

WORK PROGRAMME 2013

COOPERATION

THEME 1

HEALTH

(European Commission C(2012) 4536 of 09 July 2012)

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Objective: Improving the health of European citizens and increasing the competitiveness and boosting the innovative capacity of European health-related industries and businesses while addressing global health issues including emerging epidemics. Emphasis will be put on translational research (translation of basic discoveries in clinical applications including scientific validation of experimental results) the development and validation of new therapies, methods for health promotion and prevention including promotion of child health, healthy ageing, diagnostic tools and medical technologies, as well as sustainable and efficient healthcare systems.

I CONTEXT

Political landscape

The Theme Health is aligned with the fundamental objectives of EU research policies: improving the health of European citizens 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.

Against the backdrop of the current economic situation and increased global competition, the Union has defined a strategy to support growth and job creation, Europe 2020¹. Research and innovation are key drivers of competitiveness, jobs, sustainable growth and social progress.

The priority setting for the last work programme of the Seventh Framework Programme (FP7) will **respond to the major health-related socio-economic and societal challenges** in view of the new orientations given by the **Europe 2020 Strategy** including complementing efforts undertaken by the Innovation Union flagship initiative², the European Innovation Partnership (EIP) for “active and healthy ageing”³. In this way the work programme provides for a smooth transition towards the new research and innovation programme for 2014-2020, **Horizon 2020**⁴; for instance by strengthened priorities contributing to putting knowledge into practice and enhance the socio-economic impact of research following the **Europe 2020 strategy** with more industry-driven applied research **to boost innovation** in the health sector including social innovation. There is a determined focus on fostering new ideas, supporting world class teams tackling significant societal challenges, and on ensuring that the fruits of our investments can be properly exploited.

With its many **broad, bottom-up topics** suited for SMEs, this work programme will (**over 20% of the budget ring-fenced for SMEs and industry**) contribute very significantly to the **European renewal**⁵ while continuing "to secure world excellence in basic research" (Barroso, 2009⁶) through large-scale collaborative research efforts.

¹ Europe 2020 A strategy for smart, sustainable and inclusive growth COM(2010) 2020;

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; SEC(2010) 1161;

³ COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL Taking forward the Strategic Implementation Plan of the European Innovation Partnership on Active and Healthy Ageing. COM/2012/083 final http://ec.europa.eu/research/innovation-union/pdf/active-healthy-ageing/steering-group/implementation_plan.pdf#view=fit&pagemode=none

⁴ Horizon 2020 - The Framework Programme for Research and Innovation, COM(2011) 808 final;

⁵ European renewal – State of the Union Address 2011, Barroso 28 September 2011, speech/11/607;

⁶ Political Guidelines for the New Commission, J.M. Barroso, 2009;

Approach for 2013

This work programme further consolidates the major efforts initiated in 2011 and 2012 to stimulate innovation and SME participation via **broad, bottom-up topics** implemented by the two-stage submission and evaluation procedure. Such activities complement the on-going public-private partnership with the pharmaceutical industry, the Innovative Medicine Initiative⁷ (IMI). Overall this work programme continues to support top quality collaborative research including standardisation aspects in several topics of various areas. Coordination with other themes will also be assured in the relevant areas.

While this work programme as a whole takes into account the coverage of the specific programme, it also contributes to achieving the research and innovation goals inherent in developing a European innovation economy. The small number of areas prioritised 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.

For translational applied projects standardisation is often a key enabler for interoperability; ensures product quality, open markets and free trade and thereby building consumer confidence. Standardisation can help to foster future 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/objectives

The Health work programme 2013 has an indicative budget of EUR ~840 million to cover many health issues. **The research priorities for 2013 are: brain research, antimicrobial drug resistance and comparative effectiveness research**, complemented by topics from other areas such as developing personalised medicines approaches, cardiovascular research, safety and efficacy of therapies, cancer and public health research and a **horizontal activity for translating research results into innovative applications for health**.

Brain research is an area where the scientific challenges are enormous and where society realises that considerable new investments are needed to respond to the concerns of Member States (MS), European Parliament (EP), European Commission, general directorate for health and consumers (DG SANCO), learned societies, and many other stakeholders which are very supportive to these actions. Effective translational brain research can alleviate human suffering and have a major impact on economic and health care costs, EUR 800 billion in 2010⁸. Topics are:

HEALTH.2013.2.2.1-1: Prospective longitudinal data collection and Comparative Effectiveness Research (CER) for traumatic brain injury (TBI).

HEALTH.2013.2.2.1-2: Development of effective imaging tools for diagnosis, monitoring and management of mental disorders

HEALTH.2013.2.2.1-3: Paediatric conduct disorders characterised by aggressive traits and/or social impairment: from preclinical research to treatment.

HEALTH.2013.2.2.1-4: Patho-physiology and therapy of epilepsy and epileptiform disorders.

HEALTH.2013.2.2.1-5: Understanding and controlling pain.

⁷ The Innovative Medicines Initiative, a public-private partnership between the European Commission and the European Federation of Pharmaceutical Industries and Association (EFPIA); reference to IMI Regulation.

⁸ Gustavsson et al.: "Cost of disorders of the brain in Europe 2010". European Neuropsychopharmacology (2011) 21, 718–779

Comparative Effectiveness Research (CER) has not been addressed in FP7 before and will bridge to planned activities of Horizon 2020 where CER would be further supported. Tackling this issue is of high importance for citizens, in particular as it addresses benchmarking and identification of best practice in particular with patient outcomes in different domains. Topics are:

- HEALTH.2013.2.2.1-1: Prospective longitudinal data collection and Comparative Effectiveness Research (CER) for traumatic brain injury (TBI).
- HEALTH.2013.2.4.2-2: Comparative effectiveness research of existing technologies for prevention, diagnosis and treatment of cardiovascular diseases.
- HEALTH.2013.3.1-1: Comparative effectiveness research (CER) in health systems and health services interventions.

Making an effort in the area of **antimicrobial drug resistance (AMR)** corresponds to planned activities under Horizon 2020 and addresses a major concern of European citizens. In addition to the innovation aspects and the need for a sustainable approach, it is in line with the Commission's commitment to the Millennium Development Goals⁹. Topics are:

- HEALTH.2013.2.3.1-1: Drugs and vaccines for infections that have developed or are at the risk of developing significant anti-microbial resistance.
- HEALTH.2013.2.3.1-2: Stratified approaches to antibacterial and/or antifungal treatment.

Innovation dimension of the activities and bridging towards planned activities under Horizon 2020

The focus on innovation is 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 'Impact' evaluation criterion.

Several topics tackling issues such as antimicrobial resistance, comparative effectiveness research, social innovation, support for SMEs and medical technologies have clear links to planned activities under Horizon 2020, especially with regard to the concerns of the citizens and the specific programmes "Tackling Societal Challenges" (TSC) and "Industrial Leadership and Competitive Frameworks" (ILCF). About half of the topics address issues of direct concern to citizens. More than half of the topics are related to TSC, several topics contribute to prepare the ground for ILCF in health (bio)technologies, all together with an indicative budget of over EUR ~400 million. Furthermore, Theme Health continues to pilot specific SME-targeted topics with 50% ring-fenced budgets for SMEs. With 11 topics¹⁰ this call takes account of relevant aspects of the Strategic Implementation Plan established by the EIP on 'Active and Healthy Ageing' and contributes to its aims.

⁹ Recalled by President Barroso recently in his declaration on the State of the Union at the European Parliament (28/9/2011).

¹⁰ In certain cases topic titles have been shortened. HEALTH.2013.1.2-1: Imaging technologies for therapeutic interventions in rare diseases; HEALTH.2013.1.3-2: Immune reactions to biomedical devices, implants and transplant tissues; HEALTH.2013.1.4-1. Controlling differentiation and proliferation in human stem cells intended for therapeutic use; HEALTH.2013.2.1.1-1: Functional validation in animal and cellular models of genetic determinants of diseases and ageing processes; HEALTH.2013.2.1.1-2: Metagenomics for personalised medicine approaches; HEALTH.2013.2.3.1-2: Stratified approaches to antibacterial and/or antifungal treatment; HEALTH.2013.2.4.1-2: Strengthening the cancer patient's immune system; HEALTH.2013.2.4.1-3: Palliative care clinical trials and observational studies; HEALTH.2013.3.1-1: Comparative Effectiveness Research (CER) in health systems and health services interventions; HEALTH.2013.3.3-1: Social innovation for health promotion; HEALTH.2013-4.2-1: Investigator-driven clinical trials for off-patent medicines.

