

REVISED

Work Programme 2012

COOPERATION

THEME 1

Health

(European Commission C(2011)9493 of 20 December 2011)

THIS REVISION HAS BECOME NECESSARY TO ADD A TOPIC FOR AN ACTION TO SUPPORT THE COORDINATION OF A JOINT PROGRAMMING INITIATIVE WITH AN INDICATIVE BUDGET OF EUR 2 MILLION UNDER AREA 2.3. IN ADDITION, THREE ACTIONS UNDER OTHER ACTIVITIES HAVE BEEN ADDED WITH AN ADDITIONAL INDICATIVE BUDGET OF EUR 2 300 000. NO OTHER CHANGES HAVE BEEN MADE TO THIS WORK PROGRAMME.

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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 into 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

Innovation Union aspects

The Innovation Union initiative underlines that research and innovation are key drivers of competitiveness, jobs, sustainable growth and social progress. The work programme 2012 has been designed to support the implementation of the Innovation Union Initiative and in particular to bring together research and innovation to address major challenges.

The work programme can contribute to the innovation objective in two ways, and constitutes a significant change to the approach in earlier work programmes:

1/ By supporting more topics aimed at generating knowledge to deliver new and more innovative products, processes and services. This will include pilot, demonstration and validation activities.

The focus on innovation will be reflected in the description of the objectives and scope of the specific topics, as well as in the expected impact statements. The innovation dimension of the proposals will be evaluated under the evaluation criterion 'Impact'.

2/ By identifying and addressing exploitation issues, like capabilities for innovation and dissemination, and by enhancing the use of the generated knowledge (protection of intellectual property rights like patenting, preparing standards, etc.).

Information on the Risk-Sharing Finance Facility (RSFF), an innovative financial instrument under FP7, is available on line¹. The Commission will respond to further needs of potential beneficiaries for information on the RSFF (by, e.g. awareness-raising activities in conjunction with the European Investment Bank, participation to thematic events).

Approach for 2012

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

With a view to achieve the EU 2020 objective of a smart, sustainable and inclusive growth, the Commission launched the **European Innovation Partnership (EIP) on "active and healthy ageing"**. Its aims should be, by 2020, to enable citizens to live longer independently

¹ <http://www.eib.org/products/loans/special/rsff/?lang=en> and http://ec.europa.eu/invest-in-research/funding/funding02_en.htm

in good health by increasing the average number of healthy life years by two and, in achieving this target, to improve the sustainability and efficiency of our social and healthcare systems, and to create an EU and global market for innovative products and services with new opportunities for EU business².

Major policy initiatives, including the European Research Area (ERA), and the state of play regarding scientific opportunities and healthcare needs played an important role in the development of the work programme. The work programme will contribute to putting knowledge into practice and enhance the socio-economic impact of research following the Europe 2020 strategy³ with more industry-driven applied research and therefore contribute to achieving the research and innovation goals inherent to establishing a European innovation economy. This work programme will also continue "to secure world excellence in basic research" (Barroso, 2009⁴) through large-scale collaborative research efforts.

The 2012 work programme places a strong emphasis on the participation of small and medium sized enterprises (SMEs) in most research areas with a major focus on the medical technologies sector. In this way it will provide research support to complement the activities of the pilot innovation partnership on active and healthy ageing which may, inter alia, focus on the removal of barriers to innovation in this sector. The work programme also consolidates the major effort initiated in 2011 to stimulate innovative ideas for research and SME participation via broad, bottom-up topics to be implemented through a two-stage submission and evaluation procedure. Such activities are also envisioned to complement the ongoing public-private partnership with the pharmaceutical industry, the Innovative Medicine Initiative (IMI^{5,6,7}). Overall this work programme will continue to support top quality collaborative research that meets the stringent criteria of scientific excellence, professional management of public funding and high socio-economic impact. For its development advice has been taken from multiple stakeholders and experts in the different fields covered by this work programme as part of Theme Health's ongoing consultation processes.

For projects whose results are nearing market introduction, standardisation is often a key enabler for interoperability to ensure product quality, open markets and free trade and thereby building consumer confidence. Standardisation can help to foster access to the market of innovative solutions and thus help ensure the practical application of research results. As such, projects could strengthen future innovation by considering the inclusion of pre- and co-normative research tasks and the integration of standardisation organisations to support standardisation.

Key Challenges

² Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Europe 2020 Flagship Initiative, Innovation Union; COM(2010) 546

³ Europe 2020 A strategy for smart, sustainable and inclusive growth COM(2010) 2020

⁴ Political Guidelines for the New Commission, J.M. Barroso, 2009

⁵ IMI: the Innovative Medicines Initiative, a public-private partnership between the European Commission and the European Federation of Pharmaceutical Industries and Association (EFPIA)

⁶ 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

⁷ http://imi.europa.eu/index_en.html

The Health work programme 2012 has an indicative budget of EUR 689⁸ million to cover many health issues. Prioritisation allows the mobilisation of a critical mass of resources and the implementation of a coherent set of actions, to ensure greater effectiveness, impact and visibility. A number of complementary areas will be open mainly to support one of the Key challenges, including the realisation of the European Innovation Partnership⁹ “active and healthy ageing”. **The research priorities for 2012 will be ageing, including health systems, medical technologies and rare diseases**, complemented by other areas **such as** developing personalised medicines approaches, improving availability of organs for replacement; gaining a better understanding of ageing; tackling chronic diseases linked to ageing; adapting healthcare systems to meet specific needs.

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

Innovation dimension of the activities

- **Active and healthy ageing:** Theme Health will contribute to the realisation of the EIP "active and healthy ageing" with the strategic aim of contributing to the Europe 2020 objectives of inclusion, sustainability and growth. More specifically it will promote and enable EU citizens to lead healthy, active and independent lives until old age; contribute to ensuring the sustainability and efficiency of social and healthcare systems; and contributing to the creation of a European and global market for innovative products and services related to healthy and active ageing. Theme Health will make a major contribution with ageing-related research to a longer healthy period at old age supported by 11 topics related to medical technologies for different purposes, e.g. detection, diagnosis & monitoring¹⁰, innovative therapies¹¹, large scale data gathering¹², systems biology¹³, human development and ageing¹⁴, chronic diseases¹⁵, health care systems¹⁶ and

⁸ An amount of EUR 4.3 million have been added to different parts of this work programme; EUR 2 million for a new topic (Health.2012.2.3.1-1) supporting a joint programming initiative and EUR 2.3 million to cover three new activities under OTHER ACTIVITIES.

⁹ Communication from the Commission to the European parliament, the Council, the European Economic and Social Committee and the Committee of the regions, Europe 2020 Flagship Initiative, Innovation Union; SEC(2010) 1161

¹⁰ HEALTH.2012.1.2-1: Development of technologies with a view to patient group stratification for personalised medicine applications

¹¹ HEALTH.2012.1.4-3: Innovative Strategies for translation of stem cell based therapies in regenerative medicine

¹² HEALTH.2012.2.1.1-2: Validation of -omics-based biomarkers for diseases affecting the elderly

¹³ HEALTH.2012.2.1.2-1: Systems medicine: SME-driven research; HEALTH.2012.2.1.2-2: Applying systems biology approaches for understanding co-morbidities; HEALTH.2012.2.1.2-3: Preparing for the future research and innovation activities in systems medicine

¹⁴ HEALTH.2012.2.2.2-1: Integrative systems biology and comparative genomics for studying human ageing and/or most common age-related diseases; HEALTH.2012.2.2.2-2: Investigator-driven clinical trials¹⁴ for optimisation of management of elderly patients with multiple diseases

¹⁵ HEALTH.2012.2.4.5-1: Technological approaches to combating sensory impairments; HEALTH.2012.2.4.5-2: Biomarkers and diagnostics for chronic inflammatory diseases of the joints and/or digestive system

¹⁶ HEALTH.2012.3.2-1: Improving the organisation of health service delivery; HEALTH.2012.3.2-2: New methodologies for health technology assessment; HEALTH.2012.3.2-3: Social innovation for ageing research.

support actions¹⁷. "In addition clinical trials may also contribute, if they include elderly people.

- **SME-relevant research:** Promoting innovation by strengthening the links between academia and industry is the driving force of this work programme. Broad, SME-targeted topics (almost 50 % of all topics) are set out in areas of great interest to SMEs, such as medical technologies, and where, for each project, a minimum of 15%, 30% or 50% of EU funding must go to SMEs. SMEs are encouraged via specific conditions for several topics to take a leading role in projects to foster innovation in health research.
- **Medical technologies** with a focus on organ transplantation and artificial organs, diagnostics for infectious diseases, management of diabetes, sensory impairment, chronic inflammatory disease and health technology assessments.
- **Rare diseases** including the development of new technologies for diagnosis and treatment, as well as drug development; in this area, a major effort is envisaged in using “-omics” technologies to achieve better both diagnosis and treatment. There will also be a major push for pre-clinical or clinical development of orphan drugs, as well as observational trials.
- **Specific support for clinical trials:** In 2012, also investigator-driven clinical trials will be foreseen for optimisation of treatment in the elderly, on paediatric/adolescent diabetes medicines and on orphan drugs (treatments for rare diseases).
- **Dissemination actions:** The health market is highly fragmented in Europe, with different public health policies in Member States. To sustain the competitiveness of the health sector, it is necessary to improve the framework conditions for business to innovate¹⁸: creating the single EU Patent and a specialised Patent Court, harmonising the regulatory framework, improving access of SMEs to Intellectual Property Protection. Therefore in 2012 training actions linked to intellectual property rights management and knowledge transfer are foreseen. A complementary action will emphasis the creation of a network to encourage knowledge transfer activity in FP-funded research to address the innovation lifecycle.

Open Access in FP7: Beneficiaries funded partially or entirely by the Cooperation Programme under the Health Theme are required to deposit peer-reviewed articles resulting from projects to an institutional or subject-based repository, and to make their best efforts to ensure open access to these articles within six months.¹⁹

- **Overall expected impact:** It is evident that projects generated through this work programme will contribute to various social innovations in the health sector, independently of whether they are related to medical technologies, ageing, health care, specific diseases and/ or disorders. Two main categories are envisaged, providing support to SME(s) and to the EIP "active healthy ageing" pilot. Many topics require that between 15-30% or, for three topics, even 50% of funding is allocated to SME(s). A conservative estimate suggests that ~€150 million (~20% of the indicative budget of the calls) will be allocated to SME(s). Topics of relevance to the innovation partnership (including those on medical technologies) have a total budget of ~€330 million (~55%). These efforts should increase

¹⁷ HEALTH.2012.4.1-5: Preparing the future for health research and innovation

¹⁸ Europe 2020 Innovation Partnerships

¹⁹Further information: http://cordis.europa.eu/fp7/find-doc_en.html, http://ec.europa.eu/research/science-society/open_access, http://ec.europa.eu/research/science-society/scientific_information/.

the drive to develop new technologies, new drugs, as well as new therapies and thus contribute to *i-economy* goals in the health sector, while improving the quality of life of people in Europe and around the world. In addition to topics with a focus on providing support to SME(s), certain topics²⁰ also support the aims and objectives of the Innovation Union, including: support to proof of principle or bringing products to market²¹; the involvement of end-users (both patient and health professional) in product development and implementation²²; anticipation of regulatory needs²³; focus on standardisation²⁴; addressing market failure²⁵; harnessing social innovation²⁶; translation and dissemination of results²⁷.

International Cooperation

The strategy for international cooperation in Theme Health is many fold: tackling global challenges, such as addressing diseases of poverty, including neglected diseases; improving the competitiveness and innovation of the European science base and industry through global cooperation; supporting external relations of the EU, noting that health issues, including health research are shared between all countries, rich and poor. Special efforts will be made by programme level collaborations in rare diseases with the US and probably with other European and international partners, and in innovative therapies with Australia. Specific actions with developing countries in the area of poverty related diseases and public health are foreseen in order to contribute to achieving the Millennium Development Goals.

All topics under the FP7-HEALTH-2012-INNOVATION-1 call are open for the participation of partners from third countries. In recognition of the opening of NIH²⁸ programmes to European researchers, participants established in the *United States of America* are eligible for funding and participation in all topics under the FP7-HEALTH-2012-INNOVATION-1 call.

Cross-thematic approaches

Theme Health contributes with a number of topics to the EIP "active and healthy ageing". The research part of this EIP will be established by Themes Information and Communication Technologies (ICT); Health; Food, Agriculture, Fisheries and Biotechnology (KBBE) and

²⁰ In some cases topic titles have been shortened

²¹ HEALTH.2012.1.2-1 – personalised medicine; HEALTH.2012.2.3.2-3 - low cost interventions for disease control

²² HEALTH.2012.2.1.1-1 – -omics for rare diseases; HEALTH.2012.2.2.2-2 - clinical trials for treatment optimisation in elderly; HEALTH.2012.2.4.3-2 – clinical trials for type 1 diabetes; HEALTH.2012.3.2-1 - improving the organisation of health service delivery

²³ HEALTH.2012.1.4-1 – solid organ transplantation; HEALTH.2012.2.1.1-1 – -omics for rare diseases; HEALTH.2012.2.4.3-1 - innovative approaches to manage diabetes; HEALTH.2012.2.4.5-1 – technological approaches to sensory impairment

²⁴ HEALTH.2012.1.2-1 – personalised medicine; HEALTH.2012.4.1-5 - roadmap towards standardisation and harmonisation of new medical devices and technologies

²⁵ HEALTH.2012.2.4.4-1 - orphan drugs

²⁶ HEALTH.2012.3.2-1 - improving the organisation of health service delivery; HEALTH.2012.3.2-2 - health technology assessment; HEALTH.2012.3.2-3 – Social innovation for ageing research:

²⁷ HEALTH.2012.2.1.1-3 – statistical methods for collection and analysis of –omics data; HEALTH.2012.2.3.2-2 – prevention and treatment for poverty related diseases; HEALTH.2012.3.2-1 - improving the organisation of health service delivery

²⁸ National Institutes of Health of the US Department of Health and Human Services

Socio-economics Sciences and the Humanities (SSH). Furthermore Theme Health is complemented by several topics from Themes ICT; KBBE and Nanosciences, nanotechnologies, Materials and new Production technologies (NMP).

Theme specific information

With regard to submission, evaluation and selection procedures a major simplification is foreseen for implementing the Health work programme 2012: to use **the two-stage submission and evaluation procedure** (with the exception of one ERA-Net and one Joint Programming Initiative topic). The implementation will be via two two-stage calls: **FP7-HEALTH-2012-INNOVATION-1 as main call with an indicative budget of EUR 546 million** with **broader topics** of which **many are tailored for SME participation** (bottom-up with a minimum percentage of EU funding requested going to SMEs) and **FP7-HEALTH-2012-INNOVATION-2 as a pilot call with an indicative budget of 108 million EUR** with very specific conditions (see section III of this document).

In general, applicants are reminded that the **minimum number of applicants** in most funding schemes (except SICA and SA) is 3 (see section III, Implementation); however **there is no obligation to go beyond this number unless additional partners are needed to achieve the objectives of the project**. Likewise the duration of the project should be in line with the realistic planning of the project and so, can be quite short (e.g. 1-2 years), or long enough to achieve the goals of the project. Similarly, the size of the EU contribution to the budget should also be in line with the needs of the respective consortium, within the maximum EU contribution, but not necessarily at the maximum by default.

- **Ethical issues:** 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 issues²⁹ 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.
- **Use of animals in research:** Research activities should take into account the Protocol on the Protection and Welfare of Animals, and reduce the use of animals in research and testing (Decision 1982/2006/EC). The principle of the three Rs (Reduction, Refinement and Replacement) should be applied where appropriate in all research funded by the European Union.
- **Gender dimension:** The pursuit of scientific knowledge and its technical application towards society requires the talent, perspectives and insight that can only be assured by increasing diversity in the research workforce. Therefore, all projects are encouraged to have a balanced participation of women and men in their research activities and to raise awareness on combating gender prejudices and stereotypes. When human beings are involved as users, gender differences may exist. These will be addressed as an integral part of the research to ensure the highest level of scientific quality. In addition, specific actions to promote gender equality in research can be financed as part of the proposal, as specified in Appendix 7 of the Negotiation Guidance Notes³⁰.
- **Socio-economic dimension of research:** Where relevant, account should be taken of possible socio-economic impacts of research, including its intended and unintended consequences and the inherent risks and opportunities. A sound understanding of this issue should be demonstrated both at the level of research design and research management. In this context, where appropriate, research actions and Coordination and Support Actions should ensure engagement of relevant stakeholders (e.g. patients'

²⁹ http://cordis.europa.eu/fp7/ethics_en.html

³⁰ ftp://ftp.cordis.europa.eu/pub/fp7/docs/negotiation_en.pdf

organisations, civil society organisations, policy-makers, user groups) as well as cultivate a multi-disciplinary approach (including, where relevant, researchers from social sciences and humanities) and social innovation. Projects raising ethical or security concerns are also encouraged to pay attention to wider public outreach.

