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**Work Programme 2011**  
**Second draft for PC**

***COOPERATION***

**THEME 1**

**Health**



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**Objective:** Improving the health of European citizens and increasing the competitiveness and boosting the innovative capacity of European health-related industries 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 2011**

The work programme 2011 is to be published in July 2010 for proposals to be selected in 2011. It aims to ensure complementarity with the previous work programme and to concentrate on specific activities within the budgetary constraints. The estimated total budget allocation for work programme 2011 is EUR ~640 000 000 (to be confirmed) drawing from the 2011 budget<sup>1</sup>. 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<sup>2</sup> and other actions. The estimated budget breakdown for work programme 2011 is provided in section V. Priorities are based on the coverage of the specific programme, input from all relevant stakeholders, such as Programme Committee members, advisory group, learned societies, as well as major policy initiatives, including the European Research Area (ERA), and the state of play regarding scientific opportunities and healthcare needs.

### **Strategic framework and responding to EU policy needs**

The Specific Programme for the Health theme is aligned with the fundamental objectives of EU research policy: improving the health of European citizens and increasing innovation and competitiveness of European health-related industries and services, as well as addressing global health issues and the socio-economic dimension of health care.

Major efforts concentrating on small and medium enterprise (SME) topics in the work programme (WP) for the 2011 call(s) for the Health theme will contribute to the new Commission's emphasis on "competitiveness for the future" including "boosting the new sources of growth..." which "requires a strengthening of Europe's industrial base" (Barroso, 2009<sup>3</sup>). Whereas, two very large pilot projects (with a maximum of 30 million each) in the fields of epigenomics and immunisation will both contribute to the "European innovation economy" or "i-conomy" and contribute to the completion of the European Research Area (ERA). Both, the SME orientation of the 2011 health research work programme and the large pilot projects represent an excellent potential for innovation.

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<sup>1</sup> Under the condition that the preliminary draft budget for 2011 is adopted without modifications by the budgetary authority.

<sup>2</sup> FP7-HEALTH-2011-single-stage; FP7-HEALTH-2011-two-stage; FP7-ERANET-2011-RTD;

<sup>3</sup> Political Guidelines for the New Commission, J.M. Barroso, 2009.

Furthermore, with a major effort into clinical trials in various fields and with the concentration on brain-related diseases, diabetes, and cancer by tackling also life style issues and social determinants of health, the 2011 work programme addresses major health-related societal challenges. Finally, with a focus on antimicrobial drug resistance and emerging epidemics, the health theme continues to address global health issues of utmost importance.

Research actions will continue to support EU efforts to adapt off-patent medicines to the needs of paediatric populations and to investigate adverse drug reactions at European level. Efforts will continue to ensure coherence with the *Innovative Medicines Initiative (IMI)*<sup>4,5</sup> priorities for 2010 and 2011 and complementarities with the *European and Developing Countries Clinical Trials Programme (EDCTP)*<sup>6</sup> to combat poverty-related diseases.

### **Key research challenges**

The work programme health 2011 focuses on the following several key research challenges:

#### ***How lifestyle affects health and how can this be mitigated***

Lifestyle factors (nutrition, environment, stress, smoking, alcohol and drug intake, exercise, etc.) have a considerable, but not always well understood, impact on a variety of health issues of individuals. A coordinated effort is needed to achieve a better understanding of the underlying causes, mechanisms and possible mitigating factors or intervention for better health.

- **Brain-related diseases, including lifestyle-related health issues.** In this area the focus is on lifestyle-related health problems such as addiction as well as other mental health issues not yet covered by the previous calls such as compulsive disorders in children. In the area of neurodegenerative diseases, in particular Alzheimer's disease, a set of topics is foreseen to complement the objectives and actions of the Joint Programming initiative thereby contributing to ERA objectives.
- **Lifestyle determinants: diabetes, obesity and cardiovascular diseases.** The emphasis is on clinical trials, prevention approaches, epidemiology and controlled intervention. Actions include research on life-style and/or therapeutic approaches for diabetes; controlled intervention trials on life-style changes and concomitant therapeutic intervention on high-risk populations; epidemiological studies on paediatric obesity. Coordination with Theme 2 ('KBBE') is foreseen on diet/nutrition and disease development. There could be a strong component of international cooperation, through global approaches, on diabetes / obesity and on early life programming.
- **Social determinants of health.** The size scale, persistence and increase in the differences in health of people living in different parts of the EU and between socially advantaged and disadvantaged EU citizens represents a challenge to the EU's commitment to solidarity and equality of opportunity. Tackling health inequalities requires a coordinated response across relevant policy areas, as reflected in the Commission Communication on Solidarity

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<sup>4</sup> 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

<sup>5</sup> [http://imi.europa.eu/index\\_en.html](http://imi.europa.eu/index_en.html)

<sup>6</sup> European and Developing Countries Clinical Trials Partnerships

in Health<sup>7</sup>, and more intersectoral and interdisciplinary research to support actions addressing health inequalities taking into account differences in lifestyle. This approach also applies to low and middle income countries where the challenges and the related burden of disease are even greater.

### ***Supporting clinical trials<sup>8</sup> to verify safety and efficacy***

Specific actions under clinical trials will have a major European added value into translating research to clinical practice, increasing therapeutic options for patients, stimulating the implementation of best practices in all MS and for establishing the basis for a coherent programme addressing the issue of personalized medicine and improved therapeutic outcomes. Currently the majority of clinical trials are being performed by health-related industries during the development of novel products such as new pharmaceuticals. In addition to these industry-driven studies, clinical trials initiated by academic investigators are of high relevance for public health.

This work programme lists several topics for clinical trials, most of which are for investigator-driven clinical trials. In all cases the aim is to strengthen clinical research in Europe in a number of areas with unmet medical needs. Topics for clinical trials can be found in a number of areas of the work programme including brain-related diseases, antimicrobial drug resistance, cancer, cardiovascular diseases, diabetes and obesity and off-patent medicines for children.

In these areas where the focus is on investigator-driven clinical trials, it is considered that the use of the definition of the typical phases of clinical trials in the context of the development of new drugs (phase I to phase III – approval – post-marketing or phase IV trials) is only of limited utility. For example, clinical trials on life-style interventions do not fit into the phase definitions. Such trials may for example be funded in the topic 2.4.3-1.

Where drug interventions will be tested, depending on the individual topic, it is expected that most studies to be funded will be phase II trials, if the intervention to be tested is used outside its approved indication, or phase IV trials if the intervention is used within its marketing authorisation. In particular, it is foreseen that comparative effectiveness trials (phase IV) will be funded in several topics. If evidence warranting advanced clinical testing is already available, phase III trials can also be supported. For topic 1.4-1 it is expected that phase I or II trials will be funded. The topic 4.2-1 "Off patent Medicines for Children" specifically funds phase III clinical trials. In all cases the maximum available EU contribution needs to be considered.

As no minimum or maximum duration for projects to be funded under FP7 is foreseen, applicants should properly evaluate the time needed to conclude their study, including relatively short durations, such as 1-3 years, when deemed appropriate; unnecessary addition of participants to projects or inappropriate study duration will play negatively in the evaluation process. As for all FP7 projects, evolution of consortia is in principle possible. However, no additional funding can be made available during the implementation of a project; major changes that cannot be peer reviewed are discouraged, as the fact that the original proposal was evaluated and selected by the experts needs to be considered.

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<sup>7</sup> Solidarity in Health - Reducing Health Inequalities in the EU" (20th October 2009)

<sup>8</sup> <http://ec.europa.eu/enterprise/sectors/pharmaceuticals/documents/eudralex/vol-10/>

The early involvement of patients and their advocacy groups in the planning of a clinical trial is considered important so that patients' needs are appropriately considered. This may also increase the rate of enrolment of trial participants and can have a positive effect on the performance of the clinical trial. All studies must carefully consider the ethical and regulatory framework for the conduct of clinical trials.

***Increasing innovation and competitiveness of European health-related industries and services***

Tackling key health research challenges together with the major effort on SME participation will stimulate innovation, increase the participation of SMEs in clinical trials, increase the drive to development of new therapies, technologies and drugs to marketable products, and thus create a considerable European added value in the European health research area. There is a strong need for research-intensive SMEs to participate in the Health theme to ensure that new research and development (R&D) findings are brought to the market and to the bedside.

In order to attract SMEs participation, both quantitatively and qualitatively, a number of special topics are included to provide more opportunities for SMEs not only to participate, but to take leading roles in projects. To ensure a more bottom-up and innovative approach, the topics are broadly defined and proposals will be evaluated using the two-stage submission and evaluation procedure. SMEs topics include: bioinformatics tools, tools for structural determination of proteins, targeting in-patient medicines, medical technologies, synthetic antibodies and rapid multi-analyte diagnostics. In addition SMEs are encouraged to participate in all other topics, including clinical trials.

***Two pilot actions for high impact research initiatives (large-scale integrating research projects, up to €30m)***

- **Epigenomics.** This pilot action will be launched to integrate several components, such as epigenomic mapping in health and diseases, high-throughput technology, diagnostic tools, targeted interventions drug screening in the context of comparative clinical trials. This integrated research effort should contribute to understanding diseases and the impact of lifestyle on health. It should also help integrating research and structure the ERA in a global context on an unprecedented scale in this emerging field of research.
- **Immunisation strategies and applications.** The aim is to apply advanced technologies to the study of human immune responses under conditions of health and disease and to develop improved immunisation strategies depending on the pathological condition. This new knowledge generated should lead to a rational strategy in immunisation. Different ways of immunisation (systemic, local, mucosal) using different platforms and formulations will have pronounced effects on the effectiveness of new interventions.

***Global health issues***

The work programme also covers the complementary policy objective of addressing specific global health issues. For 2011 it is foreseen to focus further on **antimicrobial resistance** and continuing to address **emerging epidemics**. In antimicrobial resistance the focus will be on understanding of the evolution and the transfer of antibiotic resistance as well as antimicrobial



drug resistance in Gram negative infections, development of tools to control microbial biofilms and developing multi-analyte diagnostics. For emerging epidemics transmission and immunology issues, as well as behavioural aspects relevant to preparation for and action during pandemics are also addressed in topics of this work programme.

### International Cooperation

International cooperation continues to be an integral part of the Health theme with many opportunities throughout the work programme to include international cooperation partner countries. In particular, in the area of diabetes, considerable expectation and need for a global approach encompassing several regions of the world such as the Mediterranean region, Sub-Saharan Africa, Latin America, Asia, etc. is envisioned.

SICA topics are particularly targeted for research activities in the areas of proteomics (Russia), human genetics (EECA), infectious diseases (Latin America and Asia), cancer (India), diabetes/obesity (integrated initiative with multiple international partners), addressing health inequalities, health systems, supporting the realisation of the Millennium Development Goals (MDG). The area of comprehensive and integrated interventions and programmes to improve reproductive health and health equity will be undertaken as well as a focus on capacity building. Input from relevant INCO-Nets, which have conducted Health specific workshops, have been considered. Furthermore, programme level cooperation, where the *cooperating countries finance their own complementary projects*, will be pursued in the coming calls on common priorities with individual countries (such as Brazil, Russia, India, Mexico and Australia). In recognition of the opening of NIH<sup>8</sup> 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.