- **SME-relevant research:** Promoting innovation by strengthening the links between academia and industry is the driving force of this work programme. Broad, SME and/or industry including SMEs-relevant topics¹¹ (at about 60 % 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 shall go to SMEs and/or industry. It is expected that about 20% of the total budget for 2013 will be awarded to SMEs in collaborative projects
- **Dissemination actions:** The health market is highly fragmented in Europe, with different public health policies in Member States and Associated Countries. To sustain the competitiveness of the health sector, it is necessary to improve the framework conditions for business to innovate in creating the single EU Patent and a specialised Patent Court, in harmonising the regulatory framework, in improving access of SMEs to intellectual property protection (IPR). Therefore in 2013 an action is included for health research projects to address the innovation lifecycle by boosting the translation of projects' results into innovative applications for health.
- **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 months¹².
- **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. A conservative estimate suggests that ~EUR 160 million (about ~20% of the indicative budget of the calls) will be allocated to SMEs. Topics of relevance to the innovation partnership (including those on medical technologies) have a total budget of ~ EUR 300 million (~40%). These efforts should increase the drive to develop new technologies, new vaccines, 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

¹¹ In certain cases topic titles have been shortened. HEALTH.2013.0-1: Boosting the translation of FP projects' results into innovative applications for health; HEALTH.2013.1.2-1: Imaging technologies for therapeutic interventions in rare diseases; HEALTH.2013.1.3-1: Modelling toxic responses in case studies for predictive human safety assessment; HEALTH.2013.1.3-2: Adverse immune reactions to biomedical devices, implants and transplant tissues; HEALTH.2013.1.3-3: Safety and efficacy of therapeutic vaccines; HEALTH.2013.1.3-4: Development of alternative in vitro, analytical, immunochemical, and other test methods for quality control of vaccines; HEALTH.2013.1.4-1: Controlling differentiation and proliferation in human stem cells intended for therapeutic use; HEALTH.2013.2.1.1-1: Functional validation in animal and cellular models of genetic determinants of diseases and ageing processes; HEALTH.2013.2.1.1-2: Metagenomics for personalised medicine approaches; HEALTH.2013.2.2.1-2: Effective imaging tools for diagnosis, monitoring and management of mental disorders; HEALTH.2013.2.2.1-3: Paediatric conduct disorders characterised by aggressive traits and/or social impairment; HEALTH.2013.2.2.1-4: Patho-physiology and therapy of epilepsy and epileptiform disorders; HEALTH.2013.2.3.0-1: Innovation in vaccines; HEALTH.2013.2.3.1-1: Drugs and vaccines for infections that have developed or are at the risk of developing significant anti-microbial resistance; Health.2013.2.3.4-2: Drug development for neglected parasitic diseases; HEALTH.2013.2.4.1-2: Strengthening the cancer patient's immune system; HEALTH.2013.2.4.2-1: Novel targets for cardiovascular disease treatment; HEALTH.2013.3.3-1: Social innovation for health promotion; HEALTH.2013.4.2-1: Investigator-driven clinical trials for off-patent medicines; HEALTH.2013.4.2-2: Adverse drug reaction research.

¹² Further information: http://cordis.europa.eu/fp7/find-doc_en.html
<http://ec.europa.eu/research/sciencesociety/>

focus on providing support to SMEs, certain topics¹³ also support the aims and objectives of the Innovation Union, including the support to proof of principle¹⁴; the involvement of end-users (both patient and health professionals) in product development and implementation¹⁵; the anticipation of regulatory needs¹⁶; the focus on standardisation¹⁷; addressing market failure¹⁸; harnessing social innovation¹⁹;

¹³ In certain cases topic titles have been shortened.

¹⁴ HEALTH.2013.0-1: Boosting the translation of FP projects' results into innovative applications for health; HEALTH.2013.1.3-2: Adverse immune reactions to biomedical devices, implants and transplant tissues; HEALTH.2013.1.4-1: Controlling differentiation and proliferation in human stem cells intended for therapeutic use; HEALTH.2013.2.1.1-1: Functional validation in animal and cellular models of genetic determinants of diseases and ageing processes; HEALTH.2013.2.1.1-2: Metagenomics for personalised medicine approaches; HEALTH.2013.2.3.0-1: Innovation in vaccines; HEALTH.2013.2.3.1-1: Drugs and vaccines for infections that have developed or are at the risk of developing significant anti-microbial resistance; HEALTH.2013.2.3.1-2: Stratified approaches to antibacterial and/or antifungal treatment; HEALTH.2013.2.4.1-1: Investigator-driven treatment trials to combat or prevent metastases in patients with solid cancer; HEALTH.2013.2.4.1-2: Strengthening the cancer patient's immune system; HEALTH.2013.2.4.1-3: Palliative care clinical trials and observational studies; HEALTH.2013.2.4.2-1: Novel targets for cardiovascular disease treatment; HEALTH.2013.3.1-1: Comparative Effectiveness Research (CER) in health systems and health services interventions; HEALTH.2013.4.2-1: Investigator-driven clinical trials for off-patent medicines.

¹⁵ HEALTH.2013.1.2-1: Imaging technologies for therapeutic interventions in rare diseases; HEALTH.2013.1.3-2: Adverse immune reactions to biomedical devices, implants and transplant tissues; HEALTH.2013.2.3.3-1: Clinical management of patients in severe epidemics; HEALTH.2013.2.4.1-3: Palliative care clinical trials and observational studies; HEALTH.2013.3.1-1: Comparative Effectiveness Research (CER) in health systems and health services interventions; HEALTH.2013.3.3-1: Social innovation for health promotion.

¹⁶ HEALTH.2013.1.3-1: Modelling toxic responses in case studies for predictive human safety assessment; HEALTH.2013.1.3-2: Adverse immune reactions to biomedical devices, implants and transplant tissues; HEALTH.2013.1.3-4: Development of alternative in vitro, analytical, immunochemical, and other test methods for quality control of vaccines; HEALTH.2013.1.4-1: Controlling differentiation and proliferation in human stem cells intended for therapeutic use; HEALTH.2013.2.4.1-1: Investigator-driven treatment trials to combat or prevent metastases in patients with solid cancer; HEALTH.2013.2.4.1-2: Strengthening the cancer patient's immune system; HEALTH.2013.2.4.2-1: Novel targets for cardiovascular disease treatment; HEALTH.2013.2.4.2-2: Comparative effectiveness research of existing technologies for prevention, diagnosis and treatment of cardiovascular diseases; HEALTH.2013.4.1-2: Interactions between EU legislation and health research and/or innovation; HEALTH.2013.4.2-1: Investigator-driven clinical trials for off-patent medicines using innovative, age-appropriate formulations and/or delivery systems; HEALTH.2013.4.2-2: Adverse drug reaction research; HEALTH.2013.4.2-3: New methodologies for clinical trials for small population groups.

¹⁷ HEALTH.2013.1.2-1: Imaging technologies for therapeutic interventions in rare diseases; HEALTH.2013.1.3-4: Development of alternative in vitro, analytical, immunochemical, and other test methods for quality control of vaccines; HEALTH.2013.1.4-1: Controlling differentiation and proliferation in human stem cells intended for therapeutic use; HEALTH.2013.2.1.1-1: Functional validation in animal and cellular models of genetic determinants of diseases and ageing processes; HEALTH.2013.2.2.1-1: Prospective longitudinal data collection and Comparative Effectiveness Research (CER) for traumatic brain injury (TBI); HEALTH.2013.2.4.2-1: Novel targets for cardiovascular disease treatment; HEALTH.2013.2.4.2-2: Comparative effectiveness research of existing technologies for prevention, diagnosis and treatment of cardiovascular diseases; HEALTH.2013.4.2-3: New methodologies for clinical trials for small population groups.

¹⁸ HEALTH.2013.2.3.1-1: Drugs and vaccines for infections that have developed or are at the risk of developing significant anti-microbial resistance; HEALTH.2013.2.3.1-2: Stratified approaches to antibacterial and/or antifungal treatment; Health.2013.2.3.4-1: Neglected infectious diseases of Central and Eastern Europe; Health.2013.2.3.4-2: Drug development for neglected parasitic diseases.

¹⁹ HEALTH.2013.2.4.1-3: Palliative care clinical trials and observational studies; HEALTH.2013.3.1-1: Comparative Effectiveness Research (CER) in health systems and health services interventions; HEALTH.2013.3.3-1: Social innovation for health promotion.

the translation and dissemination of results²⁰.

International Cooperation

Theme Health is addressing multiple issues related to international cooperation: tackling global challenges, such as emerging epidemics; neglected diseases (of interest for many EU and neighbourhood countries); improving the competitiveness 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 and to join forces, to avoid duplication and speed up developments in large scale initiatives. All topics under the FP7-HEALTH-2013-INNOVATION-1 call are open for the participation of partners from third countries and offer many opportunities for "bottom-up" international collaboration. In recognition of the opening of NIH²¹ programmes to European researchers, participants established in the *United States of America* are entitled to participate and to receive funding in all topics under the FP7-HEALTH-2013-INNOVATION-1 call. Specific programme level cooperation is foreseen with the US and Canada in the field of brain injury, and further support for rare diseases contributing to the international consortium in rare diseases, now counting more than 23 funding entities.

Cross-thematic approaches

Theme Health again 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 Socio-economic 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, the major simplification introduced with work programme 2012 continues for 2013 by implementing the Health work programme via the **two-stage submission and evaluation procedure**. The implementation will be via two calls: **FP7-HEALTH-2013-INNOVATION-1 as main call** with an indicative budget of **EUR 680 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-2013-INNOVATION-2 as a specific call to boost SME participation for innovative solutions in the health sector** with an indicative budget of **EUR 140 million**. This call has 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 support actions) is 3 (**see section III, Implementation**); however **there is no obligation imposed on the applicants to go beyond this number unless additional partners are needed to achieve the objectives of the project**. Likewise the duration of the project will be in line with the realistic planning of the project and so, may be quite short (e.g. 1-2 years), or long enough to achieve the goals of the project with the exception of topics

²⁰ HEALTH.2013.2.1.1-2: Metagenomics for personalised medicine approaches; HEALTH.2013.2.2.1-1: Prospective longitudinal data collection and Comparative Effectiveness Research (CER) for traumatic brain injury (TBI); HEALTH.2013.2.4.2-2: Comparative effectiveness research of existing technologies for prevention, diagnosis and treatment of cardiovascular diseases; HEALTH.2013.3.1-1: Comparative Effectiveness Research (CER) in health systems and health services interventions; HEALTH.2013.3.3-1: Social innovation for health promotion.