- ***Funding schemes:*** The work programme 2012 is implemented through a range of funding schemes. The types 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 EU contribution (see topic descriptions in section II and conditions in section III for details). **It is important to note that funding limits will be applied as eligibility criteria. Proposals that do not respect the corresponding limit will be considered ineligible.**
- ***Statistics in health research:*** Appropriate study design, data processing and statistical analysis of results are important for the quality and efficiency of the science and reliability of conclusions, and hence also ethically. Therefore, whenever applicable, the proposal should explain the statistical aspects. This may, for example, include description of the experimental plan and data gathering, method for uncertainty or measurement error estimation, statistical analysis of data and methods of inference (e.g. statistical tests and p-values to be used, accounting for multiple comparisons or small sample size, dealing with missing or noisy data), statistical power analysis and estimate (justification) of the number of needed animals or human subjects. If these are not applicable or not justified, the proposal should briefly explain why not.
- ***Innovative clinical trials³¹ to verify safety and efficacy:*** Specific actions under clinical trials will have a major European added value in translating research into clinical practice, increasing therapeutic options for patients, stimulating the implementation of best practices in all Member States and in establishing the basis for a coherent programme addressing the issue of personalised medicine and improved therapeutic outcomes. Currently, the majority of clinical trials are performed by health-related industries during the development of novel products such as new pharmaceuticals. Nevertheless, clinical trials initiated by academic investigators are of high relevance for public health. This work programme lists several topics for clinical trials, most being investigator-driven clinical trials. 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 innovative therapies, human development and ageing, diabetes, and rare diseases.

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 be penalised 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 respected.

³¹ http://ec.europa.eu/health/human-use/clinical-trials/index_en.htm

The early involvement of patients³² and their advocacy groups in the planning, implementation, and monitoring 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 at European and national level for the conduct of clinical trials.

Clinical trials may be carried out internally by a participant or outsourced to a third party (subcontractor).

1) When carried out internally:

- *the participant may either charge his actual costs of the trials; or*
- *where it is difficult to substantiate each of the actual costs involved for each individual test, the participant may opt to charge an average cost per patient or test or type of test, calculated with a methodology based on its actual costs and that is auditable.*

2) The participant may also propose to outsource the performance of the clinical trials to a third party:

- *either on a commercial basis by means of a subcontract, for which a price is agreed upon by the participant and the third party.*
- *or on a cost basis, on a non-commercial basis, that is where the third party charges only its costs to the participant who reimburses them fully and is in turn reimbursed by the Commission according to the applicable funding rate.*

Participants are reminded that it is up to them to demonstrate that their choice of a third party secures the best value for money, for example by providing the various offers requested, or, if a long term-cooperation with that third party to carry out such tests pre-exists, to demonstrate its added value.

Participants that are public bodies are reminded that the selection of such a third party has to follow their internal rules and applicable legislation, in particular those related to public procurement, as a matter of eligibility.

³² <http://www.eu-patient.eu/Initatives-Policy/Projects/ValuePlus/>

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 enable the production of new knowledge and its translation into practical applications in the area of health and medicine.

1.1 HIGH-THROUGHPUT RESEARCH

Closed in 2012

1.2 DETECTION, DIAGNOSIS AND MONITORING

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

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

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

HEALTH.2012.1.2-1: Development of technologies with a view to patient group stratification for personalised medicine applications³³. FP7-HEALTH-2012-INNOVATION-1. The aim of this topic is to support research and development and/or proof of principle of technologies for application in the area of personalised medicine, i.e. tailored medical interventions which are more effective and have fewer undesirable adverse effects in specifically defined patient groups. These technologies should be of use for research, screening, diagnostics and/or guidance of therapeutic interventions. The projects must include quality control aspects for data generated and where appropriate use statistical tools. Potential end-users should actively be included in the project, at least for proof of principle projects. **Note:** Limits on the EU financial contribution apply. These are implemented strictly as formal eligibility criteria.

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

One or more proposals can be selected.

³³ The topic is open for proposals in all relevant research areas covered by the topic description; however some proposals, depending on their scientific content, may contribute to the EIP "Active and Healthy Ageing".

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

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

Additional eligibility criteria:

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

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

1.3 SUITABILITY, SAFETY, EFFICACY OF THERAPIES

Closed in 2012

1.4 INNOVATIVE THERAPEUTIC APPROACHES AND INTERVENTIONS

For this call for proposals, the main focus is on transplantation, with subsidiary topics on international cooperation in stem cell research and targeted nucleic acid delivery. Topics are drafted in broad terms to encourage innovation.

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

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

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

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

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

HEALTH.2012.1.4-1: Innovative approaches to solid organ transplantation³⁴. FP7-HEALTH-2012-INNOVATION-1. The aim of this topic is the practical exploitation of recent research findings to improve the outcome, increase efficiency or widen the scope of solid organ transplantation. Projects are required to include clinical work and the necessary regulatory work as appropriate. Full attention needs to be paid to safety and immunological aspects of the work. Research should be translational, and may include improvement of understanding of mode of action if needed. For projects on xenotransplantation, if the work is not yet ready for clinical application, proposals should include a reasoned plan indicating the main development and regulatory steps needed to move the technology to the clinic. Research should involve European industry, in particular the SME sector. **Note:** Limits on the EU financial contribution apply. These are implemented strictly as formal eligibility criteria.

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

One or more proposals can be selected.

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

Additional eligibility criteria:

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

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

HEALTH.2012.1.4-2: Medical technology for transplantation and bioartificial organs. FP7-HEALTH-2012-INNOVATION-2. Work on transplantation may involve the use of cells, tissues or organs. Work on bioartificial organs should take into account the fact that these are composed of both biological and artificial components.

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

One or more proposals can be selected.

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

Specific feature:

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

Expected project results should be of clear interest and potential benefit to SME(s).

³⁴ Please consult also the text for clinical trials provided in the introduction to activity 2. Translating research for human health in this work programme on pages 9/10

Additional eligibility criteria:

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

The proposed **project duration** indicated in the proposal should be up to 3 years.

Projects will only be selected for funding on the condition that the estimated EU contribution to **SME(s)** is 50% or more of the total estimated EU contribution to the whole project. This will be assessed at the end of the negotiation, before signature of the grant agreement. Proposals not fulfilling this criterion will not be funded.

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

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

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

HEALTH.2012.1.4-3: Innovative Strategies for translation of stem cell based therapies in regenerative medicine (European Union-Australia cooperation)³⁵. FP7-HEALTH-2012-INNOVATION-1. Projects should aim to develop innovative strategies to stem cell-based therapies based on allogeneic and/or autologous sources, with an emphasis on understanding the mechanisms of action, nature of the donor cells, and the host response. Proposals should include thorough characterisation, quality control of the product(s), efficacy and safety in relevant pre-clinical models and, if possible, early assessment in humans or relevant bridging studies. The selected project should capitalise on the strong expertise and synergistic opportunities available in Australia and Europe in the fields of stem cell biology, cell-host interactions, and bioengineering, bio-processing and clinical trial management. Therapeutic products and clinical protocols should be developed through collaboration with industry partners and in consultation with appropriate regulatory bodies and health economic advisors. Part of the research project will be conducted by Australian researchers in Australia while the other part would be conducted by collaborative partners in the EU. The work carried out in Australia would be funded through the NHMRC European Union Collaborative Research Grants scheme³⁶. With regard to the EU funded part of the project, it should follow a two-phase process, including a mid-term review at 3 years. For the second phase of the project, success must be proven as defined by approval of a regulatory filing of an

³⁵ The topic is open for proposals in all relevant research areas covered by the topic description; however some proposals, depending on their scientific content, may contribute to the EIP "Active and Healthy Ageing".

³⁶ <http://www.nhmrc.gov.au/grants/types/granttype/strategic/austeu.htm>

Investigational Medicinal Product Dossier (IMPD) with the European Medicines Agency (EMA). Industrial participation is required. **Note:** Limits on the EU financial contribution apply. These are implemented strictly as formal eligibility criteria.

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

Only up to one proposal can be selected.

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

Specific feature: Programme Level Cooperation between the EU and Australia: Although each proposal shall be submitted as single, common application, the National Health and Medical Research Council will only support the Australian partners, if approved, on grants. Other partners can request funding from the EU. The proposal shall though be complete and detail the activities of all partners, including the full financing requirements but not requesting EU funding for the Australian partners. Details of submission dates for Australian researchers will be provided through the NHMRC website.

Additional eligibility criteria:

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

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

HEALTH.2012.1.4-4: Targeted nucleic acid delivery as an innovative therapeutic or prophylactic approach³⁷. FP7-HEALTH-2012-INNOVATION-1. The aim of this research is to exploit technology for nucleic acid delivery through testing in clinical trials carried out within the lifetime of the project. Recent innovative developments in DNA and/or RNA vaccination, immunotherapy, gene therapy or RNA interference are very encouraging but remain challenging and more proof-of-principle is needed. Any justified disease or disorder may be targeted. Detailed safety, immunogenicity, toxicity and feasibility studies in a preclinical setup (animal models) should preferably be already available. The necessary regulatory work should be included as appropriate. Proposals should develop multidisciplinary and translational research with potential for exploitation by the clinical and/or industrial sectors. Active participation by industry (minimum 30% of the EU contribution to the budget) is required and this will be considered in the evaluation of the proposal. **Note:** Limits on the EU financial contribution apply. These are implemented strictly as formal eligibility criteria.

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

One or more proposals can be selected.

Expected impact: Building on recent results the projects should link promising emerging technologies with clinical application in the area of nucleic acid delivery for prophylactic or therapeutic purposes. This would enhance European expertise and competitiveness in an

³⁷ Please consult also the text for clinical trials provided in the introduction to activity 2. Translating research for human health in this work programme on pages 9/10

important emerging market. Research will also support the European biotechnology industry, especially the SME sector.

Additional eligibility criteria:

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

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

2. TRANSLATING RESEARCH FOR HUMAN HEALTH

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

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

2.1.1 Large-scale data gathering

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

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

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

For this call for proposals, topics focus on the clinical use of -omics approaches and the analysis of their outcomes. The first topic (with three sub-topics) aims at fostering a structured approach for exploring the clinical utility of -omics for rare diseases in view of developing better diagnosis and ultimately, treatments. The second topic will be dedicated to the validation of -omics-based biomarkers for diseases affecting the elderly. The third topic will address the need for statistical methods for the collection and analysis of -omics data.

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

2.1.1-1 –Omics for rare diseases

Projects funded under this heading should contribute towards the ambitious 2020 goals of the International Rare Diseases Research Consortium (IRDiRC): 200 new therapies for rare diseases (orphan drugs) and diagnostics tests for all rare diseases³⁸. The present call focuses on the construction of a solid foundation for the molecular characterisation of rare diseases by a systematic application of -omics approaches and technologies. A key success factor will be the establishment and/or harmonisation of databases and bio-resources, including standardisation and quality control aspects, of the data and samples collected. Where appropriate the selected projects will build on the European research infrastructures for biobanking and -omics technologies.

³⁸ http://ec.europa.eu/research/health/medical-research/rare-diseases/irdirc_en.html

This sub-area will be implemented via three topics: One support action (duration: six years), one collaborative project as a large-scale integrating project (duration: six years) and up to two collaborative projects, as large-scale integrating projects (duration: up to five years) can be funded.

Expected impact: These projects are expected to provide better means for ensuring the correct diagnosis and treatment of rare diseases for which currently there is no or unsatisfactory diagnosis and/or treatment available. The projects should contribute to the International Rare Disease Research Consortium (IRDiRC) goals.

Specific feature: Each proposal submitted to one of the topics within this sub-area has to clearly describe the interconnections and interfaces with the other topics under this sub-area, and has to indicate a clear commitment to work with the other projects to be selected. This will be taken into consideration under the first criterion during evaluation. This is essential in order to optimise the co-operation between projects and to ensure the optimum of synergies. The partners in all projects selected for funding should adhere to IRDiRC policies³⁹.

HEALTH.2012.2.1.1-1-A: Support for international rare disease research. FP7-HEALTH-2012-INNOVATION-1. The support action should:

- provide the organisational support to the implementation of the international rare disease research consortium (IRDiRC), in close collaboration with the European Commission, research funding agencies from Member States and from other third countries involved.
- assist the IRDiRC executive committee, notably for the organisation of and reporting on meetings (e.g. *ad hoc* meetings of working groups),
- support information exchange among members of the participating organisations in projects funded under HEALTH.2012.2.1.1-1-B and HEALTH.2012.2.1.1-1-C, as well as with other IRDiRC members and research initiatives,
- communicate progress of IRDiRC research, notably results stemming from projects funded under HEALTH.2012.2.1.1-1-B and HEALTH.2012.2.1.1-1-C, and activities with relevant stakeholders groups and with the public at large (e.g. development of website, communication materials, etc.).

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

Funding scheme: Coordination and Support Action (supporting action)

Only up to one proposal can be selected.

Expected impact: Reinforced international cooperation in research on rare diseases, through the development of policies and guidelines aimed at accelerating such research. The project should contribute to the International Rare Disease Research Consortium (IRDiRC) goals.

Additional eligibility criterion:

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

HEALTH.2012.2.1.1-1-B: Clinical utility of -omics for better diagnosis of rare diseases. FP7-HEALTH-2012-INNOVATION-1. The projects will in a systematic way apply -omics

³⁹ http://ec.europa.eu/research/health/medical-research/rare-diseases/irdirc_en.html

approaches and technologies for the molecular characterisation of a large group or category of rare diseases in view of development of new diagnostics and treatments. Applying -omics approaches in the chosen group of rare diseases should help understanding the clinical heterogeneity of certain individual rare diseases, as well as help revealing pathophysiological commonalities between clinically disparate rare diseases. Collaboration between clinicians and -omics scientists will hence be vital for improving the interpretation of clinical data and in particular the definition of harmonised ontologies. In addition, appropriate *in silico*, *in vitro* and/or *in vivo* models should be used with the aim to support future clinical trials. The project should include:

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

The establishment and/or harmonisation of databases and bio-resources (including standardisation and quality control aspects) must be done through collaboration with the project funded by topic HEALTH.2012.2.1.1-1-C. The project is expected to have appropriate plans to engage with relevant stakeholders, such as patient organisations and regulatory bodies, and a clear plan for the project-long inter-relation with the other topics under this sub-area. **Note:** Limits on the EU financial contribution apply. These are implemented strictly as formal eligibility criteria.

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

Up to two proposals can be selected.

Expected impact: These projects are expected to provide better and faster means for the correct diagnosis and treatment of rare diseases for which there is no or unsatisfactory diagnosis and/or treatment available. The projects should contribute to the International Rare Disease Research Consortium (IRDiRC) goals.

Additional eligibility criterion:

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

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

HEALTH.2012.2.1.1-1-C: Databases, biobanks and 'clinical bio-informatics' hub for rare diseases. FP7-HEALTH-2012-INNOVATION-1. Information from the different -omics platforms needs to be integrated with clinical data in order to support the development of reference omics profiles for rare diseases. This project aims at developing an integrated platform supporting the collection and storage of -omics and clinical data, and samples collected through projects funded under HEALTH.2012.2.1.1-1-B and from other relevant projects supporting IRDiRC objectives. The platform will provide a user-friendly access to

reference profiles and their corresponding biological resources, of high value for timely and accurate diagnosis. Focus must be put on the harmonisation, standardisation and quality control aspects of collected data and samples (i.e. development of standard operating procedures, etc.). Wherever feasible, activities should build on already existing databases and biobanks; their integration needs to be part of this project. The project will contribute to IRDiRC policies and guidelines and ensure their implementation in European projects contributing to IRDiRC. The project is expected to have appropriate plans to engage with relevant stakeholders, such as patient organisations and regulatory bodies, and a clear plan for the project-long inter-relation with projects selected under the other topics under this sub-area. **Note:** Limits on the EU financial contribution apply. These are implemented strictly as formal eligibility criteria.

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

Only up to one proposal can be selected.

Expected impact: A centralised access to reference -omics profiles of diseases, based on standardised and validated data and sample collection, and on the integration of databases and bio-banks.

Additional eligibility criterion:

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

HEALTH.2012.2.1.1-2: Validation of -omics-based biomarkers for diseases affecting the elderly. FP7-HEALTH-2012-INNOVATION-1. This topic as a whole contributes to the EIP “active and healthy ageing”. The projects should aim at clinical validation of already identified -omics-based potential biomarkers for age-related diseases or disorders affecting the elderly. The biomarkers should be potentially usable indicators for at least one of the following: prediction, diagnosis, prognosis or response to therapy. The validity should be demonstrated with existing or new studies involving human subjects. The clinical validation should show the extent to which the biomarker correlates with the disease and should be measured by sensitivity, specificity, and predictive power. The projects must take into account the use of appropriate statistical models and well as include quality control aspects for data generated. **Note:** Limits on the EU financial contribution apply. These are implemented strictly as formal eligibility criteria.

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

One or more proposals can be selected.