### Cross thematic approach

Coordination with Theme 2 ('KBBE') is foreseen on diet/nutrition and diseases development. There could be a strong component of international cooperation, through global approaches, on diabetes / obesity and on early life programming.

### Dissemination

An extensive set of actions stemming from the first 3 calls for proposals are ongoing. In 2011 complementary actions are foreseen with an emphasis on valorisation of research results, as well as the networking of major research institutions participating in the Health theme to coordinate dissemination actions. Furthermore, for health promotion and disease prevention, brokerage actions are foreseen to ensure a direct translation of research findings in this area to the relevant users.

### Complementarities with IMI

Complementarity and coherence with IMI priorities for 2010 and 2011 will be pursued.

### 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<sup>9</sup> are described in the Guide for Applicants (Annex 4, section 4).

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

**Funding schemes:** The work programme 2011 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 upper 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 the upper funding limits will be applied as eligibility criteria so that proposals that do not respect this limit 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)<sup>10</sup>, see details in topic descriptions in section II.

For all funding schemes, there may be topics for which none of the proposals submitted to this topic are of sufficient quality to be selected for funding, as there will be competition not only within topics but also between proposals submitted to different topics based on the quality of the proposals.

**It is important to note that once the basic conditions for eligibility are met – such as the minimum number of participants (in most cases 3) or the ceiling for the maximum EU contribution to the budget – it is entirely up to the applicants to decide on the number of partners, the duration of the project or the financial contribution requested from the EU.** The quality and feasibility of the proposed work as well as the match between the expertise of the consortium and the project goals are subject to the evaluation carried out by independent experts.

**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.** Proposals extending beyond these limitations will not be considered in the evaluation.

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<sup>9</sup> [http://cordis.europa.eu/fp7/ethics\\_en.html](http://cordis.europa.eu/fp7/ethics_en.html)

<sup>10</sup> 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 (bio-banks) standardisation, acquisition and analysis. The focus is on new technologies for: sequencing; gene expression, genotyping and phenotyping; structural and functional genomics; bioinformatics and systems biology; other 'omics'.

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

**HEALTH.2011.1.1-1: SME-targeted research for developing tools and technologies for high-throughput research. FP7-HEALTH-2011-two stage.** Research should focus on the development and improvement of high throughput research tools and technologies. The proposed activities should also take into account quality control aspects as appropriate. **Note:** Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria.

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

**EC contribution per project:** Maximum EUR 6 000 000.

**One or more proposals can be selected.**

**Expected impact:** The development of new and improved tools and technologies will support the competitiveness of Europe in the areas of "-omics" research and systems biology, and their applications are expected to have an important impact in medicine and in the biotechnology industry (in particular for SME's).

**Specific feature:** SME-targeted research is designed to encourage SME efforts towards research and innovation. Priority will be given to proposals demonstrating that research intensive SMEs play a leading role. The projects will be led by SMEs with R&D capacities, but the coordinator does not need to be an SME. The expected project results should clearly be of interest and potential benefit to SME(s). All consortia should aim at having 30-50 % of the requested EC contribution budget going to SMEs (subcontracting is discouraged).

**Additional selection criteria:** SME-targeted Collaborative Projects will only be selected for funding on the condition that the requested EU contribution going to SME(s) is 30% or more of the total requested EC contribution. ***This will be assessed during evaluation and checked during negotiation. Proposals not fulfilling this criterion will not be funded.***

**HEALTH-2011-1.1-2: Genome-based biomarkers for patient stratification and pharmacogenomic strategies. FP7-HEALTH-2011-two-stage.** The objective of this SME-driven research is to distinguish responders and/or adverse responders from non-responders to drugs that are already established treatments through the identification and characterisation of genome-based biomarkers. The research may focus on adults, children and/or the elderly where appropriate. Ethical, social, legal and public health aspects, as well as health technology assessments (health economics, cost effectiveness) have to be considered. The research should lead to validated pharmacogenomic methods to predict response to drug treatment, avoid chronicity, prevent relapse and reduce adverse effects. Research should focus on a disease where there is evidence of heterogeneity of response to the existing drugs and a significant burden of unmet need. **Note:** Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria.

**Funding scheme:** Collaborative Project (small or medium scale focussed research project targeted to SMEs).

**EC Contribution per project:** Maximum EUR 6 000 000.

**One or more proposals can be selected.**

**Expected impact:** Encouraging research performed by the European SME towards personalized medicine, and fostering industry-regulatory entities dialogue.

**Specific feature:** SME-targeted research is designed to encourage SME efforts towards research and innovation. Priority will be given to proposals demonstrating that research intensive SMEs play a leading role. The projects will be led by SMEs with R&D capacities but the coordinator does not need to be an SME. The expected project results should clearly be of interest and potential benefit to SME(s). All consortia should aim at having 30-50 % of the requested EC contribution budget going to SMEs (subcontracting is discouraged).

**Additional selection criteria:** SME-targeted Collaborative Projects will only be selected for funding on the condition that the requested EU contribution going to SME(s) is 30% or more of the total requested EC contribution. ***This will be assessed during evaluation and checked during negotiation. Proposals not fulfilling this criterion will not be funded.***

**HEALTH.2011.1.1-3: High-throughput proteomics for human health and disease. FP7-HEALTH-2011-single-stage.** The project should develop improved tools and technologies for proteomics, addressing the challenges and bottlenecks in high-throughput data generation and data analysis. The project results should be applicable to studying proteins relevant to human health and disease in different *in vivo* and *in vitro* model systems (cells, tissues, organisms). The cooperation with a complementary future project(s) from Russia will be an obligation, and a part of the budget should be set aside for this cooperation (*e.g.* for participation in meetings). SME participation is encouraged. **Note:** Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria.

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

**EC contribution per project:** Maximum EUR 3 000 000.

**One or more proposals can be selected.**

**Expected impact:** The project will aim at strengthening the scientific cooperation between the EU, FP7 associated countries (AC), and the countries of the EECA regions, in particular Russia. The initiative will address important problems in proteomics and should contribute to structuring the participation of the respective scientific communities in large-scale proteomics initiatives. The project will benefit from mutual exchange of information, researchers and a combination of efforts and thus will bring together scientists from participating countries. It is expected that the Russian Federal Agency for Science and Innovations (FASI) will fund complementary project(s) that will actively cooperate with the EC-funded project.

### **1.2 DETECTION, DIAGNOSIS AND MONITORING**

*Closed in 2011*

### **1.3 SUITABILITY, SAFETY, EFFICACY OF THERAPIES**

*Closed in 2011*

### **1.4 INNOVATIVE THERAPEUTIC APPROACHES AND INTERVENTIONS**

For this call for proposals, topics focus on regenerative medicine, protein scaffolds as alternatives to antibodies and oligonucleotides, immunisation strategies and international cooperation. Regenerative medicine aims to restore the function of diseased or injured tissues and organs by cell transplantation or by the activation of endogenous cells. It also offers possibilities for addressing complex problems of an ageing population and has potential for combating rising healthcare costs. It is a high-value new technology offering Europe competitiveness and this opportunity is enhanced by the recent adoption of a European Regulation on advanced therapy medicinal products.

To meet the challenges and promise of regenerative medicine, two topics for medium-sized Collaborative Projects are presented. One concerns therapy itself and aims to drive translation of promising therapeutic approaches along the pathway to practical clinical use. The other topic focuses on the tools and technologies required to enable progress in regenerative medicine. Substantial involvement of SMEs is a prerequisite for both topics.

A second focus is to exploit progress in the development of innovative protein binding scaffolds as alternatives to classical antibodies and oligonucleotides. Substantial involvement of SMEs is also required.

Immunisation is addressed through a high-impact initiative that aims to apply advanced technologies to the the development of new immunisation strategies.

For international cooperation, a topic concerned with therapy of chronic inflammatory autoimmune diseases with participation of Brazilian teams is described.

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

**HEALTH.2011.1.4-1: Regenerative medicine clinical trials<sup>11</sup>. FP7-HEALTH-2011-two-stage.** Research should aim to develop regenerative therapies, involve SMEs and test promising products or techniques in the clinic. Since it is intended to encourage regenerative medicine as an approach, proposals may address any justified disease or condition. Execution of clinical/in-patient trials should represent a central part of the project. To indicate real promise, pre-clinical or early clinical results should be already available. Rigorous toxicology studies should precede clinical trials. The biological basis of product mode of action should already be known but may be further developed during the project. Up-scaling, good manufacturing practice (GMP) and regulatory work should be included as appropriate. It is preferred that clinical work starts at an early stage of the project, in which case regulatory affairs, including investigational medicinal product dossier (IMPD) status should be indicated in the proposal. Consortia should be constructed so that results can be exploited by clinical and/or industrial sectors (especially SMEs) as appropriate. **Note:** Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria.

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

**EC contribution per project:** Maximum EUR 6 000 000.

**One or more proposals can be selected.**

**Expected impact:** The main impact of this work will be the extent to which regenerative medicine is tested in the clinic and adopted in practice. Projects may target any justified specific disease or condition but are required to aid the establishment of the regenerative approach to therapy. Research will be multidisciplinary and will boost the European biotechnology industry, and in particular the SME sector; it should also address regulatory issues as appropriate.

**HEALTH.2011.1.4-2: Tools, technologies and devices for application in regenerative medicine. FP7-HEALTH-2011-two-stage.** This topic focuses on tools, technologies and devices that enable the development of innovative regenerative therapies and their application in the clinic. Projects should be directed towards the preparation, delivery or follow-up of regenerative medicine treatment; they should also address scale-up, regulatory work and clinical investigations as appropriate. 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. **Note:** Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria.

**Specific feature:** SME-targeted research is designed to encourage SME efforts towards research and innovation. Priority will be given to proposals demonstrating that research intensive SMEs play a leading role. The projects will be led by SMEs with R&D capacities but the coordinator does not need to be an SME. The expected project results should clearly be of interest and potential benefit to SME(s). All consortia should aim at having 30-50 % of the requested EC contribution budget going to SMEs (subcontracting is discouraged).

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<sup>11</sup> <http://ec.europa.eu/enterprise/sectors/pharmaceuticals/documents/eudralex/vol-10/>

Please consult also the text for clinical trials provided in the introduction to this work programme on page 6



**Additional selection criteria:** SME-targeted Collaborative Projects will only be selected for funding on the condition that the requested EU contribution going to SME(s) is 30% or more of the total requested EC contribution. *This will be assessed during evaluation and checked during negotiation. Proposals not fulfilling this criterion will not be funded.*

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

**EC contribution per project:** Maximum EUR 6 000 000.

**One or more proposals can be selected.**

**Expected impact:** Projects should lead to new tools, technologies or devices which will assist the establishment of regenerative therapies in the clinic. Projects should boost the European biotechnology industry, especially the SME sector.