²¹ National Institutes of Health of the US Department of Health and Human Services

under the FP7-HEALTH-2013-INNOVATION-2 call where the maximum project duration is limited to 3 years. Similarly, the size of the EU contribution to the budget shall also be in line with the needs of the respective consortium, within the maximum EU contribution but not necessarily at the maximum by default.

- **Support for clinical trials will be continued:** This gives the opportunity to test the effectiveness of therapies for traumatic brain injury through a large-scale trial, cancer therapies, and palliative care, adapting off-patent medicines for paediatric or elderly use. This initiative addresses one of the most costly and time consuming steps in drug development which, if not realised, can block innovation from basic research to marketable products for the ultimate benefit of the patients.

Innovative clinical trials²² to verify safety and efficacy: The early involvement of patients²³ and their advocacy groups in the planning, implementation, and monitoring of a clinical trial are 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 shall carefully consider any relevant national and supra-national ethical and regulatory framework in force at European and national level for the conduct of clinical trials. Specific guidance on important information to be included in proposals involving clinical trials as well as specific information on the financing of clinical trials under FP7 rules can be found on the call page and in the guide for applicants.

- **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 issues²⁴ are described in the Guide for Applicants (Annex 4, section 4). The differences of gender or sex in research (risk factors, biological mechanisms, causes, clinical features, consequences and treatment of diseases and disorders) will 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 the use of animals in research and testing²⁵. The principle of the three Rs (reduction, refinement and replacement) should be applied where appropriate in research funded by the EU.
- **Gender dimension:** The pursuit of scientific knowledge and its technical application towards society requires the talent, perspectives and insight that may 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 may be financed as part of the proposal, as specified in Appendix 7 of the Negotiation Guidance Notes²⁶.

²² http://ec.europa.eu/health/human-use/clinical-trials/index_en.htm

²³ <http://www.eu-patient.eu/Initatives-Policy/Projects/ValuePlus/>

²⁴ http://cordis.europa.eu/fp7/ethics_en.html

²⁵ Para (30): http://eur-lex.europa.eu/LexUriServ/site/en/oj/2006/l_412/l_41220061230en00010041.pdf.

²⁶ ftp://ftp.cordis.europa.eu/pub/fp7/docs/negotiation_en.pdf

- ***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' 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 2013 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. As a consequence, proposals that do not respect the corresponding limit will be considered ineligible. The same is valid for the limitation of the project duration for some of the topics.**
- ***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 will include and 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 will explain why.

II PROPOSED CONTENT FOR CALLS 2013

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

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

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

HEALTH.2013.0-1: Boosting the translation of health research projects' results into innovative applications for health. FP7-HEALTH-2013-INNOVATION-2. The main aim of this topic is to allow SMEs to take up health research outcomes resulting from earlier FP funding under FP7 Theme Health and FP6 "Life sciences, genomics and biotechnology for health", to prove the viability of methodologies, processes, prototypes, models, technologies, clinical trials, etc. developed under these projects, with a potential for application. However, the consortium does not need to be the same as in the previously funded project, but include participants as appropriate to exploit those particular results in the most logic and efficacious manner. Research activities under this topic will focus on testing and validation of results in order to reach the final development stage before products or processes enter into production, reach the market and/or patients. Proposals will fit into the overall business and innovation needs of the partners involved and will demonstrate clear exploitation potential and socio-economic benefits for the patients, for them and the society at large. Applicants should have the freedom to exploit the results for commercial use. Applicants will describe clearly and convincingly how the results, knowledge and/or technology will be brought forward enough to reach the stage of application.

Note: Limits on the EU financial contribution and project duration will apply and will be implemented strictly as eligibility criteria.

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

One or more proposals may be selected.

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

Specific requirements to be considered under the evaluation:

- Specific innovation initiative designed to encourage strong SME efforts towards the translation of research results into innovative applications for health.
- Leading role of SMEs in the project (see also section III, p.65 of this document).

- Developing a short business plan clearly describing the valorisation of the technology(ies) when presenting a full proposal for stage 2.
- Expected outcomes being of clear interest and potential benefit to SME(s).

Additional eligibility criteria:

1. The **requested EU contribution** per project will **depend on the needs of the project indicated in the proposal but shall not** exceed EUR 6 000 000.

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

3. The **financial viability of all partners** in projects shall fulfil the Commission applicable rules²⁷. This will be checked at negotiation stage before the signature of the grant agreement.

4. **Number of participants:** minimum 3 established in at least three different EU Member States or Associated Countries with the specific condition for SMEs under point 6 below. The maximum number of participants is 5.

5. The **estimated EU contribution going to SMEs** shall **be 50% or more** of the total estimated EU contribution for the project as a whole. The SME status and the financial viability will be assessed at the end of the negotiation, before signature of the grant agreement.

6. **Participation of SMEs or SME joint ventures is restricted** to entities established in EU Member States and Associated Countries. In addition, SMEs shall fulfil any of the following conditions: 1) be 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) be at least 51% owned and controlled by another business that is itself at least 51% owned and controlled by individuals who are citizens of, or permanent residents in those countries.

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

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

1.1 HIGH-THROUGHPUT RESEARCH

Closed 2013

1.2 DETECTION, DIAGNOSIS AND MONITORING

The objectives are to develop visualisation, imaging, detection and analytical tools and technologies for biomedical research, for prediction, diagnosis, monitoring and prognosis of diseases, and for support and guidance of therapeutic interventions. The focus will be on a

²⁷ ftp://ftp.cordis.europa.eu/pub/fp7/docs/rules-verif_en.pdf

multidisciplinary approach integrating areas such as: molecular and cellular biology, physiology, genetics, physics, chemistry, biomedical engineering, micro-systems, devices and information technologies. Non- or minimally invasive and quantitative methods and quality assurance aspects will be emphasised. For this call for proposals, the focus will be on the development of imaging technologies for guiding therapeutic interventions for personalised medicine applications.

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

HEALTH.2013.1.2-1: Development of imaging technologies for therapeutic interventions in rare diseases. FP7-HEALTH-2013-INNOVATION-1. The aim is to support development and/or proof of principle of new or improved combined imaging technologies for therapeutic interventions in rare diseases. Two or more techniques, of which at least one should be molecular imaging, should be integrated into a complete simultaneous system for application in one or more rare diseases in the frame of personalised medicine, *i.e.* tailored medical interventions which are more effective and/or have fewer undesirable adverse effects in specific patients. The technologies should be of use as biomarkers during the therapeutic interventions. Clinicians should actively be included in the project.

Note: Limits on the EU financial contribution will apply and will be implemented strictly as eligibility criterion.

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

One or more proposals may be selected.

Expected impact: The development of new and improved technologies for therapeutic interventions in groups or categories of rare diseases, facilitating the uptake of personalised medicine into clinical practice and support the competitiveness of Europe in this area. The applications are expected to advance research in personalised medicine and have an impact in the relevant industry (in particular for SMEs). The projects will contribute to the International Rare Diseases Research Consortium (IRDiRC)²⁸.

Specific requirements to be considered under the evaluation:

- SME-targeted research is designed to encourage SME efforts towards research and innovation.
- Leading role of research intensive SMEs.
- Leading role of SMEs with R&D capacities, but the coordinator does not need to be an SME.
- Expected outcomes being of clear interest and potential benefit to SMEs.

Additional eligibility criteria:

1. The **requested EU contribution per project** shall not exceed EUR 6 000 000.
2. The **estimated EU contribution going to SMEs shall be 30% or more** of the total estimated EU contribution for the project as a whole. The SME status and the financial

²⁸ <http://www.e-rare.eu/content/irdirc>

viability will be assessed at the end of the negotiation, before signature of the grant agreement.

1.3 SUITABILITY, SAFETY, EFFICACY OF THERAPIES

The development of novel therapeutics, vaccines or biomedical tools and devices is often severely impeded by safety and efficacy issues that should exhaustively be addressed already at an early stage of product development. The focus of this call is therefore to efficiently address aspects of toxicology, adverse immune reactions, reduced potency and impaired efficacy of novel medical products in a broad way, encouraging the employment of novel approaches including modelling efforts, novel tests, assays and preclinical models as well as focused human studies, that help to assess earlier, better and more cost-efficiently safety and efficacy aspects of medical interventions and devices. Predictive toxicology and efficacy assessment should be validated by appropriate human studies.