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

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

Additional eligibility criteria:

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

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

HEALTH.2012.2.1.1-3: Statistical methods for collection and analysis of -omics data. FP7-HEALTH-2012-INNOVATION-1. The objective is to improve or develop new statistical methods and tools for an appropriate and accurate analysis of -omics data to better understand the results and use them more efficiently. The project may focus on a specific data type, such as genomics or proteomics, or target a particular class of analyses. Planning of experiments (e.g. through -omics-specific optimal statistical testing approaches), data gathering (including how to deal with missing or 'dirty data') and the problem of meta-analyses (to exploit limited availability and individually insufficiently powered studies) should also be considered. Clinical trials per se are explicitly excluded. The project should also include appropriate training and dissemination activities to increase awareness of current best practices and facilitate the rapid uptake by the scientific community and the industry. **Note:** Limits on the EU financial contribution apply. These are implemented strictly as formal eligibility criteria.

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

One or more proposals can be selected.

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

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

Additional eligibility criteria:

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

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

2.1.2 Systems biology

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

For this call for proposals, topics focus on multidisciplinary research that will integrate a wide variety of biological, medical and clinical data and will develop and apply systems biology

approaches to understand and model complex human diseases. A major goal of this call is to stimulate systems biology approaches for medical and clinical applications and therefore to establish the basis for systems medicine.

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

HEALTH.2012.2.1.2-1: Systems medicine: SME-driven research applying systems biology approaches to address medical and clinical needs⁴⁰. FP7-HEALTH-2012-INNOVATION-1. Research should focus on the development, improvement and application of systems biology approaches to medical/clinical questions; a non-exhaustive list of examples would be:

- Re-design of clinical trials by shortening times and costs
- Re-definition of clinical phenotypes based on molecular and dynamic parameters
- Development of tools for *in vivo* dynamic and quantitative clinically-relevant measurements at the cellular/tissue/organ level
- Development of combinatorial therapies and/or chronotherapies for complex diseases
- Development of combinatorial biomarkers
- Development of new and/or improvement of existing computational models to meet the needs of bio-medical or clinical research.

Consortia should aim to demonstrate the medical and clinical utility of systems biology approaches as well as the usefulness of their results for exploitation. **Note:** Limits on the EU financial contribution apply. These are implemented strictly as formal eligibility criteria.

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

One or more proposals can be selected.

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

Specific feature: SME-targeted research is designed to encourage SME efforts towards research and innovation. Priority will be given to proposals demonstrating that research intensive SMEs play a leading role. The projects will be led by SMEs with R&D capacities but the coordinator does not need to be an SME. The expected project results should clearly be of interest and potential benefit to SME(s). In particular, this specific SME-driven topic, aims to encourage small or minimum consortia size, maximum project duration up to 2 years, and a simplified approach to future negotiation and reporting. This type of SME-driven topic is designed to enable significant progress towards proof-of-concept and exploitation of results in the short-medium term.

Additional eligibility criteria:

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

The proposed **project duration** indicated in the proposal should be up to 2 years.

⁴⁰ The topic is open for proposals in all relevant research areas covered by the topic description; however some proposals, depending on their scientific content, may contribute to the EIP "Active and Healthy Ageing".

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

HEALTH.2012.2.1.2-2: Systems medicine: Applying systems biology approaches for understanding multifactorial human diseases and their co-morbidities⁴¹. FP7-HEALTH-2012-INNOVATION-1. Multidisciplinary research that crosses the borders of different disciplines including basic, pre-clinical and clinical research, network analysis and computational modelling, should focus on improving understanding of the patho-physiological mechanisms, prognosis, and diagnosis of multifactorial human diseases and their co-morbidities. The research should be driven by clearly defined clinical need and provide new avenues for disease diagnosis and/or treatment. Active participation of SMEs and patient organisations could lead to an increased impact of the research proposed and this will be considered in the evaluation of the proposal. **Note:** Limits on the EU financial contribution apply. These are implemented strictly as formal eligibility criteria.

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

One or more proposals can be selected.

Expected impact: Recent advances in systems biology and network analysis have opened new ways of understanding the patho-physiology of multifactorial diseases. It is of equal importance to address also the clinical needs in cases where several diseases co-occur (co-morbid) in the same patient, and hence the pathology and subsequently the potential treatments become even more complex. Projects are expected to demonstrate the impact of systems biology approaches for delivering new insights into multifactorial human diseases and their co-morbidities.

Additional eligibility criterion:

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

HEALTH.2012.2.1.2-3: Preparing for the future research and innovation activities in systems medicine⁴². FP7-HEALTH-2012-INNOVATION-1. The project should aim to promote and support the networking and coordination of European research activities for systems biology applications to medicine. The focus should be on bringing together different national and European efforts with the aim: (i) to develop a road-map and set-up of research priorities for developing and structuring systems medicine in Europe; (ii) to establish a plan for addressing the educational needs and multidisciplinary training in systems approaches for the next generation of scientists and medical doctors; (iii) to share best practices, information/resources on successful methodological approaches by developing and implementing standardised operational procedures; (iv) to strengthen the innovation activities such as technology transfer and exploitation; (v) to integrate national efforts in systems medicine. The partnership should include the appropriate stakeholders, such as systems biology scientists, clinicians, programme managers, industry, SMEs, media, in order to have a

⁴¹ The topic is open for proposals in all relevant research areas covered by the topic description; however some proposals, depending on their scientific content, may contribute to the EIP "Active and Healthy Ageing".

⁴² The topic is open for proposals in all relevant research areas covered by the topic description; however some proposals, depending on their scientific content, may contribute to the EIP "Active and Healthy Ageing".

major impact in the area. **Note:** Limits on the EU financial contribution apply. These are implemented strictly as formal eligibility criteria.

Funding scheme: Coordination and Support Action (coordinating action)

Only up to one proposal can be selected.

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

Additional eligibility criterion:

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

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

2.2.1 Brain and brain-related diseases

Closed in 2012

2.2.2 Human development and ageing

Europe currently has the highest proportion of older people in the world and is expected to maintain this leading position for the next 50 years. This area is in particular contributing to the realisation of the EIP “Active and Healthy Ageing” goals, e.g. living a longer healthier life.

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

For this call of proposals the focus will be on the use and application of -omics knowledge and tools to gain a clear understanding of the fundamental mechanisms of human ageing and on the detection, monitoring and development of innovative therapeutic tools for age-related diseases as well as the optimisation of treatment for elderly patients. Ageing research is characterised by large-scale, heterogeneous data sets that require strong expertise from molecular biology and medicine, as well as engineering, computer science, mathematics and statistics.

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

HEALTH.2012.2.2.2-1: Integrative systems biology and comparative genomics for studying human ageing and/or most common age-related diseases. FP7-HEALTH-2012-INNOVATION-1. This topic as a whole contributes to the EIP “Active and Healthy Ageing”.

This topic will address the basis of human ageing by studying genes, gene regulation and pathways involved in the process and defining the interactions through which the ageing phenotype develops in normal and/or disease conditions. Research will encompass computational approaches and comparative genomics building on existing data and the use of appropriate models when needed. Depending on the nature of research, tools for diagnostic and prognostic procedures as well as for the monitoring of therapies can also be included. The role of known drug combinations, nutrients, lifestyle and environmental determinants on the whole body over a long period of time will also be considered. **Note:** Limits on the EU financial contribution apply. These are implemented strictly as formal eligibility criteria.

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

One or more proposals can be selected.

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

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

Additional eligibility criteria:

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

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

HEALTH.2012.2.2.2.-2: Investigator-driven clinical trials⁴³ for optimisation of management of elderly patients with multiple diseases. FP7-HEALTH-2012-INNOVATION-1. This topic as a whole contributes to the EIP “Active and Healthy Ageing”. The aim of the projects should be the comparison of outcomes of various treatment regimens for those diseases that are most common in elderly populations. Research will focus on drug therapy and other interventions for patients affected by and treated for multiple diseases. Studies should include the evaluation of efficacy and adverse events. Applicants must demonstrate that clinical trials are appropriately powered to produce statistically significant evidence. *Gender aspects and differences related to age groups, ethnicity and socio-economic status should be appropriately considered.* The clinical trials to be supported must be registered in a publicly accessible clinical trials registry. The applications must consider the relevant governance issues for clinical trials such as good clinical practice and respect of the appropriate international, European and national legislation and guidelines. Patient advocacy groups, which can contribute to the quality, feasibility and impact of clinical trials, should be involved where appropriate. **Note:** Limits on the EU financial contribution apply. These are implemented strictly as formal eligibility criteria.

⁴³ Please consult also the text for clinical trials provided in the introduction to activity 2. Translating research for human health in this work programme on pages 9/10

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

One or more proposals can be selected.

Expected impact: Three main impacts are expected: treatments better suited to the needs of older people, lowering healthcare costs and engaging in the pre-normative setting of geriatric medicines.

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

Additional eligibility criteria:

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

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

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

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

2.3.0 Cross-cutting

Note: For topic **HEALTH.2012.2.3.0-1** applicants will have to follow the rules for **two-stage submission procedure** (see also respective call fiche in section III). For topic **HEALTH.2012.2.3.0-2** applicants will have to follow the rules for **single-stage submission procedure** as set out in the **ERA-NET call in Annex 4 to the work programme**.

HEALTH.2012.2.3.0-1: Diagnostics for infectious diseases in humans. FP7-HEALTH-2012-INNOVATION-2. This topic covers the development and/or validation of diagnostic tests for infectious diseases with the aim of meeting real clinical and public health needs.

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

One or more proposals can be selected.

Expected impact: **Projects** should deliver new or improved diagnostic tools which will lead to more appropriate patient management in the clinical setting and/or help reducing the spread of infections of global importance.

Specific feature:

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

Additional eligibility criteria:

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

The proposed **project duration** indicated in the proposal should be up to 3 years.

Projects will only be selected for funding on the condition that the estimated EU contribution to **SME(s)** is 50% or more of the total estimated EU contribution to the whole project. This will be assessed at the end of the negotiation, before signature of the grant agreement. Proposals not fulfilling this criterion will not be funded.

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

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

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

HEALTH.2012.2.3.0-2: ERA-NET on infectious diseases. FP7-ERANET-2012-RTD⁴⁴.

This action shall further improve the linking, efficient integration and coordination of national/regional programmes for infectious diseases research, building on previous activities in this field. The proposed new ERA-NET could build upon the previous ERA-NET PathoGenoMics and capitalise on its achievements. It should aim to develop new technologies and employ modern genomic approaches to advance our understanding of pathogenic organisms and interactions with their hosts as well as support the development of new tools to combat or prevent infectious diseases. The action should include a strategy for mutual opening of national/regional programmes to the participants and for the implementation of a series of joint transnational calls, as well as activities aimed at fostering the development of infectious diseases research programmes beyond the participating Member States and Associated Countries. Due consideration should be given to increase the number of participants from Member States and Associated Countries. The ERA-NET should

⁴⁴ Call fiche: see Annex 4 to the Cooperation work programme

complement the potential implementation of Joint Programming Initiatives (JPIs), such as the JPI on antimicrobial resistance.

Funding scheme: Coordination and Support Action (coordinating action)

The **EU contribution** available for this topic is limited to a maximum of 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 infectious diseases and be complementary to other European activities in this area. It should provide knowledge of pathogenic organisms and develop tools to combat or prevent infectious diseases.

Additional eligibility and specific evaluation criteria for an ERA-NET: Please refer to Annex 4 to the Cooperation work programme.

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 in a multidisciplinary approach and to strengthen the European research activities in the area. For topic **HEALTH.2012.2.3.1-1** applicants will have to follow the rules for **single-stage submission procedure** as set out in the **JPROG call in Annex 4 to the work programme.**

HEALTH.2012.2.3.1-1: Coordination action in support to the Joint Programming Initiative on "The microbial challenge – an emerging threat to human health". FP7-JPROG-2012-RTD⁴⁵. Following the Communication "Towards Joint Programming in Research: working together to tackle common challenges more effectively"⁴⁶, the Commission has been encouraging Member States to pursue common visions and strategic research agendas in the domains identified by the High Level Group for Joint Programming (GPC) as suitable for Joint Programming Initiatives (JPIs).

In its conclusions of 26 May 2010, the Competitiveness Council welcomed the identification and substantiation of six "second wave" themes for JPIs. Further, the Competitiveness Council invited the Commission to sustain the implementation of the proposed JPIs and "Act as a facilitator by suggesting complementary measures to support the Joint Programming initiatives"⁴⁷.

Therefore, the Commission decided to facilitate, by funding dedicated coordination actions, the JPIs which have reached a satisfactory level of maturity testified by:

- a) Adoption of a challenge-oriented problem-solving approach, backed by a solid and firm commitment by participating Member States or Associated Countries, which should include also provision of adequate human and financial resources.
- b) Development of a Strategic Research Agenda that, on the basis of an up-to-date mapping of research activities in the concerned areas, should have identified at least a limited number of measurable scientific-technological or socio-economic objectives,

⁴⁵ Call fiche: see annex 4 to the Cooperation work programme

⁴⁶ COM(2008)468 final

⁴⁷ Council Conclusions on Joint Programming of 12 October 2010

translating the challenge into operational terms, supported by an appropriate analysis of their relevance in relation to the addressed challenge and innovation potential.

- c) The presence of a governance system commensurate to the tasks, involving the participating organisations at an appropriate level.
- d) The European added value of the proposal be justified in terms of its scale, scope, increased effectiveness and/or cost savings potentially achieved.

Scope of the Action: The Commission foresees to sustain the overall coordination and capacity-building process for the JPI "**The microbial challenge – an emerging threat to human health**⁴⁸", with the initial aim of shortening the time required to reach the implementation phase and then allow the adoption of effective and efficient methods of collaboration, such as those proposed within the "Voluntary Guidelines on Framework Conditions for Joint Programming in Research", adopted by the GPC on 11 November 2010⁴⁹.

Funding scheme: Coordination and Support Action (coordinating action)

Only up to one proposal can be selected.

Expected impact: This action should help establish effective JPI governance structures. It should help develop a sharply focused and realistic strategic research agenda, based on the mapping and analysis of the state of the art in the specific field both at European and international level. Furthermore it should raise the scale and ambition of the research carried out in the specified domain beyond the level that would be otherwise sustainable, globally increasing the coherence and efficiency in the use of European resources.

Additional eligibility criteria for this action: This topic is included in the cross-thematic call FP7-JPROG-2012-RTD. Complete information on the applicable additional eligibility criteria can be found in the corresponding call fiche. Please refer to the updated annex 4 to the 2012 Cooperation work programme.

2.3.2 HIV/AIDS, malaria and tuberculosis

The focus will be on promoting translational research aiming at bringing basic knowledge through to clinical application in developing new therapies, diagnostic tools and vaccines for HIV/AIDS, malaria and tuberculosis. Research efforts will confront the three diseases at global level, but will also address specific European aspects. The objective is to create a European research environment, where highly innovative ideas are conceived and new approaches to prevention, treatment, diagnosis and management of the diseases can be developed.

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

⁴⁸ Commission recommendation on the research Joint Programming Initiative 'The Microbial Challenge – An Emerging Threat to Human Health' - C(2011) 7660 of 27.10.2011

⁴⁹ Annex to "Joint Programming in research 2008-2010 and beyond - Report of the High Level Group on Joint Programming to the Council" <http://ec.europa.eu/research/era/docs/en/joint-programming-in-research-2008-2010-and-beyond---report-of-the-high-level-group-on-joint-programming-to-the-council.pdf>

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

HIV/AIDS, malaria and tuberculosis cross-cutting 2012

HEALTH.2012.2.3.2-1: Co-infection of HIV/AIDS, malaria, tuberculosis and/or hepatitis. FP7-HEALTH-2012-INNOVATION-1. The objective of this topic is to support basic, translational and/or clinical research with the aim of improving basic knowledge, disease prevention, therapeutic management and prognosis of patients that are co-infected with two or more of the infectious agents causing AIDS, malaria, tuberculosis or hepatitis. The proposals are expected to address key research questions, such as immunological mechanisms and responses to co-infection, and may include investigator driven clinical trials on prevention, treatment or treatment combinations for co-infected individuals as well as clinical and epidemiological consequences. **Note:** Limits on the EU financial contribution apply. These are implemented strictly as formal eligibility criteria.

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

One or more proposals can be selected.

Expected impact: The successful projects should increase knowledge of co-infection between two or more of the major infectious diseases (AIDS, malaria, tuberculosis and hepatitis) and contribute to better prevention, treatment and patient management. The expected impact includes optimised treatment, reduced mortality and ameliorated quality of life of patients.