**HEALTH.2011.1.4-3: Development and production of new, high-affinity protein scaffolds for therapeutic use. FP7-HEALTH-2011-two-stage.** Research should focus on the development and production of new high-affinity, non-immunoglobulin protein scaffolds as an alternative to antibodies or oligonucleotides. Projects should aim at developing new, efficient and safe therapies by combining high specificity with stable production characteristics. Projects should include preclinical studies, methods for scale-up and GMP as appropriate, should combine academic, clinical and industrial expertise and implement a translational approach towards clinical trials (clinical proof-of-concept and/or phase I/II clinical studies). A strong level of SME participation is required 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.

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

**EC contribution per project:** Maximum EUR 6 000 000.

**One or more proposals can be selected.**

**Expected impact:** Projects will be judged on the basis of the advantages displayed by the new materials in relation to classical antibodies or oligonucleotides. Successful projects will demonstrate clinical proof of concept and safety, particularly lack of immunogenicity. Scale-up and production methods should also be demonstrated. Benefits for the SME sector will also need to be displayed.

**HEALTH.2011.1.4-4: High impact project for better immunisation. FP7-HEALTH-2011-single-stage.** The aim is to apply advanced technologies to study human immune responses under conditions of health and disease. New knowledge generated by the project should be used to develop informed and rational strategies and technologies with wide potential applications for immune stimulation, or modulation of immune responses, depending on the pathological condition. Research should be targeted to prevention or cure of infections but aspects of age-dependent immune senescence or gender specific responses may also be addressed, to understand and inform targeted immune modulation.

Major research questions, such as, molecular signatures of immune protection, the relationship between systemic and local immune responses, and the interplay between immune adaptive and innate mechanisms, should be integrated and research capacities be harnessed to develop immunisation strategies and vaccines designed to elicit the specifically desired human immune responses.

Dedicated project components should focus on:

- adjuvants and immune modulators, platforms and delivery technologies with improved effectiveness and safety;
- routes of immunisation (systemic, local, mucosal, transdermal);
- efficacy- and longevity-enhancing immunisation schemes (prime boost approaches, age related aspects of immune responses, specific target groups);
- rational design of therapeutic vaccines.

The applications-orientated concept of the programme implies that technological, methodological and clinical research components of the programme will determine the research agendas followed by underpinning immunology research. This overall conceptual orientation should be reflected in substantial and influential participation of industry active in the area of vaccines and immune modulating products. In particular, involvement of research intensive SMEs is required.

A dedicated project component should aim to establish and implement European training curricula for translational immunology and vaccinology research. Synergising with pertinent existing training schemes and support structures is encouraged.

The proposal should include a management structure appropriate for the scope of the project. The project should launch calls to add new subprojects and/or partners in defined areas as required. While building on the support given by an optimum number of core institutions participating in the project, the programme management should be sufficiently independent from partner institutions in order to allow the programme to develop its own momentum, corporate identity and visibility. Careful consideration should be given to the governance of the programme, with due involvement of external expertise and relevant stakeholders.

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

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

**EC contribution per project:** Maximum EUR 30.000.000

**Only up to one proposal can be selected.**

**Expected impact:** The project should lead to new interventions modulating the human immune responses to prevent, alleviate or cure disease. It should structure this area of research in such a way that it favours enhanced exploitation by European industries. Longer-term sustainability of the programme could also be achieved. To this end elaboration of appropriate interfaces for co-funding by other agencies, including Member State and Associated State national programmes could be a major outcome.



**HEALTH.2011.1.4-5: New therapeutic approaches in chronic inflammatory and autoimmune diseases. FP7-HEALTH-2011-single-stage.** Projects should aim to develop innovative strategies to therapy based on approaches, such as small molecules, antibodies, peptides or cells, where understanding of mechanism of action has already been established. Proposals should include validation in relevant pre-clinical models and, if possible, early assessment in humans. The selected project should capitalise on the strong experience available in Brazil and Europe in the fields of immunology and immunopathology. Cooperation with related national and international projects in Brazil should be ensured and a part of the budget should be set aside for this cooperation and for training activities. Industrial participation is required 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.

**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:** Results are expected to lead to a much closer cooperation between Member States and Associated Countries and Brazil than is the case for traditional FP projects. It is expected that the Brazilian authorities will issue a complementary call to finance Brazilian projects in this field and that the EC funded project will cooperate closely with those and other related projects.

## **2. TRANSLATING RESEARCH FOR HUMAN HEALTH**

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

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

#### **2.1.1 Large-scale data gathering**

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

In the post-genome era the "-omic" technologies are advancing to the bedside. Personalized medicine is taking advantage of the cutting edge "-omics" technologies (genomics, proteomics, structural biology, interactomics, metabolomics, pharmacogenomics) to enable new approaches in diagnosis, drug development, and individualized therapy. There is a need to streamline the research in order to help understanding and evaluating predisposition to diseases still before the onset. The selected projects will set up the necessary data resource and technological platforms for developing personalized medicine approaches. **Note:** Depending on the topics listed below, applicants will have to follow the rules for single or two-stage submission procedure (see also respective call fiche in section III).

**HEALTH.2011.2.1.1-1: High impact initiative on the human epigenome. FP7-HEALTH-2011-two-stage.** This research project should aim to characterise the human epigenome in human health and disease. This project should address how histone modifications, nucleosome positioning and remodelling, DNA methylation, and small and non-coding RNAs are governing the way in which the genomic information is organized within the cell and how these phenomena play a role in regulating gene expression and in controlling specific cellular functions in health and diseases. This large effort should involve several components under the same management structure: data generation, research, technology development, networking and training to foster the competitiveness of European research on epigenetics. The envisioned components are:

**Generation of reference epigenome maps in health and diseases.** This project component should implement powerful and standardised high throughput approaches to generate at least 100 reference human epigenomes in conditions relevant to human health and diseases. This large data gathering component should follow the International Human Epigenome Consortium (IHEC) policies concerning data release and accessibility.

**Identification and validation of epigenetics makers in human disease(s).** This project component should address the epigenetic mechanisms at the origin of human disease(s). The important aspect of this action will be to demonstrate causality between the epigenetic changes and disease whether the mechanism is direct or indirect as an expression of genomic alteration. Where relevant the influence of environmental and life style factors should be considered. This component should also identify and validate important epigenetic markers of human diseases that will open avenues for new diagnostic tools and for therapeutic approaches.

**High throughput technologies for epigenome mapping in health and diseases.** The project component should catalyse the development of technologies that will accelerate high throughput epigenome mapping. The project should decrease substantially the cost of epigenetic mapping thereby making these approaches feasible for future clinical use. Research-intensive SMEs involvement is required for this component and this will be considered in the evaluation of the proposal.

**Identification of new compounds interfering with the regulators of epigenetics profiles.** This research-intensive SME-based component should screen for new compounds interfering with the enzymes that are important regulators of epigenetic mechanisms.

**Networking activities.** The research activities should be linked together through a networking component that should facilitate the flow of knowledge between basic research and the more applied research component (technology development and compounds screening). The HIP will also develop an open-access data management strategy to enable data storage and dissemination. Thereby, the consortium should establish a common website and database that will increase the visibility and relevance to the scientific community of this important European effort.

**Training and communication.** This multi-component project should also implement a joint training programme that will offer training opportunities across the spectrum of research (from basic to applied research). Importantly, this project should implement an efficient communication plan to the public and other stakeholders (scientific community, industry and patient associations).

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

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

**EC contribution per project:** Maximum EUR 30 000 000.

**Only up to one proposal can be selected.**

**Expected impact:** This project should aim at structuring European epigenetic research. Furthermore, this project should generate the technology, knowledge and know-how that should increase Europe's competitive position in exploiting the vast amount of epigenome data that will become available in the near future. This project should deliver important new high throughput technologies that will decrease the cost of epigenetic mapping and will facilitate in the medium to long-term the introduction of these approaches in a clinical environment. The project should also deliver new compounds that will modulate the activities of important regulators of epigenetics mechanisms in health and diseases. These new compounds would represent important tools for the characterisation of the epigenetic mechanisms that are involved in diseases. Importantly, by its size and its networking

component, this project should have a strong impact on European Research Area in this fast growing epigenetic research field and should allow researchers crossing the borders of different disciplines in epigenetic research.

Finally, the training programme should allow preparing the next generation of scientists to be ready to fully exploit the vast amount of data that will soon be generated in human epigenome research worldwide.

**HEALTH.2011.2.1.1-2: Proteins and their interactions in health and disease. FP7-HEALTH-2011-two-stage.** The project should gather a large amount of data on proteins relevant to human health and disease and their interactions in order to obtain an integrated view of biological processes. The research proposed may range from studying large multi-protein machineries and their structure-function relationships at cellular level to analysing protein-protein interactions at the pathway level. The time component should also be considered. The computational and experimental aspect may be combined as required to achieve the project goals. New technological developments may be encompassed as necessary. The optimal public access and use of data generated within the project should be ensured for the benefit of the broad scientific community. Active participation of research intensive 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.

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

**EC contribution per project:** Maximum EUR 12 000 000.

**One or more proposals can be selected.**

**Expected impact:** The project will aim at gathering, organizing and analyzing data and thereby integrating the communities in proteomics, interactomics, structural biology and cell biology to provide the basis for global understanding of cellular processes. The project(s) should help understand how important pathways and systems function in order to facilitate disease prevention, diagnosis and therapy. The ultimate project outcome will be building the necessary knowledge base for personalised medicine.

**HEALTH.2011.2.1.1-3: Large-scale genomics approaches to identify host determinants of infectious diseases. FP7-HEALTH-2011-single-stage.** The project should aim at identifying host genetic markers predicting susceptibility and severity for infectious diseases utilising primarily large-scale biobanks and patient databases and, when appropriate, well established animal models for functional validation. The focus will be on multidisciplinary approaches bringing together areas such as high-throughput genomics, immunogenetics, infectious diseases, microbiology, bioinformatics and public health genomics. Research-intensive SME participation is highly encouraged 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.

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

**EC contribution per project:** Maximum EUR 12 000 000.

**Only up to one proposal can be selected.**

**Expected impact:** This project should meet bio-medical research and clinical needs. The genomic markers should have the potential for subsequent clinical validation and exploitation in public health.

**HEALTH.2011.2.1.1.-4: Population genetics studies on cardio-metabolic disorders in EU/AC and EECA populations. FP7-HEALTH-2011-single stage.** The aim of this project is to study genetic predisposition to cardio-metabolic disorders, such as metabolic syndrome, arterial thrombosis, type 1 and type 2 diabetes, hypertension, stroke and pregnancy-related disorders in different EU/AC and EECA populations. The project should evaluate the prevalence of gene variants in patients and control groups in various populations and compare obtained results with clinical data. This will allow identifying population/patient groups which are at high risk for disease and complications and help in optimising therapeutic approaches. **Note:** Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria.

**Funding scheme:** Specific International Cooperation Action (SICA), Collaborative Project (small or medium-scale focused research project).

**EC contribution per project:** Maximum EUR 6 000 000.

**Only up to one proposal can be selected.**

**Expected impact:** This project is expected to lead to a much closer cooperation between the EU/AC and EECA countries than is the case for traditional FP projects, while helping identifying genetic differences between various population that predispose to cardio-metabolic diseases.

## **2.1.2 SYSTEMS BIOLOGY**

*Closed in 2011*

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

### **2.2.1 Brain and brain-related diseases**

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

neurological and psychiatric diseases and disorders, including regenerative and restorative therapeutic approaches.