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

HEALTH.2013.1.3-1: Modelling toxic responses in case studies for predictive human safety assessment. FP7-HEALTH-2013-INNOVATION-1. The main objective of this topic is to exploit in case studies recent advances in computational chemistry and systems biology in order to provide the basis for innovative approaches to predictive human safety assessments. Integrated research should be undertaken that:

- Considers modelling transport and interactions from molecular to cellular/organelle levels;
- Integrates with *in vitro* experimentation designed specifically to inform this modelling activity;
- Couples directly to systems modelling from cellular to organ level;
- Takes account of mechanistic understandings of toxic responses in specific organs; and
- Uses existing and appropriate infrastructure for computation data basing and sharing.

Besides the development of a comprehensive strategy and research concept, the following issues should be addressed either at the theoretical or at the experimental level:

- Identifications of metabolites (and metabolites of metabolites) and their reactivity, through a combination of computational chemistry, *in vitro* experimentation and enzyme expression profiling.
- Identification of the proteins and potentially other intracellular targets, affected by each metabolite, through computational chemistry and *in vitro* work.
- Identification of the pathways affected by these proteins, through *in vitro* cell assays and systems biology.
- Identification of cell functions affected by these pathways, by defining the boundaries of normal function, and understanding of the physiology and systems biology.

Note: Limits on the EU financial contribution will apply and will be implemented strictly as eligibility criterion.

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

Only up to one proposal may be selected.

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

Additional eligibility criteria:

1. The **requested EU contribution per project** shall not exceed EUR 12 000 000.
2. The **estimated EU contribution going to *industry including SMEs shall be 15% or more*** of the total estimated EU contribution for the project as a whole. The SME status and the financial viability will be assessed at the end of the negotiation, before signature of the grant agreement.

HEALTH.2013.1.3-2: Innovative approaches to address adverse immune reactions to biomedical devices, implants and transplant tissues. FP7-HEALTH-2013-INNOVATION-1. Administration of biomedical devices, implants or tissue transplants can cause severe and often chronic, adverse reactions of the human immune system. Projects will aim to identify adverse immune reactions caused by such devices or tissues using systems immunological studies and other innovative approaches, and develop remedial strategies. Research consortia will be multidisciplinary, bringing together basic immunology, epidemiological and clinical expertise, with systems and cellular biology know-how and a thorough understanding of product development and regulatory issues. A strong participation of key players from industry and the clinical field is essential.

Note: Limits on the EU financial contribution will apply and will be implemented strictly as eligibility criterion.

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

One or more proposals may be selected.

Expected impact: A better holistic understanding of adverse immune reactions should allow the better design of medical devices and materials for implants, and improve outcome of tissue transplantation. Development of novel therapeutic or preventive strategies to combat adverse immune reactions.

Additional eligibility criteria:

1. The **requested EU contribution per project** shall not exceed EUR 6 000 000.
2. The **estimated EU contribution going to *industry including SMEs shall be 30% or more*** of the total estimated EU contribution for the project as a whole. The SME status and the financial viability will be assessed at the end of the negotiation, before signature of the grant agreement.

HEALTH.2013.1.3-3: Safety and efficacy of therapeutic vaccines. FP7-HEALTH-2013-INNOVATION-1. The aim is to advance promising new therapeutic vaccines into clinical safety and efficacy testing. Chronic infectious diseases (including infections in immunocompromised patients), inflammatory and autoimmune diseases, allergies, degenerative, and metabolic diseases as well as vaccines against drug addictions, may be addressed. Excluded are cancer vaccines addressed in area 2.4.1-1. The suggested therapy

should be based on an active vaccination effect triggering a human immune response hence bearing particular innovation potential. Projects should focus on therapeutic vaccines for which efficacy has been demonstrated in preclinical work, *e.g.* in appropriate animal models. Projects will demonstrate that a therapeutic vaccine in the envisaged area is superior to existing or competing therapies under development, and that the expected cost-medical benefits ratio meets public health needs. Consortia should be strongly product-focused and should comprise only an essential number of contributing partners. Consortia will include industry, especially from the SME sector from EU Member States and/or Associated Countries.

Note: Limits on the EU financial contribution will apply and will be implemented strictly as eligibility criterion.

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

One or more proposals may be selected.

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

Additional eligibility criteria:

1. The **requested EU contribution** per project shall not exceed EUR 6 000 000.
2. The **estimated EU contribution going to industry including SMEs shall be 30 % or more** of the total estimated EU contribution for the project as a whole. The SME status and the financial viability will be assessed at the end of the negotiation, before signature of the grant agreement.

HEALTH.2013.1.3-4: Development of alternative *in vitro*, analytical, immunochemical, and other test methods for quality control of vaccines. FP7-HEALTH-2013-INNOVATION-1. Novel technological approaches are needed to ensure faster and more reliable testing of vaccine products. While upholding full compliance with the regulatory requirements that govern the development and production of vaccine products, research activities will be directed at exploring to which extent animal-based safety and potency testing of experimental or licensed vaccines can be replaced (in totality or partially) by alternative *in vitro*, analytical, immunochemical or other (*e.g.* molecular) tests or processes. Support is therefore given to studies aiming to develop and validate novel, rapid and reliable safety and potency assays that demonstrate correlation of safety of vaccine products with animal-tested batches. Research consortia should be led by regulatory bodies or industry, including SME participants, familiar with all aspects of the development and the production of vaccines for use in humans. To fully exploit potentially synergistic expertise from the field of animal vaccines, key players from the field of veterinary vaccines can be useful partners in research consortia to be formed. Preference will be given to projects not exceeding three years project duration.

Note: Limits on the EU financial contribution will apply and will be implemented strictly as eligibility criterion.

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

One or more proposals may be selected.

Expected impact: An EU-supported research effort for the development of *in vitro* potency tests for vaccines closely coordinated with industry and regulatory bodies will complement

existing efforts, and should prove the potential of new tests to reduce, refine and replace animals in vaccine research.

Additional eligibility criteria:

1. The **requested EU contribution per project** shall not exceed EUR 3 000 000.
3. The **estimated EU contribution going to industry including SMEs shall be 30% or more** of the total estimated EU contribution for the project as a whole. The SME status and the financial viability will be assessed at the end of the negotiation, before signature of the grant agreement.

1.4 INNOVATIVE THERAPEUTIC APPROACHES AND INTERVENTIONS

The focus of this year's topic is human stem cell research. Stem cells offer great promise for therapy but practical applications are still limited. This topic focuses on the key area of differentiation, proliferation and biological activity/potency where further knowledge of mechanisms of action, development of cell technology and fulfilment of regulatory standards are required²⁹.

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

HEALTH.2013.1.4-1. Controlling differentiation and proliferation in human stem cells intended for therapeutic use. FP7-HEALTH-2013-INNOVATION-1. The aim of this topic is to develop the application of stem cells and reprogrammed cells towards new therapies. Projects should be developed around a concept based on the use of human stem cells, reprogrammed cells and/or differentiated cells derived from them to address an identified and justified therapeutic objective. Specifically, projects should focus on control of self-renewal, differentiation and proliferation, *in vitro* and/or *in vivo*, and assessment of the biological activity/potency of the therapeutic effect. Proposals should not make cancer a target since this is covered in another part of the work programme. Applications using haematopoietic stem cells and their lineages are excluded. Projects may include pre-clinical and clinical testing as appropriate. Preference will be given to projects involving the use of advanced research tools and *in vivo* investigations. Consortia will include industry, especially from the SME sector from EU Member States and/or Associated Countries.

Note: Limits on the EU financial contribution will apply and will be implemented strictly as eligibility criterion.

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

One or more proposals may be selected.

Expected impact: Creation of new knowledge or development of new techniques controlling differentiation and proliferation of human stem cells and reprogrammed cells for therapeutic purpose that can progress the translation of this research to the clinic.

Additional eligibility criteria:

²⁹ See *Reflection Paper on Stem Cell-based Medicinal Products adopted by the European Medicine Agency's Committee for Advanced Therapies (EMA/CAT/571134/2009) on 14 January 2011*, available at:

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

1. The **requested EU contribution per project** shall not exceed EUR 6 000 000.
2. The **estimated EU contribution going to SMEs shall be 15 % or more** of the total estimated EU contribution for the project as a whole. The SME status and the financial viability will be assessed at the end of the negotiation, before signature of the grant agreement.

2. TRANSLATING RESEARCH FOR HUMAN HEALTH

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

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

2.1.1 Large-scale data gathering

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

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

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

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

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

HEALTH.2013.2.1.1-1: Functional validation in animal and cellular models of genetic determinants of diseases and ageing processes. FP7-HEALTH-2013-INNOVATION-1. The project should use various animal and cellular models to discover and ascribe functions of genes known to be associated to human diseases and/or ageing processes. It will aim at

better understanding of the disease and ageing processes in view of creating a portfolio of new and validated therapeutic targets. This project should include large-scale metabolic and molecular phenotyping in model organisms and *in vitro* model systems (including human embryonic (hES) or induced pluripotent (iPS) stem cells) with priority given to the genes shown to be associated to human disease and/or involved in ageing. It could include work with human hES or iPS cells developed from patients where applicable. It should envisage generating models with the intention to investigate diseases variations in relation with different mutated human alleles. It should develop efficient, standardised and reliable tools, common ontology, standardised operating procedures and technologies for phenotyping. Data will be integrated and maintained in publically accessible web portals.

Note: Limits on the EU financial contribution will apply and will be implemented strictly as eligibility criterion.

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

One or more proposals may be selected.