Additional eligibility criterion:

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

HEALTH.2012.2.3.2-2: Co-morbidity between infectious and non-communicable diseases⁵⁰. FP7-HEALTH-2012-INNOVATION-1. Increasing evidence suggests that pathologies of many infectious diseases can be strongly influenced by concurrent presence in the same individual of non-infectious diseases, or vice-versa. The objective of this topic is to support basic, translational and/or clinical research with the aim of improving basic knowledge, disease prevention, therapeutic management and prognosis of patients with both infectious and non-communicable diseases. The proposals are expected to elucidate and clarify causative links between infectious and non-communicable diseases, and may also address diagnosis, or investigator driven clinical trials on treatments of particular relevance for patients with co-morbidities. The proposals should address combination(s) of any of the three major poverty-related diseases (HIV/AIDS, malaria or tuberculosis) or any of the neglected infectious diseases with non-infectious diseases of major importance, such as, but not limited to, rheumatic or cardiovascular diseases, cancer or diabetes. **Note:** Limits on the EU financial contribution apply. These are implemented strictly as formal eligibility criteria.

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

One or more proposals can be selected.

⁵⁰ The topic is open for proposals in all relevant research areas covered by the topic description; however some proposals, depending on their scientific content, may contribute to the EIP "Active and Healthy Ageing".

Expected impact: The successful projects will increase our knowledge of the causative links between infectious and non-communicable diseases and will contribute to better prevention, treatment and management of patients suffering from such co-morbidities. The expected impact includes optimised treatment, reduced mortality and ameliorated quality of life of patients. The selected projects need to demonstrate that collaboration between different disease areas can significantly strengthen and integrate the health systems.

Additional eligibility criterion:

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

HEALTH.2012.2.3.2-3: Prevention and treatment for HIV/AIDS, malaria and tuberculosis. FP7-HEALTH-2012-INNOVATION-1. The supported projects should aim at developing innovative strategies for the prevention and/or treatment of poverty-related diseases (HIV/AIDS, malaria or tuberculosis). Priority will be given to projects addressing current gaps in prevention and/or treatment and key research areas such as novel and combinatorial strategies for prevention, novel therapeutic and/or curative approaches, development of models for disease progression and host-pathogen interaction in humans. Projects may contain elements of both basic and translational research. A detailed plan for development and exploitation of the end results will be an important aspect. The intention is to provide individual members of the consortium with sufficient resources to deliver results in the short term. Therefore, applications from small consortia (typically 3-5 partners) as well as short duration (typically 1-3 years) with up to the expected EU contribution are welcome. **Note:** Limits on the EU financial contribution apply. These are implemented strictly as formal eligibility criteria.

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

One or more proposals can be selected.

Expected impact: Projects are expected to deliver results with a clear impact on future disease management. The projects should contribute significantly to prevention and treatment of poverty related diseases by addressing gaps and providing innovative strategies for integrating the inputs of individual research teams. Progress should be translated into improving the lives of patients with poverty related diseases, and reducing future disease incidence. In addition, where relevant, projects are expected to develop links and explore synergies with relevant ongoing EU-funded initiatives, such as the EDCTP.

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

Additional eligibility criteria:

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

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

HEALTH.2012.2.3.2-4: Low-cost interventions for disease control in resource poor settings. FP7-HEALTH-2012-INNOVATION-1. Projects should focus on innovative ways to confront and control malaria and/or neglected infectious diseases⁵¹ in resource-poor settings. Projects should focus on novel applications of current tools and combining dispersed and fragmented knowledge to provide new and cost-effective solutions. Projects may address and combine knowledge from areas such as combination therapy, treatment strategies, epidemiology, access to diagnostics and drugs, operational- and implementation research, including quality control. Projects are expected to deliver low cost medical solutions that can be implemented within the project period. The involvement of partners from disease-endemic countries is expected, and potential links and synergies with existing multilateral initiatives could be an added value. **Note:** Limits on the EU financial contribution apply. These are implemented strictly as formal eligibility criteria.

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

One or more proposals can be selected.

Expected impact: The supported projects are expected to develop low-cost interventions that can be implemented during the project period and thereby have an immediate impact on the control of malaria and/or neglected infectious diseases in resource poor countries. Where relevant, projects are expected to develop links and explore synergies with other existing multilateral initiatives.

Additional eligibility criterion:

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

2.3.3 Potentially new and re-emerging epidemics

Closed in 2012

2.3.4 Neglected infectious diseases

Closed in 2012

2.4 TRANSLATIONAL RESEARCH IN OTHER MAJOR DISEASES

2.4.1 Cancer

Closed in 2012

2.4.2 Cardiovascular diseases

Closed in 2012

⁵¹ Priority Neglected Infectious Diseases: Trypanosomiasis (sleeping sickness); Leishmaniasis; Chagas; Buruli ulcer; Leprosy; Trachoma; Infantile diarrhoea; Schistosomiasis (Bilharzia); Lymphatic filariasis (Elephantiasis); Soil-transmitted nematodes (Ascariasis, Trichuriasis, Hookworm)

2.4.3 Diabetes and obesity

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

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

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

HEALTH.2012.2.4.3-1: Innovative approach to manage diabetes. FP7-HEALTH-2012-INNOVATION-1. Taking into account state-of-the-art innovative research and technologies, the aim of this topic is to validate, in the preclinical and/or clinical setting, the performance and applicability of therapeutic devices or biological therapies aimed at improving diabetes management. This could include for instance glucose sensors, insulin delivery systems, devices that respond on low glucose levels to release glucagon or other insulin-counteracting therapies and could build on surgical, immunological, integrated physiology, cellular and bio-artificial therapy approaches. Full attention needs to be paid to safety, bio-compatibility, interoperability and regulatory aspects as appropriate. **Note:** Limits on the EU financial contribution apply. These are implemented strictly as formal eligibility criteria.

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

One or more proposals can be selected.

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

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

Additional eligibility criteria:

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

Projects will only be selected for funding on the condition that the estimated EU contribution going to **SME(s)** is at least 30 % of the total estimated EU contribution for the project as a

whole. *This will be assessed at the end of the negotiation, before signature of the grant agreement. Proposals not fulfilling this criterion will not be funded.*

HEALTH.2012.2.4.3-2: Investigator-driven clinical trials⁵² for type 1 diabetes research. FP7-HEALTH-2012-INNOVATION-1. The main aim is to launch major clinical trials in type 1 diabetes patients with a particular focus on children and adolescents, who are predominantly and severely affected. These trials should be designed to improve glycaemic control and management of the disease. The results of such trials should deliver measurable improvements to clinical management. The outcomes must be relevant for patients and change clinical practice. Research to identify optimal diet and exercise protocols could be included if appropriate. Pilot studies and systematic reviews will not be funded. Applicants must demonstrate that clinical trials are appropriately powered to produce statistically significant evidence. Gender aspects and differences related to age subgroups should be appropriately considered. The clinical trials to be supported must be registered in a publicly accessible clinical trials registry. The applications must consider the relevant governance issues for clinical trials such as good clinical practice and respect of the appropriate international, European and national legislation and guidelines. Patient advocacy groups, which can contribute to the quality, feasibility and impact of clinical trials, should be involved where appropriate. **Note:** Limits on the EU financial contribution apply. These are implemented strictly as formal eligibility criteria.

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

One or more proposals can be selected.

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

Specific feature: For 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. 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.

Additional eligibility criterion:

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

2.4.4 Rare diseases

⁵² Please consult also the text for clinical trials provided in the introduction to activity 2. Translating research for human health in this work programme on pages 9/10

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

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

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

HEALTH.2012.2.4.4-1: Preclinical and/or clinical⁵³ development of substances with a clear potential as orphan drugs. FP7-HEALTH-2012-INNOVATION-1. Support will be provided to preclinical studies (pharmacological, pharmacodynamics, pharmacokinetics and toxicological) in models and/or clinical studies (including phase III clinical trials) of EU designated orphan medicinal products. Clinical studies should focus on biopharmaceutical studies (including bioavailability, bioequivalence, *in vitro-in vivo* correlation), human pharmacokinetic and pharmacodynamic studies, human efficacy and safety studies. Clinical trials must be appropriately powered to produce statistically significant evidence. Involvement of industry, in particular SMEs, is strongly recommended. Diagnostics and therapies for cancer and nervous system diseases will not be considered. The orphan medicinal product will need to be granted the EU orphan designation at the latest on the date of the call closure⁵⁴. It is expected that the project will have appropriate plans to engage with relevant stakeholders such as patient organisations and the European Medicines Agency. Projects funded under this topic should contribute towards the goals of the International Rare Diseases Research Consortium (IRDiRC) that include the development of 200 new therapies for rare diseases by 2020⁵⁵. The partners in all projects selected for funding should adhere to IRDiRC policies⁵⁶. **Note:** Limits on the EU financial contribution apply. These are implemented strictly as formal eligibility criteria.

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

One or more proposals can be selected.

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

⁵³ Please consult also the text for clinical trials provided in the introduction to activity 2. Translating research for human health in this work programme on pages 9/10

⁵⁴ The European register of designated Orphan Medicinal Products is available from <http://ec.europa.eu/health/documents/community-register/html/alforphreg.htm>

⁵⁵ http://ec.europa.eu/research/health/medical-research/rare-diseases/irdirc_en.html

⁵⁶ To be published on the Health web site following IRDiRC meeting in Washington in April

The projects should contribute to the International Rare Disease Research Consortium (IRDiRC) goals.

Additional eligibility criteria:

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

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

HEALTH.2012.2.4.4-2: Observational trials⁵⁷ in rare diseases. FP7-HEALTH-2012-INNOVATION-1. The aim is to improve clinical practice in the management of rare diseases patients, and research should include the comparison of outcome of various prevention or treatment/intervention regimens for those rare diseases for which no orphan drug is available and that are being treated off-label. Studies should include the evaluation of effectiveness and adverse events. Particular attention should be given to the definition of appropriate outcome measures. Studies on cancer, infectious diseases and nervous system diseases will not be considered. Project should include appropriate plans to engage with relevant stakeholders such as patient organisations and dissemination plans to ensure the wide and rapid uptake of developed guidelines. Child health aspects should be taken into consideration whenever appropriate. **Note:** Limits on the EU financial contribution apply. These are implemented strictly as formal eligibility criteria.

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

One or more proposals can be selected.

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

Additional eligibility criterion:

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

HEALTH.2012.2.4.4-3: Best practice and knowledge sharing in the clinical management of rare diseases. FP7-HEALTH-2012-INNOVATION-1. This action is dedicated to the development of a networking platform supporting the collection of standardised and validated data and the exchange of information providing evidence for best clinical management of rare diseases. It should also help identifying additional research needs to further improve clinical practice. The platform should not be restricted to particular (groups of) rare diseases and the platform sustainability after the EU financing period must be established during the project. **Note:** Limits on the EU financial contribution apply. These are implemented strictly as formal eligibility criteria.

Funding scheme: Coordination and Support Action (coordinating action)

Only up to one proposal can be selected.

⁵⁷ Please consult also the text for clinical trials provided in the introduction to activity 2. Translating research for human health in this work programme on pages 9/10

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

Additional eligibility criterion:

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

2.4.5 Other chronic diseases

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

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

HEALTH.2012.2.4.5-1: Technological approaches to combating sensory impairments⁵⁸. FP7-HEALTH-2012-INNOVATION-2. Examples of possible areas to be considered: strategies aiming at prevention of damage and rejuvenation of sensory cells and systems, treatment of sensory diseases, implantable devices, cell based approaches, including stem cells, and development of artificial organs or their parts. Full attention needs to be paid to safety, bio-compatibility, interoperability and regulatory aspects as appropriate. **Note:** Limits on the EU financial contribution apply. These are implemented strictly as formal eligibility criteria.

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

One or more proposals can be selected.

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

Specific feature:

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

⁵⁸ The topic is open for proposals in all relevant research areas covered by the topic description; however some proposals, depending on their scientific content, may contribute to the EIP "Active and Healthy Ageing".

Additional eligibility criteria:

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

The proposed **project duration** indicated in the proposal should be up to 3 years.

Projects will only be selected for funding on the condition that the estimated EU contribution to **SME(s)** is 50% or more of the total estimated EU contribution to the whole project. This will be assessed at the end of the negotiation, before signature of the grant agreement. Proposals not fulfilling this criterion will not be funded.

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

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

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

HEALTH.2012.2.4.5-2: Biomarkers and diagnostics for chronic inflammatory diseases of the joints and/or digestive system⁵⁹. FP7-HEALTH-2012-INNOVATION-1. Early diagnosis of chronic inflammatory diseases, establishment of the mechanisms of initiation, identification of genes involved and relevant gene regulation mechanisms, biomarkers (e.g. biochemical, immunologic, epigenetic) of diagnostic value, as well as identification of targets for therapeutic action of pharmaceutical agents and other treatments. **Note:** Limits on the EU financial contribution apply. These are implemented strictly as formal eligibility criteria.

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

One or more proposals can be selected.

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

Specific feature: SME-targeted research is designed to encourage SME efforts towards research and innovation. Priority will be given to proposals demonstrating that research

⁵⁹ The topic is open for proposals in all relevant research areas covered by the topic description; however some proposals, depending on their scientific content, may contribute to the EIP "Active and Healthy Ageing".

intensive SMEs play a leading role. The projects will be led by SMEs with R&D capacities but the coordinator does not need to be an SME. The expected project results should clearly be of interest and potential benefit to SME(s).

Additional eligibility criteria:

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

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

3. OPTIMISING THE DELIVERY OF HEALTH CARE TO EUROPEAN CITIZENS

This activity aims at improving the necessary basis both for informed policy decisions on health systems and for more effective and efficient evidence-based strategies of health promotion, disease prevention, diagnosis and therapy. The activity takes forward the principles of the EU Health Strategy: "Together for Health: A Strategic Approach for the EU 2008-2013"⁶⁰ and aims to anticipate future priority needs. In this call topics focus on improving the organisation of health service delivery, new methodologies for health technology assessment and social innovation. Specific international cooperation actions to support the implementation of the Millennium Development Goals (MDGs), will address health systems/services research including research capacity building in terms of human resources. This activity contributes in many ways to the realisation of the Innovation Union pilot Partnership on "Active and Healthy Ageing" goals, in particular through area 3.2 by promoting targeted innovative research to enable the sustainability and efficiency of social and health care systems and services.

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

Closed in 2012

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

In Europe's health care landscape, service providers differ considerably in size and structure, varying from large structures, like general or specialised hospitals to small primary care units or health centres. Empirical evidence is a vital element in supporting informed policy decisions that can improve health care in European countries in particular in Member States undergoing restructuring in their health system and candidate countries. There is a clear need for a more systematic mapping of variations in health care practice, for understanding their causes and assessing their consequences for individual health improvement⁶¹. These issues have been highlighted both by Member States' and the Commission for example in discussions on the draft directive on the application of patients' rights in cross-border health care and in the Commission's initiative regarding the innovation partnership pilot on active and healthy ageing.

For this call for proposals the focus will be on health service delivery, health technology assessments, reimbursement systems and social innovation in ageing research. Projects should

⁶⁰ White Paper: "Together for Health: A Strategic Approach for the EU 2008-2013", 23.10.2007 COM 630 FINAL

⁶¹ As highlighted by the FP7 projects *HSREPP* – a roadmap project on health services research (<http://www.nivel.nl/oc2/page.asp?PageID=11023&path=/Startpunt/NIVEL%20international/HSREPP/Home>) and *FUTURAGE* – a roadmap project on ageing research (<http://futurage.group.shef.ac.uk/>) also highlighted this need.

contribute to the implementation of both, the European Innovation Partnership principles and measures to support the application of the cross-border directive.

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

HEALTH.2012.3.2-1: Improving the organisation of health service delivery⁶². FP7-HEALTH-2012-INNOVATION-1. The objective of this topic is to benchmark best practices regarding the structure, care processes, cost containment issues, reimbursement systems and performance of health care organisations in Europe. Applicants would be expected to address the issues of the organisational, management, financial (including costs) and regulatory aspects of health systems, including where appropriate the context of cross-border settings. The expected outputs would be an enhanced performance of Member States' health services based on proposals that address **one or more elements** given below:

- **The integration of care across organisations** and how collaboration between different health care providers can integrate primary and secondary care in pathways. Such research for example could focus on the effect of integration on patient experiences, outcomes, and efficiency; could examine the best forms of integration and under what conditions/context and for which patients groups is the integration of care suitable; and investigate the evaluation of new organisational approaches to integration.
- **Quality of cost information for patient care.** Research for example could focus on the assessment of health costing systems and practices for patient services (including the identification of best practice costing models); the analysis of the cost information quality, the impact and relevance upon decision making; the improvement of comparability of health cost data among EU countries with a view to advancing the economic efficiency of services.
- **Patient-centred care and patient involvement** and how organisations and patients, including self-help groups, can be empowered in this direction. Such research for example could focus on the evaluation of strategies, interventions, and incentives; under which conditions would new health technologies lead to more patient-centred care; investigate interventions and guideline adherence. Different health care settings should be taken into account.
- **Skill mix and management of human resources.** Such research for example could focus on the impact of changing skill mix of health professionals across Europe on quality of care and future health needs; the organisation of care processes and professional roles and competencies; the identification and comparison of successful health workforce planning strategies addressing the ageing health workforce and increasing mobility of health professionals across Europe⁶³.
- **The transfer of knowledge into practice** using results and outcomes of relevant EU FP projects with regards to health systems and health services research⁶⁴. Best practices and the factors that determine the transferability of these mechanisms⁶⁵ should be considered,

⁶² The topic is open for proposals in all relevant research areas covered by the topic description; however some proposals, depending on their scientific content, may contribute to the EIP "Active and Healthy Ageing".