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

**HEALTH-2011-2.2.1-1: Investigator-driven clinical trials<sup>12</sup> for childhood-onset neurodegenerative diseases. FP7-HEALTH-2011-two-stage.** Support will be provided to clinical trials for primary neurodegenerative diseases that develop during childhood, *i.e.* up to 18 years of age. Human pharmacokinetics, pharmacodynamics, efficacy and/or safety studies should be included. In this work programme several topics for investigator-driven, multicentre, prospective, controlled clinical trials are called for. The outcomes must be relevant for patients and change clinical practice. Pilot studies and systematic reviews will not be funded. Clinical trials must be appropriately powered to produce statistically significant evidence. Gender aspects and differences related to age subgroups should be appropriately considered. The clinical trials to be supported must be registered in a publicly accessible clinical trials registry. The applications must consider the relevant governance issues for clinical trials such as good clinical practice and respect of the appropriate international, European and national legislation and guidelines. Patient advocacy groups, which can contribute to the quality, feasibility and impact of clinical trials should be involved. The involvement of industry, in particular research-intensive SMEs, is highly encouraged 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.

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

**EC contribution per project:** Maximum EUR 6 000 000.

**One or more proposals can be selected.**

**Expected impact:** The successful projects are expected to improve current therapeutic strategies by providing concrete outcomes that lead to clear benefits for patients.

**HEALTH-2011-2.2.1-2: Understanding the role of neuroinflammation in neurodegenerative diseases. FP7-HEALTH-2011-two-stage.** An accumulating body of evidence indicates an active role of neuroinflammation not only in classical neuroinflammatory diseases like multiple sclerosis, but also in the pathophysiology of progressive neurodegenerative disorders such as Alzheimer's and Parkinson's disease. The successful project(s) should elucidate the link between neuroinflammation and neurodegeneration. The ultimate goal should be the identification of viable targets for the development of neurodegenerative disease therapeutics and/or the validation of protective strategies for neurons and axons that may improve disease outcome in patients. Inclusion of

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<sup>12</sup> <http://ec.europa.eu/enterprise/sectors/pharmaceuticals/documents/eudralex/vol-10/>

Please consult also the text for clinical trials provided in the introduction to this work programme on page 6



early phase clinical trials to prove the benefit of immunomodulatory therapies will be considered an asset. The participation of clinical centres, research-intensive SMEs and industry is highly encouraged and this will be considered in the evaluation of the proposal. Transmissible and infectious diseases causing neuroinflammation are excluded. **Note:** Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria.

**Funding scheme:** Collaborative Project (large scale integrating project).

**EC contribution per project:** Maximum EUR 12 000 000.

**One or more proposals can be selected.**

**Expected impact:** The funded projects will contribute to better understanding of brain dysfunction, help structuring European research efforts and lead to a better management of costly neuroinflammatory and subsequent neurodegenerative diseases such as Alzheimer's disease, Parkinson's disease and multiple sclerosis, with a potential to reduce healthcare costs while improving the health of European citizens.

**HEALTH-2011-2.2.1-3: Addictive and/or compulsive behaviour in children and adolescents: translating pre-clinical results into therapies. HEALTH-2011-two-stage.**

The projects should focus on one or more paediatric and adolescent neuropsychiatric disorders characterized by addictive and/or compulsive behaviour such as addiction, obsessive compulsive disorders and tic disorders. In addition to increasing our knowledge of the pathogenesis and mechanisms of these disorders, the successful project is expected to have well-specified clinical relevance. To this end, pre-clinical studies in relevant animal models and humans should be complemented by cohort studies for evaluating and validating of preventive and/or therapeutic strategies. The projects funded should address inequalities by gender, ethnicity and socioeconomic status. The participation of research-intensive SMEs and industry is highly encouraged 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.

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

**EC contribution per project:** Maximum EUR 6 000 000.

**One or more proposals can be selected.**

**Expected impact:** The identification of susceptibility factors for addictive and/or compulsive behaviour in children and adolescents is essential for targeted prevention and health care management. Moreover, this will enable researchers to understand the underlying mechanisms, translate their findings into new therapies, and ultimately decrease the onset of these diseases to a significant degree or prevent them.

**HEALTH-2011-2.2.1-4: Creating instruments for experimental therapy for paediatric neurodegenerative disorders by clinical and molecular analysis. FP7-HEALTH-2011-single-stage.**



Collaborative research should address one or more of the neurodegenerative diseases causing childhood dementia such as mitochondrial disorders, amino- and organic acid disorders, NCL and leukodystrophies, which are important issues for child health in both Europe and India. The project should undertake a multidisciplinary approach to study these diseases. It should include aspects such as prevalence, quantitative description of natural histories, characterization of molecular basis and pathophysiology in relevant models, and development of new testing and screening methods applicable to the wider community. The project should take advantage of the diversity of clinical manifestations and genetic basis in different population groups of Europe and India and should aim at the prevention, early detection and innovative therapies of these diseases. Active participation of research-intensive 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.

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

**EC contribution per project:** Maximum EUR 3 000 000.

**One or more proposals can be selected.**

**Expected impact:** The project is expected to contribute to the description of the natural course and the clinical spectrum, prevention, early detection and evaluation of innovative therapies of paediatric neurodegenerative diseases in Europe and India, which might take place through gene- and or enzyme-based therapies, early detection and identification of high risk populations. A close cooperation between Europe and India is expected to result from the projects. It is expected that the Indian Council of Medical Research will issue a complementary call to support Indian projects in this field and that the funded projects will commence at the same time and will cooperate closely. The cooperation may also include joint meetings, exchange of scientists, technology transfer, etc.

**HEALTH.2011.2.2.1-5: ERA-Net on disease-related neurosciences. FP7-ERANET-2011-RTD.** This action should improve the linking and efficient integration and coordination of national/regional programmes for disease-related neuroscience 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 a series of joint transnational calls, as well as activities aimed at fostering the development of disease-related neuroscience research programmes in non-participant Member States and Associated States. Due consideration should be given to the enlarged European Research Area. In the research area of neurodegenerative diseases, in particular Alzheimer's disease, a Joint Programming initiative has been initiated. The ERA-Net should perform work complementary to the implementation of the Joint Programming initiative.

**Funding scheme:** Coordination and Support Action (Coordinating Action).

**EC contribution per ERA-NET:** Maximum 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 disease-related neurosciences in fields complementary to the ones implemented by

the Joint Programming initiative in the area of neurodegenerative diseases, in particular Alzheimer's disease.

### **2.2.2 Human development and ageing**

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

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

The focus will be on the study of human and model systems, including interactions with factors such as environment, genetics, behaviour, lifestyle and gender to gain a clear understanding of the mechanisms that lead to the development of age-related disorders and therefore of age-related therapies. **Note:** Applicants under this area will have to follow the rules for the two-stage submission procedure (see also respective call fiche in section III).

**HEALTH.2011.2.2.2-1: Investigator-driven clinical trials<sup>13</sup> for therapeutic interventions in the elderly populations. FP7-HEALTH-2011-two-stage.** Elderly people are susceptible to a wide range of medical conditions, including Alzheimer's and Parkinson's disease, cancer, cardiovascular disease, pulmonary diseases, muscular diseases, bone diseases, endocrine disorders and psychiatric disorders, which can often be associated (co-morbidity). Thus, the therapeutic armamentarium needs to be tailored to their specific needs and conditions. Multicentre clinical trials should contribute to provide evidence for best practices in the use of concomitant multi-therapy modal therapies in an elderly population. The successful consortia should include a sufficient number of patients from different age ranges and health status. In this work programme several topics for investigator-driven, multicentre, prospective, controlled clinical trials are called for. Aspects of comparative effectiveness research should be included in the design of clinical trials. The outcomes must be relevant for patients and change clinical practice. Pilot studies and systematic reviews will not be funded. Clinical trials must be appropriately powered to produce statistically significant evidence. Gender aspects should be appropriately considered. The clinical trials to be supported must be registered in a publicly accessible clinical trials registry. The applications must consider the relevant governance issues for clinical trials such as good clinical practice and respect of the appropriate international, European and national legislation and guidelines. Patient advocacy groups, which can contribute to the quality, feasibility and impact of clinical trials, should be involved. The active participation of research-intensive SMEs is highly encouraged 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.

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<sup>13</sup> <http://ec.europa.eu/enterprise/sectors/pharmaceuticals/documents/eudralex/vol-10/>

Please consult also the text for clinical trials provided in the introduction to this work programme on page 6

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

**EC contribution per project:** Maximum EUR 6 000 000

**One or more proposals can be selected.**

**Expected impact:** The funded projects will contribute to better clinical management of the elderly with a potential to reduce healthcare costs while ultimately improving healthy ageing of European geriatric citizens.

**HEALTH.2011.2.2.2-2: Linking human development and ageing. FP7-HEALTH-2011-two-stage.** Knowledge of biological mechanisms occurring during the early stages of life, including pre- and perinatal phases, have proved to be important for understanding and potentially predicting changes occurring later in life and affecting the health or disease status during the entire life course of individuals. Research should aim at linking studies of early developmental processes with those on longevity and ageing, focussing on the identification of genes and pathways that are relevant in both early development and adult life. Active participation of research-intensive SMEs is a requirement 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.

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

**EC contribution per project:** Maximum EUR 3.000.000

**One or more proposals can be selected.**

**Expected impact:** the successful projects will contribute to the understanding of human biological variation across the lifespan in health and disease by studying genes and pathways. Ultimately this knowledge will be translated to the detection of early deviations of health and will be instrumental to allow intervention when a condition is still reversible.

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

### **2.3.1 Anti-microbial drug resistance**

The strategic objective of this area is to confront the increasing emergence and spread of antimicrobial drug resistant pathogens in Europe at broad fronts and in a multi-disciplinary approach through the development of effective infection prevention and control strategies. Clinical trials of off-patent antibiotic will take into account not only clinical outcome, but also impact on resistance development. Focus on microbial ecology will allow for a better understanding of the dynamics and evolution of resistance traits and thereby open up for new intervention opportunities. A multi-disciplinary integrated effort will be made to address the public health threat posed by Gram negative multi-drug resistant bacteria. SMEs will be

mobilized to develop new technologies for diagnostic tests and for controlling biofilm formation in the clinical environment.

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

**HEALTH.2011.2.3.1-1 Investigator-driven clinical trials<sup>14</sup> of off-patent antibiotics. FP7-HEALTH-2011-two-stage.** Research should aim at defining optimal treatment regimens (including drug choice, combinations, dosing, duration of therapy, PK/PD, individualisation) of off-patent antimicrobial agents for therapy of difficult-to-treat infections caused by multi-drug resistant bacterial pathogens in terms of maximising clinical benefit and minimising selection of resistance. Research-intensive SME participation is highly encouraged 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.

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

**EC contribution per project:** Maximum EUR 6 000 000.

**One or more proposals can be selected.**

**Expected impact:** This type of studies will allow for the identification of optimal treatment regimens by off-patent antibiotics of infections caused by multi-drug resistant bacterial pathogens, as well as an improved standardisation of such treatments. Not only clinical outcome, but also impact on drug resistance will be taken into account.