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

Specific requirements to be considered under the evaluation:

- SME-targeted research is designed to encourage SME efforts towards research and innovation.
- Leading role of research intensive SMEs.
- Leading role of SMEs with R&D capacities, but the coordinator does not need to be an SME.
- Expected outcomes being of clear interest and potential benefit to SMEs.

Additional eligibility criteria:

1. The **requested EU contribution per project** shall not exceed EUR 12 000 000.
2. The **estimated EU contribution going to SMEs shall be 30% or more** of the total estimated EU contribution for the project as a whole. The SME status and the financial viability will be assessed at the end of the negotiation, before signature of the grant agreement.

HEALTH.2013.2.1.1-2: High impact research initiative on metagenomics for personalised medicine approaches. FP7-HEALTH-2013-INNOVATION-1. This project will build on recent very promising research results on the composition of the human microbiome that highlighted the diagnostic potential and possible stratification of patients. The project should accelerate and promote research on the role of the human microbiome in health, diseases and ageing. Through metagenome profiling in large patient cohorts, the project should study the link between the micro flora composition and diseases. This multi-component project should be highly effective also through the involvement of a wider range of partners. It should contribute to the International Human Microbiome Consortium (IHMC)³⁰ and should include:

³⁰ <http://www.human-microbiome.org/>

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

The project will aim at developing metagenomics by further generating the technology, knowledge and know-how in this research area. It should increase Europe's competitive position in exploiting the vast amount of metagenomic data and related information. The project should encourage SME efforts towards research and innovation. Priority will be given to proposals demonstrating that industry is playing an important role. The expected project results should clearly be of interest and potential benefit to SMEs.

The funded project should enhance the EU contribution to the International Human Microbiome Consortium. A complimentary topic (KBBE.2013.2.2-02: Factors influencing the human gut microbiome and its effect on the development of diet related diseases and brain development) is being published in the FP7 Food, Agriculture, Fisheries and Biotechnology (KBBE) work programme 2013. During the negotiations, if collaboration between the selected projects can be demonstrated to offer added value, the interconnections and interfaces between these projects but also with other projects in the field will be discussed in order to optimise the cooperation between the projects selected and to ensure maximum synergies.

Note: Limits on the EU financial contribution will apply and will be implemented strictly as eligibility criterion.

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

Only up to one proposal may be selected.

Expected impact: Better knowledge of the human microbiome and its potential roles in health and disease. This identification of person-specific microbiomes and microbial markers should allow stratification and attribution of patients to different individual health situations or physical conditions. The project will address health care challenges by facilitating better prediction, prevention, treatment and cure of diseases on the basis of microbial characteristics of individual patients. It aims to foster innovation and strengthening the competitive position of the European health care industry (from EU Member States and Associated Countries). It should create a high impact also through the involvement of a wide range of partners.

Additional eligibility criteria:

1. The **requested EU contribution per project** shall not exceed EUR 30 000 000.
2. The **estimated EU contribution going to industry including SMEs shall be 30% or more** of the total estimated EU contribution for the project as a whole. The SME status and the financial viability will be assessed at the end of the negotiation, before signature of the grant agreement.

2.1.2 Systems biology

Closed 2013

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

2.2.1 Brain and brain-related diseases

The objectives of this area are to better understand the integrated structure and dynamics of the brain, and to study brain diseases including relevant age related illness and search for new therapies. The overall aim is to gain a global understanding of the brain by exploring brain functions, from molecules to cognition including neuroinformatics, and brain dysfunction, from synaptic impairment to neurodegeneration. Research will address neurological and psychiatric diseases and disorders, including regenerative and restorative therapeutic approaches.

For this call for proposals, research in this area will focus in particular on mental health, neurological disorder (epilepsy), pain, and on the implementation of a programme level cooperation with US and Canada on traumatic brain injury. Those priorities are in line with the effort on paediatric brain diseases started in 2011, with the European Pact for Mental Health and with the International Initiative for Traumatic Brain Injury Research (InTBIR)³¹ that is being set up in cooperation with the US (NIH) and Canada.

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

³¹ http://ec.europa.ipv4.eu/research/health/medical-research/brain-research/international-initiative_en.html

HEALTH.2013.2.2.1-1: Prospective longitudinal data collection and Comparative Effectiveness Research (CER) for traumatic brain injury (TBI). FP7-HEALTH-2013-INNOVATION-1. The present topic asks for a prospective, longitudinal, non-randomised clinical study on a cohort of minimum 5 000 TBI patients over 5 years or longer, with a view to better characterise TBI in Europe and identify the most effective clinical interventions (both acute and post-acute) to treat TBI. Applicants are asked to collect a set of TBI Common Data Elements (TBI-CDEs)³², the data standards endorsed by the International Initiative for Traumatic Brain Injury Research (InTBIR). Applicants will collect all relevant core TBI-CDEs. Compliance with this requirement will be taken into consideration during evaluation. The collection of supplemental/emerging CDEs and/or other clinical data in addition to the core CDEs is encouraged. Additional project components will focus on:

- Establishing an open-source database for easy storage and analysis of the collected data. The database should be compatible with the US FITBIR database³³. Where applicable, the integration with other existing databases and biobanks should be achieved.
- Applying CER analysis to the collected data to identify the most effective treatment according to patient history and type of injury.
- Development and dissemination of treatment recommendations based on the results of the CER analysis to provide evidence for future international clinical guidelines.
- Communication and networking activities (conferences, website, brochures, InTBIR meetings, etc.) to exchange information, data and best practices with other InTBIR projects funded by other agencies (NIH³⁴ and CIHR³⁵) and the scientific community at large.

The management structure and provisions need to be adequate to the size and scope of the project.

Note: Limits on the EU financial contribution will apply and will be implemented strictly as eligibility criterion.

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

One or more proposals may be selected.

Expected impact: The funded project is expected to contribute towards the goals of the International Initiative for Traumatic Brain Injury Research (InTBIR)³⁶. In particular, the project is expected to identify the most effective clinical interventions taking into consideration the type of brain injury and the history of the patient, and to contribute to the development of improved and harmonised clinical guidelines for the treatment of TBI.

Additional eligibility criterion:

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

³² The TBI-CDE, listed by category, can be found at <http://www.commondataelements.ninds.nih.gov/TBI.aspx>

³³ <http://fitbir.nih.gov/tbi-portal/jsp/about/index.jsp>

³⁴ National Institutes of Health of the US Department of Health and Human Services

³⁵ Canadian Institutes of Health Research

³⁶ http://ec.europaipv4.eu/research/health/medical-research/brain-research/international-initiative_en.html

HEALTH.2013.2.2.1-2: Development of effective imaging tools for diagnosis, monitoring and management of mental disorders³⁷. FP7-HEALTH-2013-INNOVATION-1. This topic invites researchers, industry and SMEs to develop new or optimise existing imaging technologies, and validate their application to mental disorders by integrating imaging data with complementary knowledge resulting from e.g. genomics, biomarkers, bioinformatics and clinical data. The goal is to allow the diagnosis of mental disorders at the pre-symptomatic stage or early during development, more accurate patient stratification and better measurement of disease progression.

Note: Limits on the EU financial contribution will apply and will be implemented strictly as eligibility criterion.

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

One or more proposals may be selected.

Expected impact: This topic is expected to develop new or optimise existing imaging technology for the benefit of patients with psychiatric disorders. It will also encourage SME participation and foster innovation in Europe in line with the Europe2020 agenda. In addition, it will support the goals of the European Pact for Mental Health³⁸.

Additional eligibility criteria:

1. The **requested EU contribution** per project shall not exceed EUR 6 000 000.
2. The **estimated EU contribution going to industry including SMEs shall be 30% or more** of the total estimated EU contribution for the project as a whole. The SME status and the financial viability will be assessed at the end of the negotiation, before signature of the grant agreement.

HEALTH.2013.2.2.1-3: Paediatric conduct disorders characterised by aggressive traits and/or social impairment: from preclinical research to treatment. FP7-HEALTH-2013-INNOVATION-1. This topic aims at gaining new insights into the mechanisms underlying pathological aggression as well as developing preventative and therapeutic strategies for paediatric (0-18 years) conduct disorders characterised by aggressive and impulsive traits and/or social impairment. Applicants should apply a multidisciplinary approach to translate pre-clinical findings to therapies for the benefit of patients. Research proposed may address key issues such as genomics and genes/environment interactions, neurobiology of aggression and violence, identification of predictors of persistence and/or remission of symptoms in adulthood, development of strategies to prevent and treat these disorders and/or enhance remission.

Note: Limits on the EU financial contribution will apply and will be implemented strictly as eligibility criterion.

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

One or more proposals may be selected.

Expected impact: To improve the understanding of the neurobiology of paediatric conduct disorders characterised by aggressive traits and/or social impairment and the development of

³⁷ As defined in the Diagnostic and Statistical Manual of Mental Disorders, 4th edition.

³⁸ http://ec.europa.eu/health/ph_determinants/life_style/mental/docs/pact_en.pdf

new psychological and pharmacological interventions for prevention and treatment of these disorders.

Additional eligibility criteria:

1. The **requested EU contribution** per project shall not exceed EUR 6 000 000.
2. The **estimated EU contribution going to SME(s) shall be 15% or more** of the total estimated EU contribution for the project as a whole. The SME status and the financial viability will be assessed at the end of the negotiation, before signature of the grant agreement.