⁶³ Proposals should taken into account work carried out by FP7 projects HealthPrometheus, MohProf & RN4CAST (http://ec.europa.eu/research/health/public-health/index_en.html)

⁶⁴ See relevant FP7 projects (reference booklet public health research web pages)

⁶⁵ See relevant FP7 projects such as *BRIDGE, FIRE & SURE* (reference public health project booklet)

applying relevant tools and brokerage skills, to ensure that research findings and results are indeed applicable and used for a better organisation of health service delivery in Europe.

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

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

One or more proposals can be selected.

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

Additional eligibility criterion:

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

HEALTH.2012.3.2-2: New methodologies for health technology assessment⁶⁶. FP7-HEALTH-2012-INNOVATION-1. Health Technology Assessment (HTA) is intended to provide a bridge between the world of research and the world of decision-making by providing relevant information about the medical, social, economic, legal and ethical issues related to the use of health technology. This should be achieved in a systematic, transparent, unbiased and robust manner, also highlighted by the European network for Health Technology Assessment⁶⁷. Research under this call should develop new and /or improved methodologies for HTA that address the present challenges affecting the current methodological framework regarding complexity, efficacy and effectiveness. Proposals should address **one** or more elements of the following areas:

- HTA methodologies should be broadened to expand further the spectrum and complexity of technologies assessed. For example complex interventions consisting of a wide spectrum of technologies and multidisciplinary delivery modes should be addressed, such as personalised medicines, public health interventions, organisational interventions and information and communication technologies related to health. Other challenges to be addressed could include the need for the continuous assessment of health technologies throughout their life cycles, the integration of social, organisational, ethical and legal aspects, assessment of relative effectiveness and to evaluate their implementation into health service provision.

⁶⁶ The topic is open for proposals in all relevant research areas covered by the topic description; however some proposals, depending on their scientific content, may contribute to the EIP "Active and Healthy Ageing".

⁶⁷ EUnetHTA JA is a joint action funded under the EC's 2nd Community Programme of public health in response to the 2009 call - <http://www.eunetha.net/Public/Home/>.

- Research for example could address the real need to complement those efforts already undertaken by the Member States' network of HTA organisations (EUnetHTA JA) as regards the development of HTA methodologies to assess, for example, the efficacy and effectiveness of technologies. The applicability of these technologies into broader clinical contexts requires a better understanding of their use. In addition, there is a need to strengthen HTAs so that they may be used in very specific and particular circumstances, such as in hospital settings - mini-HTAs, where very local contextual organisational considerations have to be taken into account. Non-exhaustive examples would include: advanced therapies⁶⁸, diagnostics, medical devices, personalised medicines, transfusion and transplantation, health-related information and communication technologies.

Collaboration between the selected projects should be foreseen in the proposals in view of exchanging information and promoting the development of best practice. **Note:** Limits on the EU financial contribution apply. These are implemented strictly as formal eligibility criteria.

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

One or more proposals can be selected.

Expected impact: This research should improve the scope, validity and applicability of HTA as a tool to determine the potential impact of innovative technologies on individual and population health gains. It should complement work undertaken by the European Network for Health Technology Assessment and broaden the HTA methodological framework to develop it into a truly meaningful tool that provides structured, evidence-based input into health policies that are patient-focused and promoting good quality care, equity in access and best value for money⁶⁹.

Additional eligibility criterion:

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

HEALTH.2012.3.2-3: Social innovation for active and healthy ageing. FP7-HEALTH-2012-INNOVATION-1. This topic as a whole contributes to the European Innovation Partnership (EIP) pilot initiative on “Active and Healthy Ageing”⁷⁰. Social innovation⁷¹ for active and healthy ageing should aim to develop innovative approaches to promote better quality of life and improved well-being for the elderly. Proposals should develop new ideas (products, services and/or models) that simultaneously meet social needs and create new social relationships. Such research, with a holistic approach to well-being and with open participation of a variety of stakeholders, should take into account the broad spectrum of social, economic and health needs of Europe's elderly citizens, and contribute to implement

⁶⁸ Gene therapy medicinal products, somatic cell therapy medicinal products and tissue engineered products, as defined by Regulation (EC) no 1394/2007 of the European Parliament and of the Council of 13 November 2007 on Advanced Therapy Medicinal Products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004

⁶⁹ FP7 HSREPP project– a roadmap project on health services research:
<http://www.nivel.nl/oc2/page.asp?PageID=11023&path=/Startpunt/NIVEL%20international/HSREPP/Home>

⁷⁰ This includes the creation of opportunities i) to speed up, scale up and ensure access to innovative products and services to meet the needs of elderly people so they can live longer and healthier and participate actively in the labour market and in society, ii) to overcome barriers to innovation for active and health ageing, whilst iii) increasing sustainability and efficiency of health care systems http://ec.europa.eu/research/innovation-union/index_en.cfm?section=active-healthy-ageing

⁷¹ http://ec.europa.eu/enterprise/policies/innovation/policy/social-innovation/index_en.htm

the factors enabling an improved quality of life of older people. Relevant stakeholders at the appropriate level(s) (e.g. local, regional) are expected to define how the new ideas developed in the framework of the project can be implemented. Non-exhaustive examples would include: innovative products and services aimed at promoting healthy lifestyle, nutrition and/or healthy environment, disease prevention, supporting independent and active older citizens; or reform of the health care system and services to adequately meet the needs of independent living of an ageing population. **Note:** Limits on the EU financial contribution apply. These are implemented strictly as formal eligibility criteria.

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

One or more proposals can be selected.

Expected impact: Innovation needs to be reflected not only in research, science and business but also in all areas of society including the health sector in order to make life better for European citizens. Social innovation in the public sector, the private and non-for-profit sectors must be harnessed to improve the quality of life of older citizens and society as a whole. The projects are expected to develop a new paradigm in this area based on the principles underlying the Innovation Union and subsequent reflections emerging from the EIP pilot initiative on "Active and Healthy Ageing".

Additional eligibility criterion:

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

3.3 HEALTH PROMOTION AND PREVENTION

Closed in 2012

3.4 INTERNATIONAL PUBLIC HEALTH & HEALTH SYSTEMS

The specific cooperation actions in this area focus on the priorities agreed through bi-regional dialogues in third countries/regions and international fora, as well as within the context of Millennium Development Goals (MDGs). It has been long recognised at the global level that research is needed to improve the efficiency and effectiveness of health systems in many low and middle income countries⁷².

For this call for proposals the focus will be on health systems/services research while at the same time strengthening research capacity building in terms of human resources.

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

HEALTH.2012.3.4-1: Research on health systems and services in low- and middle-income countries. FP7-HEALTH-2012-INNOVATION-1. The weakness of health systems is an obstacle to effective health care in many low-and middle-income countries. Projects

⁷² 1st Global Symposium on Health Systems Research, Montreux November 2010 <http://www.hsr.symposium.org/> & relevant public health web pages

should allow national and regional decision makers to better translate knowledge, empirical data and operational experience into policies and planning for more effective, efficient and equitable health systems and services. Research should combine inter- and intra-country comparisons, quantitative and qualitative approaches with experience about best practices with a view to increase and sustain universal health coverage. Research could also develop plans for improved management of the health workforce in low-resource settings such as rural areas and urban slums. Collaboration between selected projects as well as with relevant ongoing EU funded projects is welcome in order to develop synergies and increase impact. Proposals should allocate at least one third of the requested EU contribution to capacity building on the basis of a thorough assessment of local training needs in collaboration with key stakeholders. Particular attention should be given to the next generation of researchers and health care professionals. Measures to strengthen the scientific capacity for health systems/health policy research through South-South cooperation could also be included. A single geographical ICPC region or sub-region can be addressed. Projects should generally be 5 years in duration. **Note:** Limits on the EU financial contribution apply. These are implemented strictly as formal eligibility criteria.

Funding scheme: Specific International Cooperation Action (**SICA**), Collaborative Project (small or medium-scale focused research project) target regions: All international cooperation countries (ICPC)⁷³.

One or more proposals can be selected.

Expected impact: This research should empower national or regional decision-makers in low- and middle-income countries in the planning, management and organisation of health systems through the contribution of a robust evidence base building on best practice knowledge transfer mechanisms, to support the theory and practice of strengthening health systems. With reference to the health workforce, research could contribute to the development of innovative, effective and sustainable policies that motivate health workers to remain in their workplaces, support education and training for health workers, strengthen governance capacities, and subsequently improve overall access and quality of health care. Projects are expected to promote capacity building as a key to creating a sustainable and attractive research landscape for health systems/services research in the target countries.

Additional eligibility criteria:

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

Projects will only be selected for funding on the condition that **consortia** include a minimum of 6 different ICPC partners and a minimum of 2 EU/AC partners from different countries.

⁷³ The list of international cooperation partner countries (ICPC) is provided in Annex I to the Cooperation Programme <ftp://ftp.cordis.europa.eu/pub/fp7/docs/icpc-list.pdf>

4. OTHER ACTIONS ACROSS THE HEALTH THEME

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

4.1 COORDINATION AND SUPPORT ACTIONS ACROSS THE THEME

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

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

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

HEALTH.2012.4.1-1: Network to encourage knowledge transfer activity in FP-funded health research (especially in academic and governmental organisations). FP7-HEALTH-2012-INNOVATION-1. The objective of this three years coordination action is to further strengthen knowledge transfer offices in universities, public research organisations, hospitals and to promote industry-academia trans-national collaboration, with focus on the health sectors and its specificities, promoting the exploitation of innovative ideas, promoting contacts with investors and their associations. It will have to cover as many as possible of the following objectives: 1) It will create platforms for shared learning and networking for scientists, hospitals, program managers and policy makers in a continuous manner. 2) It will establish a mechanism for identifying and promoting good knowledge management and knowledge transfer practices in the EU Member States and Associated Countries, providing evidence on best practice on the transfer of knowledge, including standardisation. 3) It will give visibility to the best achievements at the European level, including impact of legislation and tax incentives on technology transfer and innovative SMEs. 4) It will create an on-line repository of best practices for further reference and actively promote them. 5) It will promote interaction between the universities, industry, investors and the individual researchers with the organisation of workshops, partnering events and staff exchanges. 6) The consortium shall coordinate the tasks related to the organisation of national activities. 7) It will have to organise one conference during the project lifetime. It shall clearly promote collaboration and exchanges with Industry (SMEs in particular) and SME associations. It shall complement and not overlap with organisations like Enterprise Europe Network or existing technology transfer associations, working in synergy with them and with other EU funded supports. The proposal shall provide a detailed action plan with quantitative and measurable objectives. **Note:** Limits on the EU financial contribution apply. These are implemented strictly as formal eligibility criteria.

Funding scheme: Coordination and Support Action (coordinating action)

Only up to one proposal can be selected.

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

Additional eligibility criterion:

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

HEALTH.2012.4.1-2: Training actions linked to intellectual property rights management and knowledge transfer. FP7-HEALTH-2012-INNOVATION-1. This three years coordination action shall address in particular participants in EU funded projects in health. The programme shall involved experienced practitioners with consolidated experience in the life-science sector and its specificities, who shall provide concrete case studies (on the MBA model) to be discussed and analysed by participants and, as appropriate, provide coaching and advise on specific situations, whenever appropriate will provide evidence on best practice on the transfer of knowledge, including standardisation. Hands-on training should be given in innovation management and economic exploitation of research results in health/life sciences including (i) intellectual property rights and asset management (ii) preparation of viable business/exploitation plans (iii) launching successful new companies, (iv) ad-hoc knowledge transfer for academia. The proposed action should strive to include most of the EU Member States and Associated Countries. It shall complement activities provided by organisations like Enterprise Europe Network or Fit for Health and National Contact Point activities, working in synergy with them and with other EU funded supports. Applications shall provide a detailed action plan with quantitative and measurable objectives. **Note:** Limits on the EU financial contribution apply. These are implemented strictly as formal eligibility criteria.

Funding scheme: Coordination and Support Action (coordinating action)

Only up to one proposal can be selected.

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

Additional eligibility criterion:

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

HEALTH.2012.4.1-3: Support for Presidency events: Organisation of supporting actions and events related to the Presidency of the European Union. FP7-HEALTH-2012-INNOVATION-1. An integral part of the Health theme's activity is to organise, together with successive EU presidencies, events of a strategic nature. The proposed Support Action(s) should contribute to conferences or other appropriate events to be held in a Member State which will hold a forthcoming Presidency of the European Union, specifically 2012 and 2013

Presidencies, in any area of the Health Theme. In order to ensure high political and strategic relevance, the active involvement of the relevant national authority(ies) will be evaluated under criteria 'quality' and 'impact'. The proposed Support Action(s) should address topics that are of high relevance at the date of its taking place. An appropriate equilibrium should be present in the proposed action(s), with balanced presentation of various research, societal and industrial elements and points of view. Participation of non-EU stakeholders is possible. Outreach activities may be included such as *e.g.* a press programme and/or an event dedicated to raising awareness on a specific topic in schools. **Note:** Limits on the EU financial contribution apply. These are implemented strictly as formal eligibility criteria.

Funding scheme: Coordination and Support Action (supporting action)

One or more proposals can be selected.

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

Additional eligibility criterion:

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

HEALTH.2012.4.1-4: Communicating the benefits of European research to the general public. FP7-HEALTH-2012-INNOVATION-1. The objective is to support coordination actions that communicate the effects of health related scientific research to the general public. Actions would include information on the positive effects of Europe-wide collaborative research and technology development, and the benefits of cross cultural collaborations (industry-academia). Proposals should include media professionals (filmmakers, journalists) and scientists from academic organisations and industry, and possibly information distributors. Efforts should be made to ensure the multilingual potential of the project results and may be aimed at the European public in general or a specific group. Projects should be led by SMEs with proven capacities in creating high quality public productions, but the coordinator does not need to be an SME. It is expected that a team of professionals from both media and science will participate in the project. Examples of activities could include the production of a film or series of films portraying the impact of European science and research on one or more specific health issues or diseases, focused newsletters etc. Use of internet to communicate the production is encouraged. **Note:** Limits on the EU financial contribution apply. These are implemented strictly as formal eligibility criteria.

Funding scheme: Coordination and Support Action (coordinating action)

One or more proposals can be selected.

Expected impact: These actions should target to improve the visibility of EU-funded health research not only towards scientific community but also for the larger public. Successful projects should result in a tangible production, activity, event or product aimed at a high impact promotion of European science to the general public.

Additional eligibility criterion:

The **requested EU contribution** per action shall not exceed EUR 1 000 000

HEALTH.2012.4.1-5: Preparing the future for health research and innovation⁷⁴. FP7-HEALTH-2012-INNOVATION-1. Proposals for coordination actions are sought in important and/or emerging areas of health research, where there is a need to step up coordination efforts between European key players. Different actors from academia, industry, national programmes and other relevant organisations, should come together to develop a strategy plan for the further development of the targeted health research area with high impact on competitiveness, healthcare systems and benefit for European citizens' health. For all proposed activities European added value must clearly be discernible. Under this topic activities will be supported with the aim of assessing profoundly the research and/or innovation resources, gaps and needs of the thematic target area, and to evaluate its potential as a focal area for a future innovative partnership. Expert advice may be sought, and industry interest may be probed, such that in case of positive outcomes detailed roadmaps may be developed. Existing activities, such as project(s) aiming at the development of SRAs or roadmap-oriented activities, must be taken into account and - where relevant - coordination with these shall allow for synergies and exclude competition or duplication. In addition, the proposal should demonstrate how it intends to ensure maximum transparency and openness to all relevant stakeholders. Where health issues are at stake that go beyond the confines of Europe, consideration may be given to integration of European coordination efforts with pertinent other international initiatives such that Europe may play an active and leading role in the respective thematic area of health research. Relevant target institutions and channels for diffusion of the deliverables (reports, recommendations, roadmaps, etc.) have to be clearly identified. The timeframe considered for implementation should also be duly justified.

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

One or more proposals can be selected.

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

Additional eligibility criterion:

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

HEALTH.2012.4.1-6: Setting health-related development goals beyond 2015. FP7-HEALTH-2012-INNOVATION-1. This action should provide the follow up of the current Millennium Development Goals (MDGs) and propose options for a set of new, health-related development goals for the period beyond 2015. The new development goals should capture the core health challenges of the current ones, but propose a better balance between horizontal and vertical approaches to healthcare. They should also pave the way towards an improved system for global health innovation, including aspects such as capacity building and technology transfer through partnership between private and public stakeholders from developing countries, emerging economies and industrialised countries. The proposed goals should be measurable, achievable and sustainable, and should consider the constraints of developing countries for improving health outcomes themselves. **Note:** Limits on the EU financial contribution apply. These are implemented strictly as formal eligibility criteria.

