibility criteria are set out in Annex 2 of this work programme, and in the guide for applicants for each funding scheme.

- Standard minimum number of participating legal entities for all funding schemes used in the call, in line with the Rules for Participation:

Funding scheme	**Minimum conditions**
Collaborative Projects	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 Actions (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

In addition, specific eligibility criteria apply to this call as set out below:

- Only information provided in part A of the proposal will be used to determine whether the proposal is eligible with respect to budget thresholds and/or minimum number of eligible participants.
- Please note that the completeness criterion also includes that part B of the proposal shall be readable, accessible and printable
- It is important to note that the upper and lower limits for the EU contribution given per topic in table listing the topics of this call fiche, will be applied as an additional eligibility criterion and that proposals which do not respect these limits will be considered as ineligible.

Evaluation procedure

- The evaluation criteria and scoring scheme are set out in annex 2 of the work programme.

[45] Please note that budget limits for "small or medium-scale" and "large scale integrating" collaborative projects may vary between themes.

- Proposal page limits: Applicants must ensure that proposals conform to the page limits and layout given in the guide for applicants for the appropriate funding scheme, and in the proposal part B template available through the EPSS.
  - The Commission will instruct the experts to disregard any pages exceeding these limits.
  - The minimum font size allowed is 11 points. The page size is A4, and all margins (top, bottom, left, right) should be at least 15 mm (not including any footers or headers).
- Independent external experts will carry out the individual evaluation of proposals remotely.
- The procedure for prioritising proposals with equal scores is described in annex 2 of the work programme. The priority lists will be prepared by external experts, per indicative sub-budget line as set out in this call fiche.

- ***Evaluation criteria and thresholds:***

Proposals are evaluated on the basis of the following three criteria: 1. S/T quality; 2. Implementation; 3. Impact. For each criterion marks will be given, with the possibility of 0.5 point scores. Successful proposals must pass the minimum thresholds as follows:

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

The Commission ranked list of proposals to be retained for negotiation will be based on the priority list established by the panel of independent 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 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 timetable**: Evaluation results: three months after the relevant deadline mentioned above. Grant agreement signature: It is estimated that the first grant agreements related to this call will come into force at the mid of 2010.
- **Consortia agreements**: Consortium agreements are recommended but not required for projects in this call.

- **The forms of grant and maximum reimbursement rates** which will be offered are specified in Annex 3 to the Cooperation work programme. In accordance with Annex 3 of this work programme, this call provides for the possibility to use flat rates to cover subsistence costs incurred by beneficiaries during travel carried out within grants for indirect actions. For further information, see the relevant guides for applicants for this call. The applicable flat rates are available at the following website:http://cordis.europa.eu/fp7/find-doc_en.html under 'Guidance documents/Flat rates for daily allowances'.

IV OTHER ACTIONS

Human Frontier Science Programme Organisation
An annual subscription to the international Human Frontier Science Programme Organisation (HFSPO)[46] 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 4 153 000 for 2010, EUR 2 492 000 will be paid from this Theme, and the remainder from the ICT Theme. **Funding scheme:** Other actions.[47]

Forward looking activity
A Forward-looking activity (global possible changes in a long term perspective - 2030-2050) has to be developed aiming at identifying and anticipating the key drivers of change and the related socio-economic impacts in the HEALTH theme. This Forward-looking activity should help to identify future research and innovation priorities contributing to build a strong European Research Area (ERA) in the specific HEALTH theme. It will also provide strategic intelligence useful for the preparation of the future Framework Programme. To be implemented through the use of expert working groups and/or facilities provided for through Commission services' framework contracts.
Funding scheme: Coordination and Support Action – public procurement[48]: to be implemented through a Framework Contract in 2010 and/or experts appointment.
EC contribution: max. EUR 500 000

EDCTP Impact Assessment Study
A study will be supported to assess the impact of the EDCTP programme, with the aim to prospect a potential renewal of this Art 169 initiative. It will identify the strengths and weaknesses of research in this domain covering the relevant social, economic and environmental aspects and it will identify any sector specific barriers impeding the renewal of this initiative. To be implemented through the use of expert working groups and/or facilities provided for through Commission services' framework contracts.
Funding scheme: Coordination and Support Action – public procurement[49]: to be implemented through a Framework Contract in 2010 and/or experts appointment.
EC contribution: max. EUR 300 000