HEALTH.2013.2.2.1-4: Patho-physiology and therapy of epilepsy and epileptiform disorders. FP7-HEALTH-2013-INNOVATION-1. Applicants are expected to use multidisciplinary strategies in support of basic, preclinical and/or clinical research on epilepsy and epileptiform disorders. The goal is to better understand the complex patho-physiology of epilepsy in order to develop novel preventative strategies in at-risk patients, improve diagnostic methods, achieve better patient stratification and develop more effective therapeutics. Research proposed may address key issues such as genomics of epilepsy and epileptiform disorders, mechanisms of ictogenesis and epileptogenesis, prevention of the development of epilepsy after potentially epileptogenic brain insults, mechanisms and/or epidemiology of refractory epilepsy, identification of age- and aetiology-specific drug targets for input in drug discovery process.

Note: Limits on the EU financial contribution will apply and will be implemented strictly as eligibility criterion.

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

One or more proposals may be selected.

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

Additional eligibility criteria:

1. The **requested EU contribution** per project shall not exceed EUR 12 000 000.
2. The **estimated EU contribution going to SME(s) shall be 15% or more** of the total estimated EU contribution for the project as a whole. The SME status and the financial viability will be assessed at the end of the negotiation, before signature of the grant agreement.

HEALTH.2013.2.2.1-5: Understanding and controlling pain. FP7-HEALTH-2013-INNOVATION-1. This topic targets pain syndromes whose treatments are inexistent or inadequate, such as headache and migraine, neurogenic and neuropathic pain. Further studies are needed to gain knowledge on the mechanisms of different pain syndromes as well as the significant inter-individual variation in the response to painful stimuli and analgesic drugs. The goal is to identify and develop biomarkers for pain to enable better patient stratification, mechanism-based treatment selection and targeted prevention strategies for high-risk individuals. Research proposed may address bottlenecks such as: pain predisposing genetic

polymorphisms, circuitries and processes modulating nociception and endogenous analgesia, understanding the cognitive, emotional and behavioural components of pain, and new druggable molecular targets.

Note: Limits on the EU financial contribution will apply and will be implemented strictly as eligibility criterion.

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

One or more proposals may be selected.

Expected impact: Successful projects are expected to deepen our knowledge of how pain is generated, propagated and quenched, work towards the identification of more effective diagnostic and/or treatment approaches, and help translate pre-clinical and clinical results into solutions for the benefit of the patients.

Additional eligibility criterion:

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

2.2.2 Human development and ageing

Closed 2013

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

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

2.3.0 Cross-cutting priorities

This section comprises broad research topics that address two or more of the disease-oriented sub-areas under area 2.3.

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

HEALTH.2013.2.3.0-1: Innovation in vaccines. FP7-HEALTH-2013-INNOVATION-1.

This topic supports the pre-clinical and clinical development of new, innovative, safe and effective vaccines. Proposals will focus on:

- 1) Towards "universal" influenza vaccines, providing longer-lasting and broader protection against multiple strains of influenza virus, with the ultimate aim of efficiently protecting the general population from seasonal and pandemic influenza, or
- 2) Prophylactic vaccines for any of the neglected infectious diseases. Research will be sufficiently advanced to initiate human clinical testing during early phases of the project. For the purpose of this call topic, neglected infectious diseases include

kinetoplastid diseases (sleeping sickness, leishmaniasis, Chagas disease); neglected bacterial diseases (trachoma); viral (rabies) or helminth diseases [lymphatic filariasis, cysticercosis, or soil-transmitted nematodes (Ascariasis, Trichuriasis, Hookworm)].

Note: Limits on the EU financial contribution will apply and will be implemented strictly as eligibility criterion.

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

One or more proposals may be selected.

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

Specific requirements to be considered under the evaluation:

- SME-targeted research is designed to encourage SME efforts towards research and innovation.
- Leading role of research intensive SMEs.
- Leading role of SMEs with R&D capacities, but the coordinator does not need to be an SME.
- Expected outcomes being of clear interest and potential benefit to SMEs.

Additional eligibility criteria:

1. The **requested EU contribution** per project will depend on the needs of the project indicated in the proposal but shall not exceed EUR 6 000 000.
2. The **estimated EU contribution going to SMEs shall be 30% or more** of the total estimated EU contribution to the project as a whole. The SME status and the financial viability will be assessed at the end of the negotiation, before signature of the grant agreement.

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 (AMR) pathogens in a multi-disciplinary approach through the development of effective infection prevention, treatment and control strategies.

The Commission recently launched its action plan against the rising threats from antimicrobial resistance³⁹. A package of call topics for proposals supporting the aims of this Action plan through reinforcing and coordinating research and innovation can be found in three FP7 Cooperation Work Programmes, Health-2013 (HEALTH.2013.2.3.1-1, HEALTH.2013.2.3.1-2 and HEALTH.2013.3.1-1), KBBE-2013 (KBBE.2013.1.3-05) and NMP-2013 (NMP.2013.1.2-2).

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

³⁹ Commission Communication' Action plan against the rising threats from Antimicrobial resistance' COM(2011)748

HEALTH.2013.2.3.1-1: Drugs and vaccines for infections that have developed or are at risk of developing significant anti-microbial resistance. FP7-HEALTH-2013-INNOVATION-2. Projects should aim to develop novel, safe and efficacious antimicrobials,

vaccines or alternative medical approaches to treat infections that have developed or are at the risk of developing significant anti-microbial resistance. Projects may include different components of the development pipeline from discovery phase to clinical trials.

Note: Limits on the EU financial contribution and project duration will apply and will be implemented strictly as eligibility criteria.

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

One or more proposals may be selected.

Expected impact: The research is expected to stimulate a better integration of research and development activities between different players and boost the development of novel antimicrobials or vaccines against pathogens for which there is limited treatment options due to drug resistance. Research projects funded here are expected to be complementary to any possible upcoming activities undertaken in the context of IMI in relation to antimicrobial resistance.

Specific requirements to be considered under the evaluation:

- Specific innovation initiative designed to encourage strong SME efforts towards the translation of research results into innovative applications for health.
- Leading role of SMEs in the project (see also section III, p.65 of this document).
- Developing a short business plan clearly describing the valorisation of the technology(ies) when presenting a full proposal for stage 2.
- Expected outcomes being of clear interest and potential benefit to SMEs.

Additional eligibility criteria:

1. The **requested EU contribution** per project will depend on the needs of the project indicated in the proposal but shall not exceed EUR 6 000 000.
2. The proposed **project duration** indicated in the proposal **may not exceed 3 years**.
3. The **financial viability of all partners** in projects shall fulfil the Commission applicable rules⁴⁰. This will be checked at negotiation stage before signature of the grant agreement.
4. **Number of participants:** minimum 3 established in at least three different EU Member States or Associated Countries with the specific condition for SMEs under point 6 below. The maximum number of participants is 5.
5. The **estimated EU contribution going to SME(s)** shall **be 50% or more** of the total estimated EU contribution to the project as a whole. The SME status and the financial viability will be assessed at the end of the negotiation, before signature of the grant agreement.
6. **Participation of SMEs or SME joint ventures is restricted** to entities established in EU

⁴⁰ ftp://ftp.cordis.europa.eu/pub/fp7/docs/rules-verif_en.pdf

Member States and Associated Countries. In addition, SMEs shall fulfil any of the following conditions: 1) be 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) be at least 51% owned and controlled by another business that is itself at least 51% owned and controlled by individuals who are citizens of, or permanent residents in those countries.

HEALTH.2013.2.3.1-2: Stratified approaches to antibacterial and/or antifungal treatment. FP7-HEALTH-2013-INNOVATION-1. In order to improve the use of antibacterials and antifungals (dosage, duration, indication and combinations) with regard to treatment effectiveness, reduction of adverse effects as well as emergence of drug resistance, antimicrobial administration needs to be better tailored to the actual needs of individual patients. Projects should aim to gain a better understanding of both pathogen and host factors, as well as their interaction, with the objective to allow for more stratified treatment options and improved antimicrobial administration. Where relevant, consideration should be given to gender aspects and ageing.

Note: Limits on the EU financial contribution will apply and will be implemented strictly as eligibility criterion.

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

One or more proposals may be selected.

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

Additional eligibility criterion:

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

2.3.2 HIV/AIDS, malaria and tuberculosis

Closed 2013

2.3.3 Potentially new and re-emerging epidemics

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

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

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

HEALTH.2013.2.3.3-1: Clinical management of patients in severe epidemics. FP7-HEALTH-2013-INNOVATION-1. The objective is to set up a multidisciplinary consortium

able to provide a rapid, harmonised and optimised approach to clinical management of patients in relation to any severe infectious outbreak with a pandemic potential or significant risk of major damage to health and socio-economics in the EU. The consortium will address severe acute respiratory infections, as well as other acute infections (e.g. hemorrhagic fevers, encephalopathy, severe diarrhoeas, etc.). It should build a standardised methodological approach (pre-approval of protocols and ethical issues, common definitions and databases, mechanisms to rapidly exchange high quality data and samples, etc.) that would ensure the readiness to immediately perform large-scale clinical studies in response to an emerging threat with the view of delivering harmonised and optimal clinical treatments to the affected patients in any location and helping controlling the outbreak. It also needs to have a solid "inter-epidemic" research plan, addressing issues such as, but not restricted to, multi-centre clinical trials, studies on pathogenesis, immunity and determinants of severity. It may also explore the feasibility of developing novel, rapid, reliable, sensitive, user-friendly, and affordable approaches for the detection and characterisation of pathogens in order to support patient treatment and outbreak control. Training activities should be elaborated to spread to clinical centres the new insights that should translate into optimal clinical management of patients in the context of severe epidemics. Special attention should be given to EU Member States and Associated Countries with limited capacity to respond to such epidemics. The consortium is expected to collaborate with other EU funded research projects where relevant and consult and collaborate with the European Centre for Disease Prevention and Control (ECDC) in order to improve the European preparedness and response to any emerging threat. The project should structure the European contribution towards international initiatives already existing or under development in this field.