⁷⁴ The topic is open for proposals in all relevant research areas covered by the topic description; however some proposals, depending on their scientific content, may contribute to the EIP "Active and Healthy Ageing".

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

Only up to one proposal can be selected.

Expected impact: This action should ensure that the health-related development objectives for the period after 2015 are based on the best scientific evidence available and address the main shortcomings of the current MDGs. Effective engagement in the global process for setting new development goals is expected, and the consortium should therefore ensure broad geographic and multidisciplinary coverage.

Additional eligibility criteria:

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

4.2 RESPONDING TO EU POLICY NEEDS

Closed in 2012

In the health work programme for 2012 most topics (28 out of 38) are related to various policy needs, especially for innovation, health and developing countries. As these topics are of specific nature, they are better placed in their area in order to be recognised by stakeholders. Consequently, the area of “responding to policy needs” is closed this year.

III IMPLEMENTATION OF CALLS

HEALTH-2012-INNOVATION

Call identifier: FP7-HEALTH-2012-INNOVATION-1

Proposal submission and evaluation: two-stage procedure.

Date of publication: 20 July 2011⁷⁵

Deadline for stage 1 proposals: 04 October 2011 at 17:00:00 (Brussels local time)⁷⁶

Indicative budget: EUR 546 million from the 2012 budget

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

The total budget of the call may vary by up to 10% of the total value of the indicated budget for each call; and

Any repartition of the call budget may also vary by up to 10% of the total value of the indicated budget for the call.

Table 1: Indicative budget lines

ACTIVITY/AREA	Indicative budget (EUR million)
1. BIOTECHNOLOGY, GENERIC TOOLS AND MEDICAL TECHNOLOGIES FOR HUMAN HEALTH	
1.2 DETECTION, DIAGNOSIS AND MONITORING	85
1.4 INNOVATIVE THERAPEUTIC APPROACHES AND INTERVENTIONS	42
2. TRANSLATING RESEARCH FOR HUMAN HEALTH	
2.1. INTEGRATING BIOLOGICAL DATA AND PROCESSES: LARGE-SCALE DATA GATHERING, SYSTEMS BIOLOGY	
2.1.1 LARGE-SCALE DATA GATHERING	
2.1.1-1 (A-C) –OMICS FOR RARE DISEASES	38
2.1.1-2 VALIDATION OF -OMICS-BASED BIOMARKERS FOR DISEASES AFFECTING THE ELDERLY	39
2.1.1-3 STATISTICAL METHODS FOR COLLECTION AND ANALYSIS OF-OMICS DATA	70
2.1.2 SYSTEMS BIOLOGY	
2.2. RESEARCH ON THE BRAIN AND RELATED DISEASES, HUMAN DEVELOPMENT AND AGEING	
2.2.2 HUMAN DEVELOPMENT AND AGEING	36
2.3. TRANSLATIONAL RESEARCH IN MAJOR INFECTIOUS DISEASES: TO CONFRONT MAJOR THREATS TO PUBLIC HEALTH	
2.3.2 HIV/AIDS, TB, MALARIA	54

⁷⁵ The Director-General responsible for this call may publish it up to one month prior to or after the envisaged date of publication.

⁷⁶ The Director-General responsible for this call may delay this deadline by up to two months.

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2.4. TRANSLATIONAL RESEARCH IN OTHER MAJOR DISEASES	
2.4.3 DIABETES AND OBESITY	36
2.4.4 RARE DISEASES	70
2.4.5 OTHER CHRONIC DISEASES	12
3. OPTIMISING THE DELIVERY OF HEALTHCARE TO EUROPEAN CITIZENS	
3.2 HEALTH CARE SYSTEMS	39
3.4 INTERNATIONAL PUBLIC HEALTH & HEALTH SYSTEMS	18
4. OTHER ACTIONS ACROSS THE HEALTH THEME	
4.1 COORDINATION AND SUPPORT ACTIONS ACROSS THE THEME	7

Table 2: Topics called:

Activity/Area	Topics called	Funding Schemes and particular requirements
1 BIOTECHNOLOGY, GENERIC TOOLS AND MEDICAL TECHNOLOGIES FOR HUMAN HEALTH		
1.2 DETECTION, DIAGNOSIS & MONITORING		
1.2	HEALTH.2012.1.2-1: Development of technologies with a view to patient group stratification for personalised medicine applications.	<i>SME-targeted Collaborative Project (small or medium-scale focused research project). One or more proposals can be selected. Additional eligibility criterion: Requested EU contribution per project: Maximum EUR 6 000 000. Projects will only be selected for funding on the condition that the estimated EU contribution going to SME(s) is 30% or more of the total estimated EU contribution for the project as a whole. This will be assessed at the end of the negotiation, before signature of the grant agreement.</i>
1.4 INNOVATIVE THERAPEUTIC APPROACHES AND INTERVENTIONS		
1.4	HEALTH.2012.1.4-1: Innovative approaches to solid organ transplantation ⁷⁷ .	<i>Collaborative Project (small or medium-scale focused research project). One or more proposals can be selected. Additional eligibility criterion: Requested EU contribution per project: Maximum EUR 6 000 000. Projects will only be selected for funding on the condition that the estimated EU contribution going to SME(s) is 15% or more of the total estimated EU contribution for the project as a whole. This will be assessed at the end of the negotiation, before signature of the grant agreement.</i>
1.4	HEALTH.2012.1.4-3: Innovative Strategies for translation of stem cell	<i>Collaborative Project (small or medium-scale focused research project). Only up to one</i>

⁷⁷ Please consult also the text for clinical trials provided in the introduction to activity 2. Translating research for human health in this work programme on pages 9/10

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	based therapies in regenerative medicine (European Union-Australia cooperation).	<i>proposal can be selected. Additional eligibility criterion: Requested EU contribution per project: Maximum EUR 6 000 000. Projects will only be selected for funding on the condition that the estimated EU contribution going to SME(s) is 15% or more of the total estimated EU contribution for the project as a whole. This will be assessed at the end of the negotiation, before signature of the grant agreement.</i>
1.4	HEALTH.2012.1.4-4: Targeted nucleic acid delivery as an innovative therapeutic or prophylactic approach ⁷⁸ .	<i>Collaborative Project (small or medium-scale focused research project). One or more proposals can be selected. Additional eligibility criterion: Requested EU contribution per project: Maximum EUR 6 000 000. Projects will only be selected for funding on the condition that the estimated EU contribution going to industry including SME(s) is 30% or more of the total estimated EU contribution for the project as a whole. This will be assessed at the end of the negotiation, before signature of the grant agreement.</i>
2 TRANSLATING RESEARCH FOR HUMAN HEALTH		
2.1 INTEGRATING BIOLOGICAL DATA AND PROCESSES: LARGE-SCALE DATA GATHERING, SYSTEMS BIOLOGY		
2.1.1 Large-scale data gathering		
2.1.1.1 –Omics for rare diseases		
2.1.1.1	HEALTH.2012.2.1.1.1-A: Support for international rare disease research.	<i>Coordination and Support Action (supporting action). Only up to one proposal can be selected. Additional eligibility criterion: Requested EU contribution per action: Maximum EUR 2 000 000.</i>
2.1.1.1	HEALTH.2012.2.1.1.1-B: Clinical utility of -omics for better diagnosis of rare diseases.	<i>Collaborative Project (large-scale integrating research project). Up to two proposals can be selected. Additional eligibility criterion: Requested EU contribution per project: Maximum EUR 12 000 000. Projects will only be selected for funding on the condition that the estimated EU contribution going to industry including SME(s) is 30% or more of the total estimated EU contribution for the project as a whole. This will be assessed at the end of the negotiation, before signature of the grant agreement.</i>
2.1.1.1	HEALTH.2012.2.1.1.1-C: Databases, biobanks and 'clinical bio-informatics' hub for rare diseases.	<i>Collaborative Project (large-scale integrating research project). Only up to one proposal can be selected. Additional eligibility criterion: Requested EU contribution per project: Maximum EUR 12 000 000.</i>
2.1.1	HEALTH.2012.2.1.1-2: Validation of -omics-based biomarkers for diseases affecting the elderly.	<i>SME-targeted Collaborative Project (large-scale integrating research project). One or more proposals can be selected. Additional eligibility criterion: Requested EU contribution per project:</i>

⁷⁸ Please consult also the text for clinical trials provided in the introduction to activity 2. Translating research for human health in this work programme on pages 9/10

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		<i>Maximum EUR 12 000 000. Projects will only be selected for funding on the condition that the estimated EU contribution going to SMEs is 30% or more of the total estimated EU contribution for the project as a whole. This will be assessed at the end of the negotiation, before signature of the grant agreement.</i>
2.1.1	HEALTH.2012.2.1.1-3: Statistical methods for collection and analysis of -omics data.	<i>SME-targeted Collaborative Project (small or medium-scale focused research project). One or more proposals can be selected. Additional eligibility criterion: Requested EU contribution per project: Maximum EUR 6 000 000. Projects will only be selected for funding on the condition that the estimated EU contribution going to SMEs is 15% or more of the total estimated EU contribution for the project as a whole. This will be assessed at the end of the negotiation, before signature of the grant agreement.</i>
2.1.2 Systems biology		
2.1.2	HEALTH.2012.2.1.2-1: Systems medicine: SME-driven research applying systems biology approaches to address medical and clinical needs.	<i>SME-targeted Collaborative Project (small or medium-scale focused research project). One or more proposals can be selected. Additional eligibility criterion: Requested EU contribution per project: Maximum EUR 3 000 000. The project duration should be up to 2 years. Projects will only be selected for funding on the condition that the estimated EU contribution going to SMEs is 30% or more of the total estimated EU contribution for the project as a whole. This will be assessed at the end of the negotiation, before signature of the grant agreement.</i>
2.1.2	HEALTH.2012.2.1.2-2: Systems medicine: Applying systems biology approaches for understanding multifactorial human diseases and their co-morbidities.	<i>Collaborative Project (large-scale integrating research project). One or more proposals can be selected. Additional eligibility criterion: Requested EU contribution per project: Maximum EUR 12 000 000.</i>
2.1.2	HEALTH.2012.2.1.2-3: Preparing for the future research and innovation activities in systems medicine.	<i>Coordination and Support Action (coordinating action). Only up to one proposal can be selected. Additional eligibility criterion: Requested EU contribution per action: Maximum EUR 3 000 000.</i>
2.2 RESEARCH ON THE BRAIN AND RELATED DISEASES, HUMAN DEVELOPMENT AND AGEING		
2.2.2 Human development and ageing		
2.2.2	HEALTH.2012.2.2.2-1: Integrative systems biology and comparative genomics for studying human ageing and/or most common age-related diseases.	<i>SME-targeted Collaborative Project (small or medium-scale focused research project). One or more proposals can be selected. Additional eligibility criterion: Requested EU contribution per project: Maximum EUR 6 000 000. Projects will only be selected for funding on the condition that the estimated EU contribution going to SMEs is 30% or more of the total estimated EU contribution for the project as a whole. This will be assessed at the end of the negotiation, before</i>

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		<i>signature of the grant agreement.</i>
2.2.2	HEALTH.2012.2.2.2-2: Investigator-driven clinical trials ⁷⁹ for optimisation of management of elderly patients with multiple diseases.	<i>SME-targeted Collaborative Project (small or medium-scale focused research project). One or more proposals can be selected. Additional eligibility criterion: Requested EU contribution per project: Maximum EUR 6 000 000. Projects will only be selected for funding on the condition that the estimated EU contribution going to SMEs is 15% or more of the total estimated EU contribution for the project as a whole. This will be assessed at the end of the negotiation, before signature of the grant agreement.</i>
2.3 TRANSLATIONAL RESEARCH IN MAJOR INFECTIOUS DISEASES: TO CONFRONT MAJOR THREATS TO PUBLIC HEALTH		
2.3.2 HIV/AIDS, malaria and tuberculosis		
2.3.2	HEALTH.2012.2.3.2-1: Co-infection of HIV/AIDS, malaria, tuberculosis and/or hepatitis.	<i>Collaborative Project (small or medium-scale focused research project). One or more proposals can be selected. Additional eligibility criterion: Requested EU contribution per project: Maximum EUR 6 000 000.</i>
2.3.2	HEALTH.2012.2.3.2-2: Co-morbidity between infectious and non-communicable diseases.	<i>Collaborative Project (small or medium-scale focused research project). One or more proposals can be selected. Additional eligibility criterion: Requested EU contribution per project: Maximum EUR 6 000 000.</i>
2.3.2	HEALTH.2012.2.3.2-3: Prevention and treatment for HIV/AIDS, malaria and tuberculosis.	<i>SME-targeted Collaborative Project (small or medium-scale focused research project). One or more proposals can be selected. Additional eligibility criterion: Requested EU contribution per project: Maximum EUR 6 000 000. Projects will only be selected for funding on the condition that the estimated EU contribution going to SMEs is 15% or more of the total estimated EU contribution for the project as a whole. This will be assessed at the end of the negotiation, before signature of the grant agreement.</i>
2.3.2	HEALTH.2012.2.3.2-4: Low-cost interventions for disease control in resource poor settings.	<i>Collaborative Project (small or medium-scale focused research project). One or more proposals can be selected. Additional eligibility criterion: Requested EU contribution per project: Maximum EUR 3 000 000.</i>
2.4 TRANSLATIONAL RESEARCH IN OTHER MAJOR DISEASES		
2.4.3 Diabetes and obesity		
2.4.3	HEALTH.2012.2.4.3-1: Innovative approach to manage diabetes.	<i>SME-targeted Collaborative Project (small or medium-scale focused research project). One or more proposals can be selected. Additional eligibility criterion: Requested EU contribution</i>

⁷⁹ Please consult also the text for clinical trials provided in the introduction to activity 2. Translating research for human health in this work programme on pages 9/10

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		<i>per project: Maximum EUR 6 000 000. Projects will only be selected for funding on the condition that the estimated EU contribution going to SMEs is 30% or more of the total estimated EU contribution for the project as a whole. This will be assessed at the end of the negotiation, before signature of the grant agreement.</i>
2.4.3	HEALTH.2012.2.4.3-2: Investigator-driven clinical trials ⁸⁰ for type 1 diabetes research.	<i>Collaborative Project (small or medium-scale focused research project). One or more proposals can be selected. Additional eligibility criterion: Requested EU contribution per project: Maximum EUR 6 000 000.</i>
2.4.4 Rare diseases		
2.4.4	HEALTH.2012.2.4.4-1: Preclinical and/or clinical ⁸¹ development of substances with a clear potential as orphan drugs.	<i>Collaborative Project (small or medium-scale focused research project). One or more proposals can be selected. Additional eligibility criterion: Requested EU contribution per project: Maximum EUR 6 000 000. Projects will only be selected for funding on the condition that the estimated EU contribution going to industry including SME(s) is 30% or more of the total estimated EU contribution for the project as a whole. This will be assessed at the end of the negotiation, before signature of the grant agreement.</i>
2.4.4	HEALTH.2012.2.4.4-2: Observational trials ⁸² in rare diseases.	<i>Collaborative Project (small or medium-scale focused research project). One or more proposals can be selected. Additional eligibility criterion: Requested EU contribution per project: Maximum EUR 3 000 000.</i>
2.4.4	HEALTH.2012.2.4.4-3: Best practice and knowledge sharing in the clinical management of rare diseases.	<i>Coordination and Support Action (coordinating action). Only up to one proposal can be selected. Additional eligibility criterion: Requested EU contribution per action: Maximum EUR 2 000 000.</i>
2.4.5 Other chronic diseases		
2.4.5	HEALTH.2012.2.4.5-2: Biomarkers and diagnostics for chronic inflammatory diseases of the joints and/or digestive system.	<i>SME-targeted Collaborative Project (small or medium-scale focused research project). One or more proposals can be selected. Additional eligibility criterion: Requested EU contribution per project: Maximum EUR 6 000 000. Projects will only be selected for funding on the condition that the estimated EU contribution going to SMEs is 15% or more of the total estimated EU contribution for the project as a whole. This will be assessed at the end of the negotiation, before</i>

⁸⁰ Please consult also the text for clinical trials provided in the introduction to activity 2. Translating research for human health in this work programme on pages 9/10

⁸¹ Please consult also the text for clinical trials provided in the introduction to activity 2. Translating research for human health in this work programme on pages 9/10

⁸² Please consult also the text for clinical trials provided in the introduction to activity 2. Translating research for human health in this work programme on pages 9/10