**HEALTH.2011.2.3.1-2: Multi-disciplinary research on the evolution and transfer of antibiotic resistance. FP7-HEALTH-2011-single-stage.** Research should aim to study the human microbiome with its vast number of bacterial species that forms a reservoir in which antibiotic resistance emerges in human pathogens. The resistance genes that are present in the human microbiome need to be characterized, and their potential to transfer to other pathogenic or non-pathogenic bacteria needs to be investigated. The dynamics and evolution of the interaction between the resistant and non-resistant human microbiome over time needs to be addressed using for instance metagenomics or other state-of-the-art techniques. Research should also aim to elucidate interactions of the (resistant) human microbiome with environmental, animal and food reservoirs. Part of the effort could be devoted to identifying and characterizing novel zoonotic bacteria appearing in resistance reservoirs. The characterization of the resistance reservoirs should provide deeper knowledge on the evolution and transfer of resistance and establish methods that allow for the prediction of the flow of genes and organisms between different environments and future resistance trends. Research-intensive SME participation is highly encouraged 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.

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

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<sup>14</sup> <http://ec.europa.eu/enterprise/sectors/pharmaceuticals/documents/eudralex/vol-10/>

Please consult also the text for clinical trials provided in the introduction to this work programme on page 6

**EC contribution per project:** Maximum EUR 12 000 000.

**Only up to one proposal can be selected.**

**Expected impact:** This multidisciplinary research is likely to elucidate the relationship between different reservoirs of resistant pathogenic bacteria and thereby open up avenues for novel intervention approaches.

**HEALTH.2011.2.3.1-3 Management of Gram negative multi-drug resistant infections. FP7-HEALTH-2011-single-stage.** Research should focus on innovative methods aimed at a better control of Gram negative multi-drug resistant infections both in health-care settings as well as in the community. Hospital- and community-based intervention studies will be performed; the link to carriage and colonization, dynamics of transmission, and the clinical impact of measures to decrease the burden of resistant strains will be addressed. Research will include evaluation of rapid tests for reliable detection of Gram negative multi-drug resistant infections, including clonal identification and resistance in order to direct empiric therapy and infection control measures. Observational studies should be carried out to understand the role of gastro-intestinal carriage in causing infection and in resistance gene transfer among Gram-negative organisms. Research will also include evaluation of population-based interventions to control the spread of Gram-negative multi-drug resistant organisms in the community and hospital settings, including new decolonization approaches, test of efficacy of different decolonization regimens in clinical trials, ecology and evolution of resistance in the gastro-intestinal tract including measures to preserve the gut flora and prevent the spread of resistance. Research will also determine optimal treatment regimens for common infectious disease conditions (e.g. urinary tract infection, hospital-acquired infections). Mathematical models of the within-host interaction between the multi-resistant and non-resistant Gram negative bacterial microbiome and their dynamics and evolution will be established, as well as models allowing the prediction of future spread using different macro-epidemiologic scenarios. Active participation of research intensive 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.

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

**EC contribution per project:** Maximum EUR 12 000 000.

**Only up to one proposal can be selected.**

**Expected impact:** This research is likely to improve the management of Gram negative multi-drug resistant infections in the community as well as in health-care settings.

**HEALTH.2011.2.3.1-4 Development of multi-analyte diagnostic tests. FP7-HEALTH-2011-two-stage.**

Research should aim to develop novel diagnostic tools. Managing the problem of bacterial resistance relies on a fast identification of resistant pathogens in a clinical setting. The vast numbers of pathogenic bacteria that can contain a variety of resistance mechanisms stress the need for multi-analyte diagnostic tests that are fast and reliable. Tests should aim to



distinguish bacteria from viruses, should detect markers for severity of infection and identify resistance/susceptibility patterns. The availability of robust diagnostic tests is required to allow for an evidence-based system of antibiotic resistance management. The development of such diagnostic tools and their introduction in clinical settings should be aimed for, with the ultimate goal to tailor antibiotic prescription to the individual patient. **Note:** Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria.

**Specific feature:** SME-targeted research is designed to encourage SME efforts towards research and innovation. Priority will be given to proposals demonstrating that research intensive SMEs play a leading role. The projects will be led by SMEs with R&D capacities, but the coordinator does not need to be an SME. The expected project results should clearly be of interest and potential benefit to SME(s). All consortia should aim at having 30-50 % of the requested EC contribution budget going to SMEs (subcontracting is discouraged).

**Additional selection criteria:** SME-targeted Collaborative Projects will only be selected for funding on the condition that the requested EU contribution going to SME(s) is 30% or more of the total requested EC contribution. ***This will be assessed during evaluation and checked during negotiation. Proposals not fulfilling this criterion will not be funded.***

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

**EC contribution per project:** Maximum. EUR 3 000 000.

**One or more proposals can be selected.**

**Expected impact:** The availability of multi-analyte diagnostic tests will allow for antibiotic prescription that takes both the type of (resistant) infection of the patient, and the presence of resistant pathogens in the clinical setting into account.

**HEALTH.2011.2.3.1-5 Development of tools to control microbial biofilms with relevance to clinical drug resistance. FP7-HEALTH-2011-two-stage.** Research should aim at the development of tools to control biofilm formation. The formation of biofilms of pathogenic bacteria and fungi impacts sensitivity and resistance to antibacterial and antifungal drugs and therefore represents a clinical problem. Novel tools that allow disrupting biofilm formation and decrease infection rates would be useful. Such tools aimed at controlling biofilm formation should allow developing strategies aimed at improving patient management. **Note:** Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria.

**Specific feature:** SME-targeted research is designed to encourage SME efforts towards research and innovation. Priority will be given to proposals demonstrating that research intensive SMEs play a leading role. The projects will be led by SMEs with R&D capacities, but the coordinator does not need to be an SME. The expected project results should clearly be of interest and potential benefit to SME(s). All consortia should aim at having 30-50 % of the requested EC contribution budget going to SMEs (subcontracting is discouraged).

**Additional selection criteria:** SME-targeted Collaborative Projects will only be selected for funding on the condition that the requested EU contribution going to SME(s) is 30% or more

of the total requested EC contribution. ***This will be assessed during evaluation and checked during negotiation. Proposals not fulfilling this criterion will not be funded.***

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

**EC contribution per project:** Maximum EUR 3 000 000

**One or more proposals can be selected**

**Expected impact:** The availability of tools to control biofilm formation will allow for a better management of infections caused by pathogenic bacteria and fungi.

### **2.3.2 HIV/AIDS, malaria and tuberculosis**

*Closed in 2011*

### **2.3.3 Potentially new and re-emerging epidemics**

The focus will be on confronting emerging pathogens with pandemic potential. The results of research in this area will integrate European scientific excellence and make Europe better prepared for emerging epidemics. Understanding the crucial factors needed for the influenza and other serious zoonotic viruses to cross the species barrier as well as spread from human to human is a fundamental element for development of new control strategies and in pandemic preparedness planning. A comprehensive effort on Dengue fever will take stock of Europe's research competence to develop new control measures against this scourge, which is on the rise largely due to climate change. Finally, the 2009 influenza H1N1 pandemic has demonstrated a general underestimation of the need for evidence based communication tools.

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

**HEALTH.2011.2.3.3-1: Identification of factors promoting the emergence of viruses and bacteria with human pandemic potential from pathogens with a zoonotic background and related prevention strategies. FP7-HEALTH-2011-single-stage.** Cross-disciplinary research should aim to identify the factors that render various zoonotic pathogens with human pandemic potential prone to cross the species-barrier and further to gain human-human transmissibility. Research should focus on pathogenicity, infectivity and transmissibility and take into account both pathogen and host factors as well as ecological factors in the human/animal interface. Research could address influenza, but could also involve other zoonotic pathogens. The project should bring together the veterinary and human field, should establish pathogen information sharing platforms and should include a strong training component to foster cross-disciplinary knowledge in the field. **Note:** Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria.

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



**EC contribution per project:** Maximum EUR 12 000 000.

**Only up to one proposal can be selected.**

**Expected impact:** Research will have to contribute to a better understanding of the emergence and transmission of pathogens with pandemic potential and improve preparedness planning, in particular modelling and prediction, but also development of appropriate intervention measures.

**HEALTH.2011.2.3.3-2 Comprehensive control of Dengue fever under changing climatic conditions. FP7-HEALTH-2011-single-stage.**

Research may include innovative tools for clinical management, including better diagnosis, and the development of evidence based preventive vaccination and treatment, surveillance and prediction of the spread of the Dengue fever to previously uninfected regions in the context of climate change. The risk of dengue outbreak in Europe will be assessed. Research may include the prevention of spread to previously uninfected regions, as well as studies on the underlying pathogenesis with respect to viral and host factors that can predict disease severity and lay the ground for further development of new vaccines, antiviral compounds and more targeted treatment schemes. An added value in the evaluation process will be given if projects include partners from both SICA target regions, including research-intensive SMEs. **Note:** Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria.

**Funding scheme:** Specific International Cooperation Action (SICA), Collaborative Project (small or medium-scale focused research project – target regions: Latin America and Asia).

**EC contribution per project:** Maximum EUR 6 000 000.

**One or more proposals can be selected.**

**Expected impact:** Better tools, and the use thereof, for improved comprehensive control of Dengue fever at a global level.

**HEALTH.2011.2.3.3-3: Development of an evidence-based behavioural and communication package to respond to major epidemic outbreaks. FP7-HEALTH-2011-two-stage.** Research should focus on behavioural research and how human behaviour influences disease transmission, vaccine acceptance and antiviral therapy acceptance in the general population in a crisis situation. Research should focus on developing appropriate communication methods, especially regarding complicated messages and advice based on uncertainties, a changing epidemiological picture and information gaps. Particular attention should be paid to addressing knowledge and attitudes towards vaccination for a better understanding of the level of risk people would accept when vaccinated in relation to the perceived risk of disease. The project should develop and test strategies to support vaccine uptake with special focus on new communication strategies for health professionals/agencies to engage in vaccine-resistant groups. The objective is to set up an integrated research project involving social sciences, behavioural sciences, communication, media expertise and civil

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

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

**EC contribution per project:** Maximum EUR 3 000 000.

**Only up to one proposal can be selected**

**Expected impact:** It is expected that this research will develop communication tools where the received message more closely corresponds to the original intention.