Note: Limits on the EU financial contribution will apply and will be implemented strictly as eligibility criterion.

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

Only one proposal may be selected.

Expected impact: The research should provide technical and scientific support as well as standardised protocols/definitions/strategies for the optimal clinical management of patients in any severe infectious outbreak with pandemic potential or significant risk of major damage to health and socio-economics in the EU. It is expected to help designing a coherent, adequate and rapid public health response to emerging threats. The consortium should establish and foster links with national and international public health agencies to ensure the quick implementation of its findings into optimised clinical practices in the EU member states and other countries in the world.

Additional eligibility criterion:

The **requested EU contribution** per project shall not exceed EUR 24 000 000.

2.3.4 Neglected infectious diseases

The aim of this area is to establish an integrated approach for the development of preventive, therapeutic and diagnostic tools for neglected infectious diseases.

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

HEALTH.2013.2.3.4-1: Neglected infectious diseases of Central and Eastern Europe. FP7-HEALTH-2013-INNOVATION-1. This action will support innovative, collaborative biomedical research proposals that address neglected infectious diseases, which disproportionately affect Central and Eastern Europe (CEE)⁴¹. Research will focus on one or more of the following viral (tick-borne encephalitis, Congo-Crimean haemorrhagic fever, rabies), bacterial (borreliosis and other tick-borne bacterial diseases), protozoan (babesiosis, giardiasis), and/or helminthic (trichinellosis, taeniasis and human echinococcosis) human diseases. Proposals will provide an integrated, multidisciplinary approach with significant participation of partners from disease-endemic areas and, where relevant, industry partners. Proposals should include plans for translating research results into innovation in the health systems or through product development activities.

Note: Limits on the EU financial contribution will apply and will be implemented strictly as eligibility criterion.

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

One or more proposals may be selected.

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

Additional eligibility criterion:

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

HEALTH.2013.2.3.4-2: Drug development for neglected parasitic diseases. FP7-HEALTH-2013-INNOVATION-1. Projects will bring together promising European and global attempts to discover and develop drugs for neglected parasitic diseases. For the purpose of this call topic, neglected parasitic diseases include the kinetoplastid diseases (sleeping sickness, leishmaniasis, Chagas disease) and helminth diseases [lymphatic filariasis, onchocerciasis, schistosomiasis or soil-transmitted nematodes (Ascariasis, Trichuriasis, Hookworm)]. Proposals should focus either on:

- 1) Establishing a common drug discovery platform by joining experts in the field from industry and the public sector in Europe and disease-endemic countries. The resulting platform should have the capacity to undertake screening of compound libraries, lead development, testing in relevant animal models as well as toxicology and safety testing of new drug candidates. The drug discovery platform should address a minimum of three parasitic, with a balanced distribution of resources between them. In addition to the parasitic diseases mentioned above, the platform may also, if a clear synergy can be demonstrated, include malaria drug discovery activities, or:
- 2) Undertaking advanced clinical testing of new or improved drug candidates, including new formulations or combinations of already approved drugs. The drug candidate(s) to be addressed will already have undergone first-in-man testing.

⁴¹ For the purposes of this topic CEE comprises: Albania, Bosnia and Herzegovina, Bulgaria, Croatia, Czech Republic, Estonia, Hungary, Kosovo, Latvia, Lithuania, Former Yugoslav Republic of Macedonia, Moldova, Montenegro, Poland, Romania, Slovakia, Slovenia, Serbia and Turkey.

Note: Limits on the EU financial contribution will apply and will be implemented strictly as eligibility criterion.

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

One or more proposals may be selected.

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

Specific requirements to be considered under the evaluation:

- SME-targeted research is designed to encourage SME efforts towards research and innovation.
- Leading role of research intensive SMEs.
- Leading role of SMEs with R&D capacities, but the coordinator does not need to be an SME.
- Expected outcomes being of clear interest and potential benefit to SMEs.

Additional eligibility criteria:

1. The **requested EU contribution** per project shall not exceed EUR 6 000 000.
2. The **estimated EU contribution going to SMEs shall be 15% or more** of the total estimated EU contribution for the project as a whole. The SME status and the financial viability will be assessed at the end of the negotiation, before signature of the grant agreement.

2.4 TRANSLATIONAL RESEARCH IN OTHER MAJOR DISEASES

2.4.1 Cancer

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

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

HEALTH.2013.2.4.1-1: Investigator-driven treatment trials to combat or prevent metastases in patients with solid cancer. FP7-HEALTH-2013-INNOVATION-1. The successful consortia will perform multicentre clinical trials assessing therapeutic strategies for localised or systemic metastases in patients with solid cancers or for preventing their development in patients with solid cancers. Consortia will use state-of-the-art technologies to ensure proper patient staging and assessment of treatment efficacy. The following

requirements and exclusions apply: endpoints, inclusion and exclusion criteria will be clearly described. The primary endpoint should be overall survival. The outcome of this research will be relevant for patients and have a potential to lead to changes in clinical practice. Applicants will have to demonstrate that clinical trials are appropriately powered to produce statistically significant evidence. Gender aspects and differences related to age groups will be appropriately considered. The clinical trials to be supported will have to be registered in a publicly accessible clinical trials registry and their results published in peer-reviewed journals. The applications will 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, may be involved where appropriate.

Note: Limits on the EU financial contribution will apply and will be implemented strictly as eligibility criterion.

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

One or more proposals may be selected.

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

Additional eligibility criterion:

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

HEALTH.2013.2.4.1-2: Strengthening the cancer patient's immune system. FP7-HEALTH-2013-INNOVATION-1. The successful consortia will advance pre-clinical and/or clinical research concerning cancer immunotherapy towards improved treatment efficacy of future immunotherapeutic strategies. It may address one or more of the following areas:

- (1) cell, antibody or molecule-based immunotherapy;
- (2) therapeutic cancer vaccines directed against clinically relevant tumour and/or host antigens;
- (3) immune evasion impacting on clinically relevant tumour-host microenvironment interactions in localised or systemic disease.

Where appropriate tumour response criteria must be considered. Assays must be harmonised to validate cancer immunotherapeutic regimens in models or first-in-human trials. Involvement of industry, in particular SMEs, is strongly recommended.

Note: Limits on the EU financial contribution will apply and will be implemented strictly as eligibility criterion.

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

One or more proposals may be selected.

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

Additional eligibility criteria:

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

2. **The estimated EU contribution going to industry including SME(s) shall be 30% or more** of the total estimated EU contribution for the project as a whole. The SME status and the financial viability will be assessed at the end of the negotiation, before signature of the grant agreement.

HEALTH.2013.2.4.1-3: Investigator-driven supportive and palliative care clinical trials and observational studies. FP7-HEALTH-2013-INNOVATION-1. The successful consortia will perform multicentre clinical trials and/or observational studies aiming at improving quality-of-life of cancer patients or cancer survivors. The clinical studies may address symptoms caused by cancer, by cancer treatment, by long-term side-effects in cancer survivors or address symptoms that occur at the end of life. The following requirements and exclusions apply: endpoints, inclusion and exclusion criteria will be clearly described. The outcome of this research will have to be relevant for patients or survivors and have a potential to lead to changes in clinical practice. Applicants will have to demonstrate that clinical trials and/or observational studies are appropriately powered to produce statistically significant evidence. Gender aspects and differences related to age groups should be appropriately considered. The clinical trials to be supported need to be registered in a publicly accessible clinical trials registry and their results published in peer-reviewed journals. The applications need to 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, may be involved where appropriate.

Note: Limits on the EU financial contribution will apply and will be implemented strictly as eligibility criterion.

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

One or more proposals may be selected.

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

Additional eligibility criterion:

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

2.4.2 Cardiovascular diseases

Collaborative research projects on cardiovascular diseases (CVD) have been supported in FP7 for an overall financial contribution of some EUR 163 million. This has allowed addressing the areas of atherosclerosis, aneurysm, congenital diseases, cardiomyopathies, CVD imaging, pharmacogenomics, systolic and diastolic heart failure, translational research and clinical trials in stroke, stem cell therapy for the treatment of heart ischemia, ventricular arrhythmias, atrial fibrillation, stent thrombosis and cardio-protection. For this call for proposals, topics will focus on the identification and validation of novel therapeutically relevant targets for the development of new medication for cardiovascular pathologies as well as on the clinical studies of cardiovascular technologies.