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		<i>signature of the grant agreement.</i>
3. OPTIMISING THE DELIVERY OF HEALTHCARE TO EUROPEAN CITIZENS		
3.2 QUALITY, EFFICIENCY AND SOLIDARITY OF HEALTH CARE SYSTEMS INCLUDING TRANSITIONAL HEALTH SYSTEMS		
3.2	HEALTH.2012.3.2-1: Improving the organisation of health service delivery.	<i>Collaborative Project (small or medium-scale focused research project). One or more proposals can be selected. Additional eligibility criterion: Requested EU contribution per project: Maximum EUR 3 000 000.</i>
3.2	HEALTH.2012.3.2-2: New methodologies for health technology assessment.	<i>Collaborative Project (small or medium-scale focused research project). One or more proposals can be selected. Additional eligibility criterion: Requested EU contribution per project: Maximum EUR 3 000 000.</i>
3.2	HEALTH.2012.3.2-3: Social innovation for active and healthy ageing.	<i>Collaborative Project (small or medium-scale focused research project). One or more proposals can be selected. Additional eligibility criterion: Requested EU contribution per project: Maximum EUR 3 000 000.</i>
3.4 INTERNATIONAL PUBLIC HEALTH & HEALTH SYSTEMS		
3.4	HEALTH.2012.3.4-1: Research on health systems and services in low- and middle-income countries.	<i>Specific International Cooperation Action (SICA), Collaborative Project (small or medium-scale focused research project) target regions: All international cooperation countries (ICPC)⁸³. One or more proposals can be selected. Additional eligibility criterion: Requested EU contribution per project: Maximum EUR 6 000 000. Projects will only be selected for funding on the condition that consortia include a minimum of 6 different ICPC partners and a minimum of 2 EU/AC partner from different countries.</i>
4 OTHER ACTIONS ACROSS THE HEALTH THEME		
4.1 COORDINATION AND SUPPORT ACTIONS ACROSS THE THEME		
4.1	HEALTH.2012.4.1-1: Network to encourage knowledge transfer activity in FP-funded health research (especially in academic and governmental organisations).	<i>Coordination and Support Action (coordinating action). Only up to one proposal can be selected. Additional eligibility criterion: Requested EU contribution per action: Maximum EUR 2 000 000.</i>
4.1	HEALTH.2012.4.1-2: Training actions linked to intellectual property rights management and knowledge transfer.	<i>Coordination and Support Action (coordinating action). Only up to one proposal can be selected. Additional eligibility criterion: Requested EU contribution per action: Maximum EUR 2 000 000.</i>
4.1	HEALTH.2012.4.1-3: Support for Presidency events: Organisation of supporting actions and events related to	<i>Coordination and Support Action (supporting action). One or more proposals can be selected. Additional eligibility criterion: Requested EU</i>

⁸³ The list of international cooperation partner countries (ICPC) is provided in Annex I to the Cooperation Programme <ftp://ftp.cordis.europa.eu/pub/fp7/docs/icpc-list.pdf>

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	the Presidency of the European Union.	<i>contribution per action: Maximum EUR 100 000.</i>
4.1	HEALTH.2012.4.1-4: Communicating the benefits of European research to the general public.	<i>Coordination and Support Action (coordinating action). One or more proposals can be selected. Additional eligibility criterion: Requested EU contribution per action: Maximum EUR 1 000 000.</i>
4.1	HEALTH.2012.4.1-5: Preparing the future for health research and innovation.	<i>Coordination and Support Action (supporting action). One or more proposals can be selected. Additional eligibility criterion: Requested EU contribution per action: Maximum EUR 500 000.</i>
4.1	HEALTH.2012.4.1-6: Setting health-related development goals beyond 2015.	<i>Coordination and Support Action (coordinating action). Only up to one proposal can be selected. Additional eligibility criteria: Requested EU contribution per action: Maximum EUR 2 000 000.</i>

Conditions for FP7-HEALTH-2012-INNOVATION-1

It is important to note that the basic conditions for eligibility must be met, such as the minimum number of participants (in most cases 3, except for SICA and SA) or the budget ceiling for the maximum requested EU contribution and in some cases a maximum project duration. However **there is no obligation to go beyond the minimum number of participants unless additional partners are needed to achieve the objectives of the project.** The **duration of the project** should be in line with the realistic planning of the project. The size of the **EU contribution** to the budget should also be in line with the needs of the consortia, within the maximum EU contribution, but not necessarily up to the maximum.

The quality, feasibility, implementation and impact 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.

Eligibility criteria for each proposal are checked by Commission staff before the evaluation begins. Proposals which do not fulfil these criteria will not be included in the evaluation.

Eligibility conditions (stage 1 and stage 2):

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

Table 3: Standard minimum number of participating legal entities for all funding schemes used in the call, in line with the Rules for Participation and in the below format, unless otherwise specified in section II of the work programme.

Funding scheme	Minimum conditions ⁸⁴
Collaborative Project	At least 3 independent legal entities, each of which is established in a MS or AC, and no 2 of which are established in the same MS or AC
Coordination and Support Action (coordinating action)	At least 3 independent legal entities, each of which is established in a MS or AC, and no 2 of which are established in the same MS or AC
Coordination and Support Action (supporting action)	At least 1 independent legal entity.

Specific conditions for this call:

Collaborative project for specific cooperation Action (SICA) dedicated to international cooperation partner countries, topic HEALTH.2012.3.4-1	At least 8 independent legal entities. Of these, 2 must be established in different MS or AC. The other 6 must be established in different international cooperation partner countries (ICPC ⁸⁵).
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The eligibility criteria apply to both first and second stage proposals. At stage 1, only information provided in part A of the proposal will be used to determine whether the proposal is eligible with respect to overall budget threshold (budget ceilings for requested EU contribution per project), while part B will be used to check the number of eligible participants. At stage 2, part A will be used alone to determine these eligibility conditions.

The following additional eligibility criteria apply in this call:

- **At stage 1 and stage 2**, It is important to note that the upper limits (ceilings) for the requested EU contribution given per topic in section II of this work programme will be applied as an additional eligibility criterion and that proposals, which do not respect these limits, will be considered as ineligible.
- **At stage 2**, for topics requiring a certain percentage of EU funding going to SMEs or industry, the following additional eligibility procedure will be applied: Projects will only be selected for funding on the condition that the estimated EU contribution going to SME(s) or industry is at the threshold (or more for the project as a whole) as set out with the topic description in section II. *This will be finally assessed during the negotiation, before signature of the grant agreement. Proposals not fulfilling this criterion will not be funded.*

Evaluation procedure:

⁸⁴ These can differ for specific topics, please consult always the topic description in section II

⁸⁵ The list of international cooperation partner countries (ICPC) is provided in Annex I to the Cooperation Programme <ftp://ftp.cordis.europa.eu/pub/fp7/docs/icpc-list.pdf>

- The evaluation criteria and scoring scheme are set out in annex 2 to the work programme.
- Proposal page limits: Applicants must ensure that proposals conform to the page limits and layout given in the Guide for Applicants, and in the proposal part B template available through the EPSS.
- The Commission will instruct the experts to disregard any pages exceeding these limits.
- The minimum font size allowed is 11 points. The page size is A4, and all margins (top, bottom, left, right) should be at least 15 mm (not including any footers or headers).
- A two-stage submission and evaluation procedure will be used.
- Experts will carry out the individual evaluation of proposals remotely.

Additional information regarding evaluation criteria and procedures:

- *For proposals failing to achieve a threshold for a criterion, the evaluation of the proposal will be stopped at the first criterion failing a threshold. Therefore for such proposals the ESR (evaluation summary report) will not contain marks and comments for the remaining criteria. Successful proposals must pass the minimum thresholds.*
- *In line with the objectives of each topic, additional evaluation criteria may be indicated in the work programme under the respective topic in section II.*
- *The following aspects will be considered for SME-targeted Collaborative Projects under the evaluation criterion relating to 'implementation':*
 - ➔ *Proposals are expected to have a substantial involvement of SMEs. As an indication of the expected level of involvement, evaluators should note that only proposals which fulfil the conditions as set out in the topic for the percentage of the estimated EU contribution going to SMEs will be eventually selected. This will be checked definitively at the end of any negotiation.*
 - ➔ *The leading role of SMEs with R&D capacities: the coordinator does not need to be an SME, but the participating SMEs should have a decision making power in the project management, and the output should be for the benefit of the participating SMEs and the targeted SME-dominated industrial communities.*
- ***Proposal ranking:*** *The series of priority lists will be prepared by the panels of external experts, per indicative budget line as set out in table 1 of this call fiche. The aspects taken into account for establishing a priority order for ranking of proposals are set out in annex 2 of the work programme.*

Stage 1 proposals

- *Stage 1 proposals must be submitted by the deadline mentioned above.*
- *Stage 1 proposals must follow the instructions set out in the guide for applicants and in the proposal part B template available through EPSS. Proposals should focus on the overall scientific and technological content and on clear identification of the milestones and deliverables to be reached (intended results), their intended use and the expected impact (scientific, economic, social, environmental, etc. and as set out in section II under each topic) in a maximum of 6 pages (excluding the cover page and the required tables).*

The maximum page limits of each section must be respected. The Commission will instruct the independent external experts (evaluators of proposals) to disregard any pages in excess of these limits. A minimum font size of 11 is required.

- *Stage 1 proposals will be individually evaluated remotely by independent external experts and discussed in consensus meetings.*
- *Stage 1 proposals will be evaluated on the basis of the following two criteria: **Scientific/technological quality** and **Impact**. For each criterion, marks from 0 to 5 will be given, with the possibility of half-point scores. For proposals failing to achieve a threshold for a criterion, the evaluation of the proposal will be stopped at the first criterion failing a threshold. Therefore for such proposals the ESR (evaluation summary report) will not contain marks and comments for the remaining criteria. Proposals must pass the minimum thresholds as follows:*

Table 4: Thresholds for evaluation criteria for first stage

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

- *All Proposals passing all thresholds will be retained at stage 1.*
- *Coordinators of proposals retained at stage 1 (proposals passing the evaluation thresholds) will be invited to submit a complete proposal (stage 2 proposal) that will then be evaluated against the entire set of evaluation criteria. In line with the objectives of each topic, additional eligibility criteria may be indicated in the work programme.*

Stage 2 proposals

- *The deadline for submission for stage 2 proposals will be specified in the invitation to submit. The **indicative deadline** for stage 2 proposals is in February 2012.*
- *Stage 2 proposals are evaluated on the basis of the following three criteria: **Scientific/technological quality** and **Implementation** and **Impact**.*
- *For each criterion, marks from 0 to 5 will be given, with the possibility of half-point scores. For proposals failing to achieve a threshold for a criterion, the evaluation of the proposal will be stopped at the first criterion failing a threshold. Therefore for such proposals the ESR (evaluation summary report) will not contain marks and comments for the remaining criteria. Proposals must pass the minimum thresholds as follows:*

Table 5: Thresholds for evaluation criteria for second stage

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

- *In line with the objectives of each topic, additional evaluation criteria may be indicated in the work programme under the respective topic in section II.*
- *The following aspects will be considered for SME-targeted Collaborative Projects under the evaluation criterion relating to 'implementation':*
 - ➔ *Proposals are expected to have a substantial involvement of SMEs. As an indication of the expected level of involvement, applicants and evaluators should note that only proposals which fulfil the conditions as set out in the topic for the percentage of the estimated EU contribution going to SMEs will be eventually selected. This will be checked definitively at the end of any negotiation.*
 - ➔ *The leading role of SMEs with R&D capacities: the coordinator does not need to be an SME, but the participating SMEs should have a decision making power in the project management, and the output should be for the benefit of the participating SMEs and the targeted SME-dominated industrial communities.*

Proposal ranking at stage 2:

- **For stage 2:** *There will be differing numbers of proposals short-listed according to the topic description in section II.*
- *However, there may be topics for which no proposals are of sufficient quality to be selected for funding, as there will be competition within topics and between topics on the basis of the quality of the proposals.*
- **For stage 2:** *The Commission ranked lists of proposals to be retained for negotiation will be based on the priority list established by the panel of independent external experts taking into account the budget available for each budget line (as indicated in this call for proposals). For each budget line, a number of proposals below the indicative budget cut-off line on the Commission ranked list may be kept on a reserve list to allow for eventualities such as the failure of negotiations on grant agreements, the withdrawal of proposals, budget savings agreed during negotiation, or the availability of additional budget from other sources.*

Indicative timetable for Stage 1 and 2: The stage 1 evaluation should be finalised by mid December 2011. The evaluation of the stage 2 is expected to take place in March 2012. Overall evaluation results: estimated to be available within 3 months after the closure date for stage 2 proposals. It is expected that grant agreement negotiations for short-listed proposals would begin in May 2012.

Consortium agreements: Participants in collaborative projects with a requested **EU-contribution higher than EUR 3 000 000** are required to conclude a consortium agreement. For collaborative projects with a requested **EU-contribution up to EUR 3 000 000** a

consortium agreement is not mandatory but recommended. For **coordination and support actions** a consortium agreement is not mandatory.

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

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

Dissemination. Grant agreements of projects financed under this call for proposals will include the special clause 39 on the "Open Access Pilot in FP7". Under this clause, beneficiaries are required to make their best efforts to ensure free access to peer-reviewed articles resulting from projects via an institutional or subject-based repository.

FP7-HEALTH-2012-SMEs-FOR-INNOVATION

Call identifier: FP7-HEALTH-2012-INNOVATION-2

Proposal submission and evaluation: two-stage procedure.

Date of publication: 20 July 2011⁸⁶

Deadline for stage 1 proposals: 27 September 2011 at 17:00:00 (Brussels local time)⁸⁷

Indicative budget: EUR 108 million from the 2012 budget

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

The total budget of the call may vary by up to 10% of the total value of the indicated budget for each call; and

Any repartition of the call budget may also vary by up to 10% of the total value of the indicated budget for the call.

Table 1: Indicative budget lines

ACTIVITY/AREA	Indicative budget (EUR million)
1. BIOTECHNOLOGY, GENERIC TOOLS AND MEDICAL TECHNOLOGIES FOR HUMAN HEALTH	
1.4 INNOVATIVE THERAPEUTIC APPROACHES AND INTERVENTIONS	42
2. TRANSLATING RESEARCH FOR HUMAN HEALTH	
2.3. TRANSLATIONAL RESEARCH IN MAJOR INFECTIOUS DISEASES: TO CONFRONT MAJOR THREATS TO PUBLIC HEALTH	
2.3.0 CROSS-CUTTING	36
2.4. TRANSLATIONAL RESEARCH IN OTHER MAJOR DISEASES	
2.4.5 OTHER CHRONIC DISEASES	30

Table 2: Topics called:

Activity/Area	Topics called	Funding Schemes and particular requirements
1. BIOTECHNOLOGY, GENERIC TOOLS AND MEDICAL TECHNOLOGIES FOR HUMAN HEALTH		
1.4 INNOVATIVE THERAPEUTIC APPROACHES AND INTERVENTIONS		
1.4	HEALTH.2011.1.4-2: Medical technology for transplantation and bioartificial organs.	<i>Collaborative Project (small or medium-scale focused research project). One or more proposals can be selected.</i>
2.3. TRANSLATIONAL RESEARCH IN MAJOR INFECTIOUS DISEASES: TO CONFRONT MAJOR THREATS TO PUBLIC HEALTH		

⁸⁶ The Director-General responsible for this call may publish it up to one month prior to or after the envisaged date of publication.

⁸⁷ The Director-General responsible for this call may delay this deadline by up to two months.

2.3.0 Cross-cutting		
2.3.0	HEALTH.2012.2.3.0-1: Diagnostics for infectious diseases in humans.	<i>Collaborative Project (small or medium-scale focused research project). One or more proposals can be selected.</i>
2.4 TRANSLATIONAL RESEARCH IN OTHER MAJOR DISEASES		
2.4.3 Other chronic diseases		
2.4.5	HEALTH.2012.2.4.5-1: Technological approaches to combating sensory impairments.	<i>Collaborative Project (small or medium-scale focused research project). One or more proposals can be selected.</i>

Conditions for FP7-HEALTH-2012-INNOVATION-2:

It is important to note that once the basic conditions for eligibility are met - such as the minimum number of participants 3 and maximum 5 or the budget ceiling of EUR 6 million for the requested EU contribution or the maximum project duration of 3 years – within these limits it is entirely up to the applicants to propose a number of partners, a duration of the project or the financial contribution requested from the EU. The budget should also be in line with the needs of the consortia, within the maximum EU contribution, but not necessarily at it.

The quality, feasibility, implementation and impact 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.

Eligibility criteria for each proposal are checked by Commission staff before the evaluation begins. Proposals which do not fulfil these criteria will not be included in the evaluation. However, a proposal can be declared ineligible at any time of the process, e.g. for financial eligibility.

Specific feature for this call: This call is dedicated to a specific SME innovation initiative designed to encourage stronger SME efforts towards research and innovation. SMEs need to have a leading or coordinating role in the consortium and **50 % of EU funding requested going to SMEs or SMEs joint venture**. Expected project results should be of clear interest and potential benefit to SME(s).

Eligibility conditions (stage 1 and stage 2):

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

Table 3: Specific for this call: minimum and maximum number of participating legal entities for the funding scheme used in this call.

Funding scheme	Minimum conditions
Collaborative Project	Number of participants: At least 3 and maximum 5 independent legal entities, each of which is established in a EU Member State or Associated Country, and at least 3 are established in 3 different MS or AC.