### **2.3.4 Neglected infectious diseases**

*Closed in 2011*

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

#### **HEALTH.2011. 2.4.1-1: Investigator-driven, treatment trials<sup>15</sup> for rare cancers. FP7-HEALTH-2011-two-stage.**

Research must focus on either solid or haematological rare cancers which are defined as cancers affecting not more than five in ten thousand persons in the European Union. The successful consortium will perform multicentre clinical trials aiming at the validation of novel therapeutic strategies, including targeted therapies, which improve patient survival. The project should focus on radiotherapy, chemotherapy, surgery, gene therapy, cell therapy or immunotherapy, or any combination of those. The following requirements and exclusions apply: endpoints, entry and exclusion criteria must be clearly described. *Clinical studies into*

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<sup>15</sup> <http://ec.europa.eu/enterprise/sectors/pharmaceuticals/documents/eudralex/vol-10/>

Please consult also the text for clinical trials provided in the introduction to this work programme on page 6

*off-patent medicinal products under the paediatric use marketing authorisation (PUMA) initiative and into devices are excluded.* The outcome of the research should be relevant for patients and lead to change in clinical practice. Clinical trials must be appropriately powered to produce robust evidence and a biostatistician must be part of the consortium. Gender aspects and differences related to age groups should be appropriately considered. The clinical trials to be supported must be registered in a publicly accessible clinical trials registry and their results published in peer reviewed journals. The applications must consider the relevant governance issues for clinical trials such as good clinical practice and respect of the appropriate international, European and national legislation and guidelines. Patient advocacy groups, which can contribute to the quality, feasibility and impact of clinical trials, should be involved. The 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.

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

**EC contribution per project:** Maximum EUR 6 000 000.

**One or more proposals can be selected.**

**Impact:** The results of research in this area will ultimately benefit patient survival, integrate investigator-driven, clinical research networks on rare cancers as well as structure European scientific excellence and competitiveness on rare cancers.

**HEALTH.2011.2.4.1-2: Translational research on cancers with poor prognosis. FP7-HEALTH-2011-two-stage.** Collaborative research must either focus on stomach cancer, ovary cancer, brain cancer or multiple myeloma. 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 must include clinical expertise to guarantee a clinical proof-of-principle. Active participation of research intensive 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.

**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.2011.2.4.1-3: Epidemiology and aetiology of infection-related cancers. FP7-HEALTH-2011-single-stage.** Collaborative research should address one or more of the prevalent infectious agents that cause cancers of major public health importance in India as

well as Europe, such as human *papilloma* virus, *hepatitis B* and *C* viruses, and/or *Helicobacter pylori*. The project must integrate different disciplines relevant to study both infection and cancer and include aspects such as prevalence of infection in different population groups, determinants of infection, clearance and re-infection, environmental cofactors in the carcinogenic process, mechanisms of infection-related cancers, and development of new testing and screening methods applicable to the wider community. In addition, the project must take advantage of the diversity of risk factors, cofactors and cancer incidence in different population groups of Europe and India. The project should focus on the prevention and early detection of infection-related cancers in Europe and India, addressing both established and putative associations between infectious agents and cancers. Active participation of research-intensive 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.

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

**EC contribution per project:** Maximum EUR 3 000 000.

**One or more proposals can be selected.**

**Expected impact:** The results of research in this area will contribute to the prevention and early detection of infection-related cancers in Europe and India, which might take place through vaccination, early detection and identification of high-risk populations. A close cooperation between Europe and India is expected to result from the projects. It is expected that the Indian Council of Medical Research will issue a complementary call to support Indian projects in this field and that the funded projects will commence at the same time and will cooperate closely. The cooperation may also include joint meetings, workshops, exchange of scientists, technology transfer, etc.

#### **2.4.2 Cardiovascular diseases**

Cardiovascular diseases (CVD) remain the number one cause of death worldwide. The huge social and economic burden of CVD morbidity becomes an even bigger challenge as the European population ages. Despite the progress of medical science of the past few decades, the management of many CVD have not been sufficiently explored and will need to produce further improvements. Therefore, the focus of this area in the current programme is on prevention and treatment strategies relevant to the everyday reality of clinical practice.

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

**HEALTH.2011. 2.4.2-1: Investigator-driven clinical trials<sup>16</sup> for the management of cardiovascular diseases. FP7-HEALTH-2011-two-stage.** Research should aim to address insufficiently explored aspects of cardiovascular disease management, including novel

<sup>16</sup> <http://ec.europa.eu/enterprise/sectors/pharmaceuticals/documents/eudralex/vol-10/>

Please consult also the text for clinical trials provided in the introduction to this work programme on page 6

treatments for stroke. Multicentre, controlled, interventional, treatment trials will be supported. Novelty, main research questions/hypotheses and study endpoints must be well described to allow definitive results being translated into clinical cardiovascular practice. In this work programme several topics for investigator-driven, multicentre, prospective, controlled clinical trials are called for. Aspects of comparative effectiveness research should be included in the design of clinical trials. The outcomes must be relevant for patients and change clinical practice. *Pilot studies and systematic reviews will not be funded.* Clinical trials must be appropriately powered to produce statistically significant evidence. Gender aspects and differences related to age groups should be appropriately considered. The clinical trials to be supported must be registered in a publicly accessible clinical trials registry. The applications must consider the relevant governance issues for clinical trials such as good clinical practice and respect of the appropriate international, European and national legislation and guidelines. Patient advocacy groups, which can contribute to the quality, feasibility and impact of clinical trials, should be involved. The 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.

**Funding scheme:** Collaborative project (large-scale integrating project).

**EC contribution per project:** Maximum EUR 12 000 000.

**One or more proposals can be selected.**

**Expected impact:** These projects are expected to provide tangible outcome and new evidence for recommendations to be used in the management guidelines of specific cardiovascular diseases and to demonstrate clear benefits for individual patients, doctors and society at large.

**HEALTH.2011.2.4.2-2: Evaluation and validation studies of clinically useful biomarkers in prevention and management of cardiovascular diseases. FP7-HEALTH-2011-two-stage.** Existing and emerging biomarkers and related mechanisms should be exploited to improve identification, risk assessment, clinical decision making and clinical outcome. Cost effectiveness, safety, validity and incremental benefit over existing risk prediction methods and life style determinants of investigated biomarkers must be demonstrated. The impact of biomarkers on cardiovascular disease risk prediction will need to be assessed across different European populations as they have different lifestyles (e.g. dietary patterns) and varying biomarker levels. Multidisciplinary research consortia must use state-of-the-art translational research, epidemiological and diagnostic technology (such as imaging technology) and knowledge. **Note:** Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria.

**Specific feature:** SME-targeted research is designed to encourage SME efforts towards research and innovation. Priority will be given to proposals demonstrating that research intensive SMEs play a leading role. The projects will be led by SMEs with R&D capacities, but the coordinator does not need to be an SME. The expected project results should clearly be of interest and potential benefit to SME(s). All consortia should aim at having 30-50 % of the requested EC contribution budget going to SMEs (subcontracting is discouraged).

**Additional selection criteria:** SME-targeted Collaborative Projects will only be selected for funding on the condition that the requested EU contribution going to SME(s) is 30% or more of the total requested EC contribution. ***This will be assessed during evaluation and checked during negotiation. Proposals not fulfilling this criterion will not be funded.***

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

**EC contribution per project:** Maximum EUR 6 000 000.

**One or more proposals can be selected.**

**Expected impact:** Assessment of cardiovascular risk in individuals is complementary to public health activities that aim to reducing the overall population risk of cardiovascular disease by promoting a healthy lifestyle (diet, exercise, avoidance of smoking). The results of research should lead to improved cardiovascular risk prediction and contribute to the development of personalised and predictive medicine.

### **2.4.3 Diabetes and obesity**

The focus will be on aetiologies of the different types of diabetes, and their related prevention and treatment. For the latter, the focus will be on multidisciplinary approaches including genetics, life style and epidemiology. For both diabetes and obesity, special attention will be given to juvenile diseases and factors operating in childhood. It is expected that the following topics will contribute not only to research breakthroughs in the diabetes/obesity treatments but also in prevention and treatment of complications. Considering the heavy toll taken on life expectancy of these diseases, particular attention should be given to paediatric aspects, when ever possible. Healthy life styles being a pre-requisite to any stabilisation of escalating costs of diabetes/obesity, projects should also examine how their results will contribute to the societal issues linked to the diseases.

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

**HEALTH.2011.2.4.3-1: Investigator-driven clinical trials<sup>17</sup> to reduce diabetes complications. FP7-HEALTH-2011-two-stage.** The successful consortium will perform multicentre, clinical trials in order to establish the best regimen to reduce as early as possible diabetes complications of neurodegenerative, micro-vascular, immunological, and/or hepatic origin. In this work programme several topics for investigator-driven, multicentre, prospective, controlled clinical trials are called for. Aspects of comparative effectiveness research should be included in the design of clinical trials. Psychological factors can be considered. The outcomes must be relevant for patients and change clinical practice. Pilot

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<sup>17</sup> <http://ec.europa.eu/enterprise/sectors/pharmaceuticals/documents/eudralex/vol-10/>

Please consult also the text for clinical trials provided in the introduction to this work programme on page 6



studies and systematic reviews will not be funded. Clinical trials must be appropriately powered to produce statistically significant evidence. Gender aspects and differences related to age groups should be appropriately considered. The clinical trials to be supported must be registered in a publicly accessible clinical trials registry. The applications must consider the relevant governance issues for clinical trials such as good clinical practice and respect of the appropriate international, European and national legislation and guidelines. Patient advocacy groups, which can contribute to the quality, feasibility and impact of clinical trials, should be involved. The 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.

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

**EC contribution per project:** Maximum EUR 6 000 000.

**One or more proposals can be selected.**

**Expected impact:** The successful trials should provide tangible outcomes by focusing on end-points relevant to the patient and establishing evidence for recommendations to improve clinical practice when appropriate.

**HEALTH.2011.2.4.3-2 Development of novel treatment strategies based on knowledge of cellular dysfunction. FP7-HEALTH-2011-two-stage.** The aim is to use knowledge of cell dysfunction to develop innovative therapeutic strategies for Type 1 or Type 2 diabetes that halt destruction and facilitate recovery of functionally impaired metabolic tissues, particularly beta cells and brown adipocytes. Research should be multidisciplinary and might be based on use of information on genetics and genomics of diabetes development. Interactions between organs and between tissues should be considered where appropriate. Clinical work can be included. 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.

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

**EC contribution per project:** Maximum EUR 6 000 000.

**One or more proposals can be selected.**

**Expected impact:** It is expected that the successful project will translate state-of-the-art knowledge on the role of beta-cell dysfunction in the pathogenesis of diabetes into novel treatment strategies.

**HEALTH.2011.2.4.3-3: Molecular and physiological effects of lifestyle factors including physical exercise and nutrition on diabetes/obesity. FP7-HEALTH-2011-two-stage.** Research should aim at multi-disciplinary approaches that capitalise on genetic, epigenetic, proteomic, metabolomic, physiological, and clinical disciplines to gain insight into factors behind the divergent effects of lifestyle factors including physical exercise and nutrition on metabolism. The project should focus on state-of-the-art technologies to accelerate the



translation of experimental and clinical discoveries to link novel targets and pathways with phenotype and genotype to define the lifestyle factors on metabolic health. Animal models can be used, but only in addition to human 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.

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

**EC contribution per project:** Maximum EUR 6 000 000.

**Only up to one proposal can be selected.**

**Expected impact:** It is expected that the project will have access to collections of genetic and physiological material from well-characterised humans, including individuals predisposed for the development of Type 2 diabetes. Academic efforts should be interfaced with the European biotech/pharmaceutical sector to have the greatest impact on European citizens.