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

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

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

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

Interim evaluation of the IMI Joint Undertaking
The Commission shall carry out an interim evaluation of the IMI Joint Undertaking with the assistance of independent experts on the basis of terms of reference established after consultation of the IMI Joint Undertaking. This evaluation shall cover the quality and efficiency of the IMI Joint Undertaking and progress towards the objectives set. The Commission shall communicate the conclusions thereof, accompanied by its observations and, where appropriate, proposals to amend the Regulation, including the possible early termination of the IMI Joint Undertaking, to the European Parliament and the Council. To be implemented through the use of expert working groups and/or facilities provided for through Commission services' framework contracts.
Funding scheme: Coordination and Support Action – public procurement[50]: to be implemented through a Framework Contract in 2010 and/or experts appointment.
EC contribution: max. EUR 300 000

Assessment(s) on 'Impacts of Framework Programmes in area(s) covered by Health research'
Assessment(s) to be carried out to thoroughly analyse the impacts of present and past Framework Programmes in one or two areas covered under Health research. Long term effects on the economy, the society as well as needs for future health research will be identified and when possible quantified. To be implemented through the use of expert working groups and/or facilities provided for through Commission services' framework contracts.
Funding scheme: Coordination and Support Action – public procurement[51]: to be implemented through a Framework Contract in 2010 and/or experts appointment.
EC contribution: max. EUR 100 000

Conference: Challenges and opportunities for disease-related research in Europe.
The aim is to increase the impact of EU-funded research. Participants will be leading scientists, research managers, decision-makers, funding agencies and representatives of patient organisations.
Funding scheme: Coordination and Support Action – public procurement[52]: to be implemented through a Framework Contract in 2010
EC contribution: max. EUR 100 000

Conference: Mouse models for human diseases: Bridging the gap
The aim of this conference is to demonstrate the complementary nature of mouse functional genomics and medical research in order to achieve the common goal of human health improvement. At this conference, researchers focusing on human diseases (e.g. neurodegeneration, cancer, cardiovascular disease, diabetes) will present their results on

[50] In accordance with Art 14(b) and Art 25 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).

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

[52] In accordance with Art 14(b) 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)

human genetics, endophenotyping, epidemiology and clinical research. A strong focus of this conference will be on the identification and discussion of mutual requirements to unravel the molecular basis of the disease mechanism. Another objective will be comparative mouse and human stem cell research, which represent unique tools to unravel species specific molecular mechanisms of disease aetiology. Knowing these similarities and differences between mouse and man will help to identify novel entry points into therapeutic interventions.
Funding scheme: Coordination and Support Action – public procurement[53]: to be implemented through a Framework Contract in 2010
EC contribution: max. EUR 70 000

[53] In accordance with Art 14(b) 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)

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.

Activities	**Indicative Budget 2010[54] EUR million[55]**
CALL FP7-HEALTH-2010-single-stage	333.50
CALL FP7-HEALTH-2010-two-stage	205.00
CALL FP7-AFRICA-2010	39.00
CALL FP7-INFLUENZA-2010	12.00
CALL FP7-ERANET-2010-RTD[56]	6.00
CALL FP7-HEALTH-2010-Alternative-Testing	25.00
GENERAL ACTIVITIES	8.08
OTHER ACTIVITIES: Evaluations: Assessment(s) on 'Impacts of Framework Programmes in area(s) covered by Health research' Interim evaluation of IMI Joint Undertaking: EDCTP Impact Assessment Study: Conferences: HFSP: Forward looking activity:	 5.80 0.10 0.30 0.30 0.17 2.49 0.50
ESTIMATED TOTAL BUDGET ALLOCATION	638.24

[54] Under the condition that the preliminary draft budget for 2010 is adopted without modifications by the budgetary authority.
[55] The Budget figures given in this table are rounded to two decimals points.
[56] Call fiche: see ANNEX 4 to the cooperation work programme.

Indicative budget General Activities

Activities	Indicative budget 2010 EUR million
CORDIS	1.54
Eureka/Research organisations	0.07
COST	6.25
STRAT oriented support action	0.22
Total	**8.08**