The eligibility criteria apply to both first and second stage proposals. At stage 1, only information provided in part A of the proposal will be used to determine whether the proposal is eligible with respect to overall budget threshold (budget ceilings for requested EU contribution per project), while part B will be used to check the number of eligible participants. At stage 2, part A will be used alone to determine these eligibility conditions.

The following additional eligibility criteria apply in this call:

At stage 1 and stage 2:

- The **requested EU contribution** per project should depend on the needs of the project and shall not exceed a maximum of EUR 6 000 000.
- The proposed **project duration** indicated in the proposal should be up to 3 years.
- **Participation is restricted** to 3-5 entities established in EU Member States and Associated Countries.

At stage 2:

- **Participants including SME(s)** need to be 1) at least 51% owned and controlled by one or more individuals who are citizens of one of the EU Member States or Associated Countries or permanent residents in one of those countries, or 2) at least 51% owned and controlled by another business concern that is itself at least 51% owned and controlled by individuals who are citizens of, or permanent residents in those countries.
- **50 % of EU funding requested going to SMEs or SMEs joint venture:** Projects will only be selected for funding on the condition that the estimated EU contribution going to SME(s) is at the threshold (or more) for the project as a whole as set out with the topic description in section II. This will be finally assessed during the negotiation, before signature of the grant agreement. Proposals not fulfilling this criterion will not be funded.
- The **financial viability of all partners** in selected projects needs to fulfil the Commission requirements. This will be checked at the stage 2 evaluation and at negotiation.
- Applicants invited to present a full proposal for stage 2 are requested to submit (together with the proposal) a detailed exploitation plan, clearly describing the valorisation of the technology to be developed.

Evaluation procedure for stage 1 and 2:

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

- A two-stage submission and evaluation procedure will be used.

Additional information regarding evaluation criteria and procedures for stage 1 and 2:

- For proposals failing to achieve a threshold for a criterion, the evaluation of the proposal will be stopped at the first criterion failing a threshold. Therefore for such proposals the ESR (evaluation summary report) will not contain marks and comments for the remaining criteria. Successful proposals must pass the minimum thresholds.
- In line with the objectives of each topic, additional evaluation criteria may be indicated in the work programme under the respective topic in section II.

Proposal ranking: The priority lists will be prepared by the panels of external experts, per indicative budget line as set out in table 1 of this call fiche.

Stage 1 proposals

- *Stage 1 proposals must be submitted by the deadline mentioned above.*
- *Stage 1 proposals must follow the instructions set out in the guide for applicants and in the proposal part B template available through EPSS. Proposals should focus on the overall scientific and technological content and on clear identification of the milestones and deliverables to be reached (intended results), their intended use (including an outline exploitation plan) and the expected impact as set out in section II under each topic in a maximum of 3 pages (excluding the cover page and the required tables). **The maximum page limits of each section must be respected.** The Commission will instruct the independent external experts (evaluators of proposals) to disregard any pages in excess of these limits. A minimum font size of 11 is required. The page size is A4, and all margins (top, bottom, left, right) should be at least 15 mm (not including any footers or headers).*
- *Stage 1 proposals will be evaluated remotely by independent external experts, including a remote consensus.*
- *Stage 1 proposals will be evaluated on the basis of the following two criteria: **Scientific/technological quality and Impact.** For each criterion, marks from 0 to 5 will be given, with the possibility of half-point scores. For proposals failing to achieve a threshold for a criterion, the evaluation of the proposal will be stopped at the first criterion failing a threshold. Therefore for such proposals the ESR (evaluation summary report) will not contain marks and comments for the remaining criteria. Proposals must pass the minimum thresholds as follows:*

Table 4: Thresholds for evaluation criteria for first stage

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

- *All Proposals passing all thresholds will be retained at stage 1.*
- *Coordinators of proposals retained at stage 1 (proposals passing the evaluation thresholds) will be invited to submit a complete proposal (stage 2 proposal) that will then be evaluated against the entire set of evaluation criteria. In line with the objectives of each topic, additional eligibility criteria may be indicated in the work programme.*

Stage 2 proposals

- *The deadline for submission for stage 2 proposals will be specified in the invitation to submit. The **indicative deadline** for stage 2 proposals is in December 2011.*
- *Stage 2 proposals must respect the maximum of 20 pages (excluding the cover page and the required tables) and must follow the instructions set out in the guide for applicants and in the proposal part B template available through EPSS. Proposals should focus on the overall scientific and technological content and on clear identification of the milestones and deliverables. A proper statistical section for clinical trials or experimental design should be provided where appropriate. In the section expected impact the intended results (scientific, economic, social, environmental, etc. and as set out in section II under each topic) should be described.*
- *Proposal page limits: Applicants must ensure that proposals conform to the page limits and layout given in the Guide for Applicants, and in the proposal part B template available through the EPSS.*
- *The Commission will instruct the experts to disregard any pages exceeding these limits.*
- *The minimum font size allowed is 11 points. The page size is A4, and all margins (top, bottom, left, right) should be at least 15 mm (not including any footers or headers).*
- *Stage 2 proposals are evaluated on the basis of the following three criteria: **Scientific/technological quality and Implementation and Impact.***
- *For each criterion, marks from 0 to 5 will be given, with the possibility of half-point scores. For proposals failing to achieve a threshold for a criterion, the evaluation of the proposal will be stopped at the first criterion failing a threshold. Therefore for such proposals the ESR (evaluation summary report) will not contain marks and comments for the remaining criteria. Proposals must pass the minimum thresholds as follows:*

Table 5: Thresholds for evaluation criteria for second stage

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

- *The following aspects will be considered for proposals submitted to this call under the evaluation criterion relating to 'implementation':*
 - ➔ *Proposals are expected to have 50 % of the requested EU contribution going to SMEs or SME joint ventures. Applicants and evaluators should note that only proposals which fulfil these conditions will be eventually selected. This will be checked definitively at the end of any negotiation.*
 - ➔ *The leading role of SMEs or SME joint ventures with R&D capacities: the coordinator does not need to be an SME, but the participating SMEs should have a decision making power in the project management (e.g. veto rights), and the output should be for the benefit of them.*
 - ➔ *Within the limits of a maximum requested EU contribution of EUR 6 million, any amount requested from EU is possible, including very small amounts but the adequacy of resources/budget will be strictly scrutinized during the stage 2 evaluation.*
 - ➔ *Evaluators will also consider financial capacity aspects at stage 2, as they will have a significant influence on the potential impact, exploitation plan and related capacity.*

Proposal ranking at stage 2:

- *Proposals will be short-listed per indicative budget line.*
- *There may be topics for which no proposals are of sufficient quality to be selected for funding.*
- *The Commission ranked lists of proposals to be retained for negotiation will be based on the priority list established by the panel of independent external experts taking into account the budget available for each budget line (as indicated in this call for proposals). For each budget line, a number of proposals below the indicative budget cut-off line on the Commission ranked list may be kept on a reserve list to allow for eventualities such as the failure of negotiations on grant agreements, the withdrawal of proposals, budget savings agreed during negotiation, or the availability of additional budget from other sources.*

Indicative timetable for Stage 1 and 2: The stage 1 evaluation should be finalised by end of October 2011. The deadline for stage 2 proposals is expected to be mid December 2011. The evaluation of the stage 2 is expected to take place in January 2012. Overall evaluation results: estimated to be available within 2 months after the closure date for stage 2 proposals. It is expected that grant agreement negotiations for short-listed proposals would begin in February 2012.

Consortium agreements: Participants are required to conclude a consortium agreement. Even if a SME is not the coordinator, the protection of interests of the participating SMEs should be guaranteed through appropriate governance mechanisms (e.g. veto right) within the consortium agreement.

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

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

Dissemination. Grant agreements of projects financed under this call for proposals will include the special clause 39 on the "Open Access Pilot in FP7". Under this clause, beneficiaries are required to make their best efforts to ensure free access to peer-reviewed articles resulting from projects via an institutional or subject-based repository.

IV OTHER ACTIVITIES⁸⁸ (not implemented through calls for proposals)

Prize Competition – development of a novel alternative to cold-chain technologies for vaccine formulation, preservation and transportation

This prize will reward the development of a novel alternative to cold-chain technologies for the effective formulation, preservation and transport of vaccines for human use, to and within developing countries. The rules of the contest will be established and published⁸⁹ by the European Commission, which will directly launch and manage the contest and award the prizes based on the judgement of independent experts.

Vaccines can become less effective, or even useless when exposed to temperatures outside the recommended range (at both upper and lower limits) and/or on exposure to light. Many vaccines therefore require refrigeration and a cold chain to maintain stability and viability, throughout transportation, storage and delivery to point of use. This cold chain is expensive and cumbersome, difficult to maintain, particularly in developing countries, where cost may also be prohibitive. Systems which rely on a cold chain are thus an inadequate solution to vaccination preservation and transportation. The additional necessity for protection from light presents additional constraints. Many vaccines are consequently destroyed, with investments lost, costs increased, and most importantly, potential recipients unvaccinated.

Launch of competition: 16 April 2012

Deadline for submission of proposals: 03 September 2013 at 17:00:00 (Brussels local time) with **mandatory registration for all participants by 30 April 2013** at 17:00:00 (Brussels local time)

Eligibility and specific evaluation criteria

Eligibility criteria: Participants in the competition must be legally established in an EU Member State or in countries associated to the Seventh Research Framework Programme.

Award criteria:

The prize for the "development of an alternative to cold-chain technologies for vaccine formulation, preservation and transportation" will be awarded, after closure of the competition, to the contestant who in the opinion of the jury provides a solution that best addresses the following cumulative criteria⁹⁰. Note also that applications that concern only one vaccine, or vaccines with limited impact (for example, those targeting limited populations) will not be considered. Similarly, the solution should be both developed by the contestant and novel.

1. The solution ensures that vaccines can be safely transported such that the vaccine will maintain its full potency/effectiveness.

⁸⁸ In accordance with Article 14(d) of Regulation (EC) No 1906/2006 of 18 December 2006 laying down the rules for the participation of undertakings, research centres and universities in actions under the Seventh Framework Programme and for the dissemination of research results (2007-2013).

In accordance with Article 108(2)(d) of the Financial Regulation and Article 160a of the detailed rules of the implementation of the Financial Regulation.

⁸⁹ On its 'participant portal' (<http://ec.europa.eu/research/participants/portal/page/home>) but also actively publicised elsewhere to maximise participation.

⁹⁰ Subject to further clarification in the competition rules which will be released at competition launch.

2. To maintain reasonable potential marketability, the cost of the solution to point of use (including developing countries) or cost per unit of vaccine shall not exceed the cost of existing solutions, by more than a factor of two.

Funding Scheme: Prizes⁹¹

Indicative budget: EUR 2 000 000

Expected impact: The solution would lead to an improved ability to implement vaccination programmes, irrespective of location and without significant cost increases.

The activity will be implemented through an inducement prize competition. **A group of independent experts** will assess the quality of the applications, and will determine the winner. **Funding scheme:** CSA – expert appointment⁹² (indicative budget: EUR 100 000)

Human Frontier Science Programme Organisation

An annual subscription to the international Human Frontier Science Programme Organisation (HFSPO)⁹³ will be made jointly with the Information and Communication Technologies (ICT) Theme. This will allow EU non-G8 Member States to fully benefit from the Human Frontier Science Programme (HFSP) and provide increased visibility for European research. Out of the total European Union subscription of EUR 4 492 000 for 2012, EUR 2 695 000 will be paid from this theme, and the remainder from the ICT Theme. **Funding scheme:** CSA – subscription.

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

In line with the Communication from the Belgium Presidency of the Council of the European Union to the Competitiveness Council on a second phase of the EDCTP the main objectives of the action are: i) to perform preparatory activities in view of a potentially expanded scope of EDCTP that will address all phases of clinical trials (phase I-IV) for the development of new or improved products to combat poverty-related and neglected infectious diseases, and research on the delivery of clinical interventions; ii) to deliver a comprehensive mapping of existing national programmes on research, development and external actions related to poverty-related and neglected infectious diseases ; iii) to seek further integration and profile of African sites, centre and researchers; iv) to develop further links with industry, like-minded organisations, funders, non-EDCTP member countries, and other bodies working in the field; v) to strengthening the capacity development and networking activities undertaken by EDCTP-I in coordination with training programmes from other organisations, vi) to increase awareness on EDCTP achievements and to this end organise a conference in Spring 2012 in Brussels, involving high-level representatives from African countries, the European Parliament, EU Member States, FP7 Associated Countries, like-minded organisations,

⁹¹ In accordance with Article 30 of Regulation (EC) No 1906/2006 of 18 December 2006 laying down the rules for the participation of undertakings, research centres and universities in actions under the Seventh Framework programme and for the dissemination of research results (2007-2013).

⁹² In accordance with Articles 14(c), 17 and 27(5) of Regulation (EC) No 1906/2006 of 18 December 2006 laying down the rules for the participation of undertakings, research centres and universities in actions under the Seventh Framework Programme and for the dissemination of research results (2007-2013)

⁹³ The European Union is a member of the HFSP Organisation (HFSPO) and has funded HFSP under previous Framework Programmes.

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

The impact of ethics review on health research

The objective is to examine the impact of ethics committees on the output and quality of scientific research. The work should foresee well-structured and innovative approaches to provide data regarding the different methodologies used for ethics review across the EU, to determine best practice and draft recommendations. It should include the systematic review of recent literature, the use of small but focused surveys, evaluation of conference abstracts and discussions with key opinion leaders and stakeholders. **Funding scheme:** CSA - by experts appointment (indicative budget: EUR 100 000).

Exploring the future optimal structure for health research and innovation in Europe

A high level expert group will provide recommendations to render the health research and innovation (R&I) system in Europe more effective and more efficient in order that it can generate more and better healthcare benefits for citizens and increased and sustainable economic benefits from a competitive health research and innovation sector. The group will define a vision for the future structure of health R&I in the EU and will propose concrete actions (including milestones, deliverables and timelines) for the achievement of reinforced political and operational coordination in health research and innovation programmes. The outcomes of this project will be used to design an effective and efficient European research and innovation system; they will improve co-ordination within the Common Strategic Framework, with Member States and with third countries. **Funding scheme:** CSA - by expert appointment (indicative budget: EUR 300.000)

EDCTP Impact Assessment - update

An assessment of the impact of the EDCTP programme will be supported, with the aim to launch of EDCTP- 2 initiative under Art. 185. It should build on and integrate the impact assessment carried out in 2010 and should identify the strengths and weaknesses and opportunities of research under EDCTP covering the relevant social, economic and environmental aspects. The assessment should also identify any critical issue with regards to the renewal of this initiative. **Funding scheme:** CSA - by appointment of experts (indicative budget: EUR 100 000)

Assessment(s) on 'Impacts of Framework Programmes in the area of Public Health research'

The assessment(s) should be carried out and thoroughly analyse the impact of Framework Programmes 5, 6 and 7 in the area of Public Health research. Long term effects on EU policies, the economy, the society, as well as needs for future health research will be identified and when possible quantified. **Funding scheme:** CSA - by appointment of experts (indicative budget: EUR 100 000)

V BUDGET**THEME HEALTH - INDICATIVE BUDGET**

Activities	2012 Budget EUR million⁹⁴
CALL FP7-HEALTH-2012-INNOVATION-1	546.00
CALL FP7-HEALTH-2012-INNOVATION-2	108.00
CALL FP7-ERANET-2012-RTD⁹⁵	2.00
CALL FP7-JPROG-2012-RTD⁹⁶	2.00 ⁹⁷
General activities (cf Annex) (details below)	9.62
OTHER ACTIVITIES: <ul style="list-style-type: none"> • Evaluations (EUR 6.00 million) • HFSPO (EUR 2.695 million) • Actions implemented through public procurements, expert groups and grants to identified beneficiaries (EUR 12.70 million) 	21.39 ⁹⁸
Estimated total budget	689.01

⁹⁴ The Budget figures given in this table are rounded to two decimals points.

⁹⁵ Call fiche: see Annex 4 to the Cooperation work programme.

⁹⁶ This call has been added to the Cooperation work programme (see call fiche in annex 4) with one topic (Health.2012.2.3.1-1) in this specific work programme.

⁹⁷ These EUR 2 million are the indicative budget for the CSA, new topic Health.2012.2.3.1-1.

⁹⁸ The budget of the OTHER ACTIVITIES has been increased by EUR 2 300 000 to cover three new activities added to this part of the work programme.

GENERAL ACTIVITIES - INDICATIVE BUDGET

Activities⁹⁹	2012 Budget EUR million
CORDIS	1.48
Experts (evaluators and reviewers)	0.01
ERANET horizontal support actions	0.19
EUREKA	0.07
COST	7.87
Total	9.62

All budgetary figures given in this work programme are indicative. The final budgets may vary following the evaluation of proposals.

The final budget awarded to actions implemented through calls for proposals may vary:

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

For actions not implemented through calls for proposals:

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

⁹⁹ For more details see annex 4 of the work programme.