**HEALTH.2011.2.4.3-4: Genetic and environmental factors in obesity and/or diabetes in specific populations. FP7-HEALTH-2011-two-stage.** The research should aim at understanding the genetic and environmental factors causing variations in prevalence and incidence of metabolic disorders in specific, well characterised populations that show a significantly altered risk of developing metabolic disorders in a new place or situation. The successful project should be based on new comparisons between populations in their original and new environment, *e.g.* as immigrant populations. Emphasis should be placed on the role of genetic, environmental and/or lifestyle factors, as well as their interactions, on the incidence, prevalence, and age of onset of metabolic disorders. Each project should focus on a particular geographical region. The European Commission services will ask all selected projects at the negotiation stage to interact together and with related projects from selected third 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. Proposers should take into account existing EU funded projects, including from the FP6 Food-Agri-Biotech programme, such that overlap be avoided. **Note:** Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria.

**Funding scheme:** Specific International Cooperation Action (**SICA**), Collaborative Project (small or medium-scale focused research project) Target regions: Mediterranean countries, Africa, Asia Latin-America).

**EC contribution per project:** Maximum EUR 3 000 000.

**One or more proposals can be selected.**

**Expected impact:** The selected project are expected to ultimately guide lifestyle intervention programmes, including but not limited to diet and physical activity, taking into account situations of malnutrition and possible multigenerational effect. Findings will be relevant for populations, both in their home countries and immigrant populations in Europe and throughout the world. It is expected that novel genetic and other risk factors for diabetes and obesity will be identified that will lead to improved diagnosis and treatment and possibly the development of novel therapeutic targets. The cooperation between the selected projects and

other national projects from selected third countries will ensure a global impact beyond the specific populations studied.

**HEALTH.2011.2.4.3-5: ERA-NET on diabetes prevention and treatment. FP7-ERANET-2011.** The creation of an ERA-NET in diabetes prevention and treatment will help overcoming the fragmentation of research activities, programmes and policies across Europe and contribute to increase sharing of best practices and best use of public health resources. It will bring together national funders related to diabetes prevention and create synergies by uniting vast amounts of data, resources and know-how which exist in several Member States or associated countries. It shall serve to identify important challenges and solutions, to better integrate and rationalise resources as well as to improve the use of existing infrastructures in Europe in the field of diabetes prevention and treatment. Furthermore it should integrate as appropriate international projects, both EC funded and not, that address research on diabetes and its prevention and treatment. **Note:** Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria.

**Funding scheme:** ERA-NET, Coordination and Support Action (coordinating action).

**EC contribution per project:** Maximum EUR 2 000 000.

**Only up to one proposal can be selected.**

**Expected impact:** This action should improve the linking and efficient integration and coordination of national/regional programmes where relevant. It will also provide a forum for exchange of information and best practices between Member States, helping to create national diabetes prevention programmes in countries which do not have one yet. Where relevant, it will help setting up joint, transnational calls, with due consideration for socio-economics aspects, public health costs and impact. The inclusion of existing and future international projects on the subject will further help leveraging on resources and avoid duplications. It is expected that further coordination efforts in the area of diabetes prevention will help extend partnership, pool resources for funding and implementing research activities in a synergistic manner. Ultimately, the cooperation shall lead to a self-sustainable and long lasting network of funders in the area of diabetes prevention, enabling the translation of information gained from innovative research and experiences into policy, social and economic benefits.

#### **2.4.4 Rare diseases**

*Closed in 2011*

#### **2.4.5 Other chronic diseases**

*Closed in 2011*

### **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**

*Closed in 2011*

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

*Closed in 2011*

#### **3.3 HEALTH PROMOTION**

The focus is on the reduction of inequities in the determinants of health and on the transfer of knowledge in health promotion. It will be addressed via bottom-up topics that invite investigator-driven innovative research proposals in these evolving and highly relevant fields of health research. Proposals should address one or several of the range of major scientific issues that are identified in the topic description and propose innovative means to advance the science in this field.

**Note:** Applicants for topics **HEALTH.2011.3.3-1 and HEALTH.2010.3.3-2** will have to follow the rules for two-stage submission procedure (see respective call fiche in section III). Applicants for topics **HEALTH.2011.3.3-3 and HEALTH.2011.3.3-4** will have to follow the rules for single-stage submission procedure (see also respective call fiche in section III)

**HEALTH.2011.3.3-1: Developing methodologies to reduce inequities in the determinants of health. FP7-HEALTH-2011-two-stage.** Research should identify and evaluate policy and programme interventions with the potential to reduce inequities in the determinants of health and health services and opportunities to transfer the findings of research to potential users with maximum effectiveness. Proposals could address the strategic drivers of reductions in health disparities, the differential health effects of policy interventions, and the impact of alternative options for enhancing equity. They could also identify and validate innovative research methodologies to evaluate 'natural policy experiments' in which the introduction of a specific policy provides the opportunity for a quasi-experimental design or a comparative analysis that can be used to identify the policy's impact on different social groups including vulnerable groups (*e.g.* changes in social security systems; national responses to financial crisis; health equity assessments of urban renewal initiatives). Methodologies to generate, assess, and classify scientific evidence on the effectiveness including replication of complex or system-oriented interventions could be developed. Research is further needed on how people most affected by social determinants of health can be most effectively involved in the design, implementation, and evaluation of research methods. **Note:** Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria.

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

**EC contribution per project:** Maximum 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 how to effectively address inequities in the determinants of health. Appropriate and multidisciplinary research methodologies and designs should be developed to build a robust evidence base that can integrate research from different theoretical or methodological origins.

**HEALTH.2010.3.3-2: Analysis of integrated strategies for sustainable behaviour change. FP7-HEALTH-2011-two-stage.** The aim is to define generalisable, effective, and sustainable behaviour change interventions that can be effectively translated into health promotion practice. Multi-level intervention approaches that integrate individual, community, organisational, and societal systems should be analysed with respect to effectiveness and the relevant context variables recognizing the wide range of influences on individuals and behaviours.

**EC contribution per project:** Maximum EUR 3 000 000.

**One or more proposals can be selected.**

**Expected Impact:** This research should define the factors necessary for establishing effective interventions with individuals, families, organisations, and environments that can change the behaviours, lifestyles, critical for reducing the occurrence of the most prevalent chronic diseases or improving their management in a sustainable way and improving quality of life.

**HEALTH.2010.3.3-3: Developing and implementing methods for the transfer of research into policy in the fields of health promotion and disease prevention. FP7-HEALTH-2011-two-stage.** Public health research in Europe has produced considerable evidence supporting health promotion and disease prevention. Projects under this topic should support the 'knowledge brokerage' of such results to improve the impact of EU-funded research. The aim should be to develop and assess innovative integrative approaches of linking research results to relevant policy makers and other stakeholders that include feedback loops. Due to the experimental nature of this research, the design needs to include an in-built evaluation process that documents and critically analyses the impact and other important aspects of the chosen approach. The timeframe should span a 5 year period, taking into account projects selected in future calls in the health promotion and disease prevention area. **Note:** Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria.

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

**EC contribution per project:** Maximum EUR 3 000 000.

**One or more proposals can be selected.**

**Expected impact:** Increased use of research in decision making at the population level within the fields of health promotion and disease prevention should increase the impact of EU funded public health research. The consortium should reflect a composition of appropriate participation – knowledge translators/brokers and academics – in order to engage the relevant stakeholders and to communicate the research findings and results so as to be exploited in novel and innovative ways through cooperation between researchers and target users of such research and help to identify future research priorities.

**HEALTH.2010.3.3-4: A road-map for mental health research in Europe. FP7-HEALTH-2011-single-stage.** The aim should be to address a coordinated and comprehensive approach to promote and integrate research on the biological, epidemiological, social and public health aspects of mental health and well being in Europe. Member States existing research programmes are to be examined, recent advances as well as the identification of gaps in knowledge taken into account and potential roadmaps for the future of mental health research in Europe to be developed, set within a life course perspective. **Note:** Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria.

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

**EC contribution per project:** Maximum EUR 2 000 000

**Only up to one proposal can be selected.**

**Expected impact:** A comprehensive strategy at the European level setting out a coordinated approach to promote and integrate research on the biological, epidemiological, social and public health aspects of mental health in Europe.

### **3.4 INTERNATIONAL PUBLIC HEALTH & HEALTH SYSTEMS**

The specific cooperation actions in this area focus on the priorities agreed through bi-regional dialogues in third countries/regions and international forums, as well as within the context of Millennium Development Goals. This call will focus on health services research with a particular angle on maternal and child health, reproductive health, and health equity.

A coordinated research topic on health inequalities affecting mothers and children aims to foster multilateral cooperation between Europe, Africa, and Latin America.

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

**HEALTH.2011.3.4-1: Development and assessment of comprehensive and integrated interventions and programmes to improve reproductive health and health equity: all ICPCs. FP7-HEALTH-2011-single-stage.** Research under this topic should aim at creating evidence for best practices in developing and implementing integrated and comprehensive

reproductive health programs, following a life time approach and addressing the key areas of reproductive health, such as adolescent health, control of sexually transmitted diseases, assistance in achieving the desired fertility, and maternal and newborn health. The research is expected to go beyond the assessment of specific single interventions and should focus on the community effectiveness of reproductive health intervention packages and/or operational programmes, set in a health systems context. **Note:** Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria.

**Funding scheme:** Specific International Cooperation Action (SICA), Collaborative Project (small or medium-scale focused research project).

**EC contribution per project:** Maximum EUR 3 000 000.

**One or more proposals can be selected.**

**Expected impact:** The project is expected to generate, summarize and disseminate evidence on strategies, programmes, and best practice in reproductive health promotion and care. This evidence will help policy makers and programme managers on all levels, as well as other stake holders and the community to provide and use reproductive health services more effectively and equitably.

**HEALTH.2011.3.4-2: Building sustainable capacity for research for health and its social determinants in low and & middle income countries: all ICPCs. FP7-HEALTH-2011-single-stage.** The Coordination Action should develop and implement a concept for the sustainable development of capacity for research for health and its social determinants in close collaboration with institutions in ICPC countries 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. Emphasis should be given to establishing and supporting excellent academic teaching and research networks. Active participation of young researchers in regional and international forums, as well as exchange between research institutions, could be considered. The aim is to achieve a balanced level of participation for ICPC countries. **Note:** Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria.

**Funding scheme:** Coordination-Support Action (coordination action).

**EC contribution per project:** Maximum EUR 3 000 000.

**One or more proposals can be selected.**

**Expected impact:** To promote health scientists from ICPC countries along with their institutions and research networks in order to create a sustainable and attractive research landscape for interdisciplinary research for health and its social determinants.



**HEALTH.2011.3.4-3: Multilateral cooperation between Europe, Africa and Latin America on public health and health services research. FP7-HEALTH-2011-single-stage.**

This Coordination Action is aimed at creating links between "North-South" and "South-South" efforts in addressing health inequalities in developing countries. It should map and analyse current and planned activities and strategies in order to provide evidence on best practice and policy advice for the development of future interventions and programmes in this area. Furthermore, the project should identify further research needs and pay – among others – attention to health inequalities affecting children, adolescence and mothers (families). The EC grant shall cover the participation of the European, African and Latin American partners other than partners from Brazil. The participation of Brazilian and possible other African partners is expected to be covered by complementary funding from the Brazilian side through a separate call. Participation of other countries with substantial health services cooperation with Africa is welcomed. **Note:** Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria.

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

**EC contribution per project:** Maximum EUR 2 000 000.

**Only one proposal can be selected.**

**Expected impact:** The project will provide evidence on best practice and policy advice for the development of future public health and health systems interventions, with particular emphasis on the transfer of knowledge and experience through a triangular cooperation between Europe, Africa and Latin America. The project is expected to involve stakeholders, foster synergies and enhance the capacity for related public health and health policy research.

## **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 European Union (Community) research and technological development policy. The focus of this area in this work programme will be on assessing future needs, impact assessment and dissemination of results.

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

#### **HEALTH.2011.4.1-1: Networking of major research institutions to coordinate communication actions aimed to the media and the general public. FP7-HEALTH-2011-single-stage.**

The objective is to network major research institutions to coordinate their communication actions regarding EU-funded research, among themselves and with the Commission services, in order to have a greater impact in its visibility in the general public. Proposals should include the collection, sharing and distribution of information about research results in a timely way through multilingual, communication-oriented information networks, a coordinated, multinational press and public relations strategy about research emanating from EU-funded projects, and the adaptation of the contents/language/media to relevant target audiences. The potential applications and benefits for the citizens should be particularly highlighted. Successful applications should involve or coordinate a sufficient critical mass of communication services from research institutions and SME organisations in different countries participating in EU-funded health research projects. Some examples of activities could include the generation and efficient distribution of press kits for journalists from general and specialised media, a multipartner coordination and repository of press releases, wiki pages of projects, databases of scientific images, early alert system about communicable project results among partner institutions and to the Commission, newsletters, etc. **Note:** Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria.

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

**EC contribution per project:** Maximum EUR 2 000 000.

**Only up to one proposal can be selected.**

**Expected impact:** A European-wide strategy and better networking will help to communicate more efficiently the results and benefits of European collaborative research to general audiences, either directly or through the information multipliers (press and media, including the internet and social networks). A considerable part of the results generated by European health research are still communicated only through highly specialised scientific/technical publications and websites (by the scientists themselves) or through local press releases (by their institutional communication services). These are often only released in the country of the

research institution where the first author of the primary publication works, often with poor or no reference to the EU-funded multinational consortium that facilitated the achievement of those results. The involvement of the press and communication officers from the different partner institutions should follow the networking that already occurs at the scientific level in EU-funded projects. As a result, an increase in quality and quantity of the communication actions, a better coordination of resources and messages, and a proper acknowledgement of the European dimension of collaborative health research should be achieved.

**HEALTH.2011.4.1-2: Targeting publication bias. FP7-HEALTH-2011-single-stage.** *The objective is to explore, identify and overcome failure to publish negative results, especially from clinical trials. Failure to publish negative results or unsuccessful experiments has major ramifications for the health of EU citizens and there is an ethical imperative and a significant challenge to ensure that finite health research resources are better used, avoiding replication of previous experiments leading to better use of resources. Applicants should propose well-structured, innovative approaches to define and evaluate publication bias and the impact it has on research. These approaches should include the inventory of existing sites and publications, presentation of current data on impact of the failure to published negative results via surveys and/or analysis of literature, evaluation of study protocols, conference abstracts and discussions with key opinion leaders and stakeholders, such as research journal publishers, study registries, research institutions, funding bodies, regulators and industry. These approaches should include the inventory of existing sites and publications, presentation of current data on impact of the failure to published negative results. Interactions with major journals and international groups acting in medical publication should be sought in order to point out ways to change practice and provide insights on how to avoid duplication of research efforts and allow a more effective funding of health research. **Note:** Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria.*

**Funding scheme:** Coordination and Support Action (supporting action).

**EC contribution per project:** Maximum EUR 500 000.

**One or more proposals can be selected.**

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

**HEALTH 2011-4.1-3 Linking EU and Latin American policy making institutions in the field of health research**

The project will establish a roadmap for cooperative health research between the EU and Latin America for regional scale evidence-based policy making based on needs and opportunities for cooperation. Furthermore, this project should address the coordination of regional and international funding efforts, fund management and fund raising and link with other FP7 and EU Member States actions in the region. The project will address capacity building for priority setting of funding programmes and relevant research management to reduce the gap between knowledge generation and implementation in clinical practice. It should empower national research systems at the policy and management levels. Substantial element of South-South cooperation is expected and collaboration with European Health national contact points (NCPs), as well as relevant EU member states science contacts in the region.

**Funding scheme:** Coordination action EC contribution: Maximum EUR 2 000 000.

**Expected Impact:** The expected project duration is 5 years in order to create a major impact in this field. The project will have to explore the case for creating a body that coordinates national and international health research funding in the region and with the EU. It will establish a forum for interaction between the local research policy level and the EU member states and EC cooperation efforts in health research with Latin-America.

#### **4.2 RESPONDING TO EU POLICY NEEDS**

The objective of these actions is to contribute to the support and follow-up of other European Union Community policies.

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

**HEALTH-2011-4.2-1: Investigator-driven clinical trials<sup>18</sup> on off-Patent medicines for children. FP7-HEALTH-2011-single-stage.** Research is expected to increase the availability of off-patent medicines for children as well as the level of information of these molecules to the general population. Project(s) will be required to develop and test new paediatric medicine formulations in an appropriate clinical trial in children using older off-patent medicines, with particular reference to the following criteria as appropriate: Particular priority is attached to products for:

- neonates
- oncology in infants
- paediatric epilepsy syndromes

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<sup>18</sup> <http://ec.europa.eu/enterprise/sectors/pharmaceuticals/documents/eudralex/vol-10/>

Please consult also the text for clinical trials provided in the introduction to this work programme on page 6

The outcomes must be relevant for patients and change clinical practice. Pilot studies and systematic reviews will not be funded. Clinical trials must be appropriately powered to produce statistically significant evidence. Gender aspects and differences related to age subgroups should be appropriately considered. The applications must consider the relevant governance issues for clinical trials such as Good Clinical Practice (GCP) and respect of the appropriate international, European and national legislation and guidelines. Patient advocacy groups, which can contribute to the quality, feasibility and impact of clinical trials should be involved. New data on efficacy, safety and the pharmacokinetic profiles are required as set out on the current version of the Paediatric Medicines' Priority List available at: <http://www.emea.europa.eu/pdfs/human/paediatrics/41493609en.pdf>. In view of many facilities offered by the European Medicines' Agency (EMA), 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 SME is a requirement 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.

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

**EC contribution per project:** Maximum 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 that has been devised specifically in the Paediatric Medicines Regulation for off-patent medicinal products developed exclusively for use in children. This is an intellectual property right (IPR) that can be applied to off-patent medicines to stimulate innovation, by allowing their use to treat new diseases and new populations. It provides a vehicle for awarding the incentive of data protection and is of particular interest to SMEs.

**HEALTH.2011.4.2-2. Adverse Drug Reaction Research. FP7-HEALTH-2011-single stage.** Experience with medicines that have been marketed for many years has shown that potentially serious adverse events only become apparent long after they have been launched and often as a feature of their physiochemical characteristics. This has obvious implications for entire classes of molecules that often belong to different therapeutic classes and the research of selected proposal(s) should generate new knowledge on potentially life threatening drug adverse events that affect these 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 molecule and the stated adverse event(s):

- Epoetins: Risk of tumour growth progression and thromboembolic events in cancer patients and cardiovascular and cancer risk in chronic kidney disease.
- Insulin/insulin analogues and cancer
- Anti-diabetes drugs: cardio/cerebrovascular adverse effects and pancreatitis/pancreatic cancer.
- Asthma treatments (long- & short-acting  $\beta$ -agonists and anti-cholinergics): risk of myocardial ischemia and long-term safety especially in children.

- Gadolinium containing contrast agents: nephrogenic systemic fibrosis

Further details of the expected deliverables may be found at: <http://www.emea.europa.eu/htms/human/phv/communications.htm>

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

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

**EC contribution per project:** Maximum EUR 3 000 000.

**One or more proposals can be selected per heading.**

**Expected impact:** Project results should lead to important new knowledge on major and serious adverse drug reactions that constitute public health concerns i.e. those impacting on the balance of benefits and risks of medicinal products. This will be directed towards regulatory decisions on marketing authorisations for medicinal products including the warnings in product information for doctors and patients. A safer and more effective use of medicines should result with positive implications for public health.

**HEALTH-2011-4.2-3 New methodologies for clinical trials<sup>19</sup> in personalised medicine FP7-HEALTH-2011-Two-Stage.** Support will be offered for the development of new or improved methodologies for clinical trials in small populations with the aim to assess personalised medicine approaches. These new methodologies should be cost effective without compromising the assessment of the efficacy and safety of the treatment. The project should also address the access, and the use of already existing data *e.g.* from biobanks, registries and other appropriate sources. Clinical trials as such will not be funded. **Note:** Limits on the EC financial contribution apply. These are implemented strictly as formal eligibility criteria.

**Specific feature:** SME-targeted research is designed to encourage SME efforts towards research and innovation. Priority will be given to proposals demonstrating that research intensive SMEs play a leading role. The projects will be led by SMEs with R&D capacities, but the coordinator does not need to be an SME. The expected project results should clearly be of interest and potential benefit to SME(s). All consortia should aim at having 30-50 % of the requested EC contribution budget going to SMEs (subcontracting is discouraged).

**Additional selection criteria:** SME-targeted Collaborative Projects will only be selected for funding on the condition that the requested EU contribution going to SME(s) is 30% or more of the total requested EC contribution. ***This will be assessed during evaluation and checked during negotiation. Proposals not fulfilling this criterion will not be funded.***

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

**EC contribution per project:** Maximum EUR 3 000 000

**One or more proposals can be selected.**

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<sup>19</sup> <http://ec.europa.eu/enterprise/sectors/pharmaceuticals/documents/eudralex/vol-10/>

Please consult also the text for clinical trials provided in the introduction to this work programme on page 6



**Expected Impact:** The optimisation of new clinical trial methodologies will facilitate the rapid uptake of new and emerging personalised medicine approaches, and improve the use of existing treatments. Research should be multidisciplinary and will boost the European biotechnology industry, and in particular the SME sector. It should also address regulatory issues as appropriate.

### **III IMPLEMENTATION**

Call fiches.

### **IV OTHER ACTIONS**

**Impact assessment and foresight exercise to identifying future Community health research and innovation priorities.** The assessment will aim to identify future Community health research and innovation priorities with a long-term perspective (to 2030). Building on an analysis of the socio-economic impact of a limited number of selected themes in past and present Framework Programmes, and on an analysis of the drivers of change affecting citizens' health, conclusions and recommendations will be made on future research objectives, how these might best be achieved, and how they will support the development of a European Health Research Area. (indicative budget: EUR 400 000).

**Conference: "European Perspectives in Personalised Medicine".** The conference will take stock of the recent achievements in health related research leading to personalised medicine and will aim at identification and prioritisation of the future actions needed at the European level, bringing together European and national - level policy makers, industrial and academic researchers and other stakeholders. (indicative budget: EUR 200 000).

*(Other actions will be included in next draft.)*