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

HEALTH.2013.2.4.2-1: Discovery research to reveal novel targets for cardiovascular disease treatment. FP7-HEALTH-2013-INNOVATION-1. The cutting edge research projects should explore further available and emerging molecular, genomic and other omics data from large-scale population studies and lead to the identification, characterisation and validation of *in vitro* and *in vivo* models of novel therapeutically relevant targets. Achieving this aim will have to be ensured by multidisciplinary research consortia with advanced biotechnological tools available.

Note: Limits on the EU financial contribution will apply and will be implemented strictly as eligibility criterion.

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

One or more proposals may be selected.

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

Specific requirements to be considered under the evaluation:

- SME-targeted research is designed to encourage SME efforts towards research and innovation.
- Leading role of research intensive SMEs.
- Leading role of SMEs with R&D capacities, but the coordinator does not need to be an SME.
- Expected outcomes being of clear interest and potential benefit to SMEs.

Additional eligibility criteria:

1. The **requested EU contribution per project** shall not exceed EUR 6 000 000.
2. The **estimated EU contribution going to SMEs shall be 30% or more** of the total estimated EU contribution for the project as a whole. The SME status and the financial viability will be assessed at the end of the negotiation, before signature of the grant agreement.

HEALTH.2013.2.4.2-2: Comparative effectiveness research of existing technologies for prevention, diagnosis and treatment of cardiovascular diseases. FP7-HEALTH-2013-INNOVATION-1. Cardiovascular technologies used in clinical practice including those used for imaging and therapeutic procedures may vary widely in different countries and even amongst centres. In addition, systematic evidence regarding how approaches to prediction, diagnosis, treatment, monitoring and prognosis compare with one another is lacking. The project will compare the use of *currently available* technical procedures and/or devices in selected broad populations. A comprehensive array of clinical and safety parameters, as well as socio-economic outcomes (e.g. quality of life, patient mortality, morbidity, costs, and performance of the health system) for chosen populations will be assessed. Randomised controlled trials, observational studies and meta-analyses may be considered for this topic. The study population should well address gender balance. Data sources to be used and methods to assess comparative effectiveness and cost effectiveness will be clearly defined. The project may include prospective data collection, development of clinical data networks, databases or patient registries. Dissemination activities aimed at raising awareness on the outcome of the study to the health care workforce may also be included, where appropriate.

Note: Limits on the EU financial contribution will apply and will be implemented strictly as eligibility criterion.

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

One or more proposals may be selected.

Expected impact: The purpose of this research is to inform patients, health care providers, and decision-makers, about which technologies are most effective in dealing with CVD.

Additional eligibility criterion:

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

HEALTH.2013.2.4.2-3: Optimising lifestyle interactions in the prevention and treatment of cardiovascular disease across the lifespan. FP7-HEALTH-2013-INNOVATION-1.

Projects should examine the effects of primary and secondary prevention of cardiovascular diseases using *lifestyle intervention* strategies. Research may include understanding and optimising the dose-response relationship between physical activity and cardiovascular health, as well as the interaction(s) between physical activity, other lifestyle factors and pharmacotherapy. Projects should also combine *in vivo* and *in vitro* studies to advance our current understanding of the fundamental cellular and molecular mechanisms underpinning physical activity-dependent changes in cardiovascular health.

Note: Limits on the EU financial contribution will apply and will be implemented strictly as eligibility criterion.

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

One or more proposals may be selected.

Expected impact: The purpose of this research is to provide solid evidence-based research to guide the prevention/treatment of cardiovascular diseases at primary/secondary levels. It might also lead to improved cohort stratification in existing clinical trial models. Successful application of lifestyle intervention strategies can be expected to yield substantial savings within existing unsustainable health care costs in the medium-to-long-term.

Additional eligibility criterion:

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

2.4.3 Diabetes and obesity

Closed 2013

2.4.4 Rare diseases

Closed 2013

2.4.5 Other chronic diseases

Closed 2013

3. OPTIMISING THE DELIVERY OF HEALTHCARE TO EUROPEAN CITIZENS

This activity aims at providing further evidence to underpin policy decisions for the development of health systems as well as strategies for health promotion, disease prevention, diagnosis and therapy. Topics addressed cover Comparative Effectiveness Research (CER) in health systems and health services interventions and social innovation for health promotion.

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

This area focuses on appropriate use of behavioural and organisational interventions as well as therapies and health technologies to improve health and to foster applications of evidence-based decision making. Special attention will be given to patient safety to define best clinical practice and to patient involvement, wherever appropriate, in decision making in primary and specialised care. Gender aspects and differences related to age, socioeconomic status and other differentiating factors will be appropriately considered.

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

HEALTH.2013.3.1-1: Comparative effectiveness research (CER) in health systems and health services interventions. FP7-HEALTH-2013-INNOVATION-1. Projects will evaluate the impact of two or more alternative health system and health services interventions in terms of their health benefit, patient needs, patient safety, effectiveness and quality of care. Research should also address the structural and policy components as well as cost effectiveness. It should use a multidisciplinary approach and take into account some of the different organisation of care models within Europe. A broad array of interventions and approaches may be studied under this topic, ranging from comparing effects of different models of integrated care on patient experiences, outcomes, and efficiency or comparing integrated care with more traditional models of care; analysing the uptake of new approaches such as stratified, individualised or personalised medicine; comparing the effectiveness of different quality improvement strategies in disease prevention; to assessing interventions such as promoting prudent use of antibiotics or smoking cessation. Different population groups will have to be taken into account where relevant.

Note: Limits on the EU financial contribution will apply and will be implemented strictly as eligibility criterion.

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

One or more proposals may be selected.

Expected impact: Results should assist policy makers and decision makers to make informed decisions regarding the implementation or improvement of health system and health services interventions in view of improving patient outcomes, quality of life and increase the cost-effectiveness of interventions, ultimately improving health status at individual and population levels.

Additional eligibility criterion:

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

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

Closed 2013

3.3 HEALTH PROMOTION AND PREVENTION

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

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

HEALTH.2013.3.3-1: Social innovation⁴² for health promotion. FP7-HEALTH-2013-INNOVATION-1. EU research should aim to identify, develop and better understand innovative approaches to reduce sedentary behaviour and enhance the level of physical activity in the population. Research should include the evaluation of innovative on-going initiatives that reduce sedentary behaviour, enhance the level of physical activity combined with dietary or other interventions. In this context, research should include the identification of "good practices", as well as the analysis of their economic and social benefits and impact. Correlates will have to be detected (such as cultural, environmental, economic, psychological and others) that inhibit or promote the individuals capacity to increase physical activity, reduce sedentary behaviour and self-regulate their dietary or other relevant behaviour. Research may cover various areas affecting lifestyle (e.g. sports, health, education, transport, urban planning, working environment, leisure) as well as different intervention levels (local, national, European). As a social innovation it should address the role of diverse public and private entities, such as business, including social enterprises, civil society organisations and public authorities, as well as their interaction. The views of potential end-users should be integrated in the design of the project as well as the methodology for assessing impact and outcomes throughout the project. The project should have a strong communication strategy.

Note: Limits on the EU financial contribution will apply and will be implemented strictly as eligibility criterion.

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

One or more proposals may be selected.

⁴² Social innovations are new ideas (products, services and models) that simultaneously meet social needs (more effectively than alternatives) and create new social relationships or collaborations. In other words they are innovations that are not only good for society but also enhance society's capacity to act.
http://ec.europa.eu/enterprise/policies/innovation/policy/social-innovation/index_en.htm

It covers wide fields which range from new models of child care to web-based social networks, from the provision of domestic healthcare to new ways of encouraging people to exchange cars for bicycles in cities, and the development of global fair-trade chains. It may be a new product, service, initiative, organisational model or approach to the delivery of public services.

Expected impact: The relevant research should provide the necessary basis for empowering society to reduce sedentary behaviour, increase physical activity in everyday life, thus preventing major lifestyle related diseases. This includes identifying more effective and efficient evidence-based strategies for reducing sedentary behaviour and increasing physical activity together with supportive (multi-disciplinary) policy environments. This will result in a greater uptake of innovative approaches by policy makers and making it more appealing to citizens to choose a healthy lifestyle.

Additional eligibility criteria:

1. The **requested EU contribution** per project will depend on the needs of the project indicated in the proposal but shall not exceed EUR 6 000 000.
2. The **estimated EU contribution going to SMEs shall be 15 % or more** of the total estimated EU contribution to the project as a whole. The SME status and the financial viability will be assessed at the end of the negotiation, before signature of the grant agreement.

3.4 INTERNATIONAL PUBLIC HEALTH & HEALTH SYSTEMS

Closed 2013

4. OTHER ACTIONS ACROSS THE HEALTH THEME

The objective of these actions is to contribute to the implementation of the Framework programmes and the preparation of future EU research and technological development policy.

4.1 COORDINATION AND SUPPORT ACTIONS ACROSS THE THEME

The focus of this area in this work programme will be on the dissemination and exploitation of results and on assessing future needs. For this call for proposals the focus of this area will be on technology transfer and dissemination of results.

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

HEALTH.2013.4.1-1: Supporting industrial participation in EU-funded research in the Health sector. FP7-HEALTH-2013-INNOVATION-1. This four year coordination action will support participants of running FP7 Health projects (as well as IMI⁴³ and EDCTP⁴⁴ projects), with focus on industry, especially European research performing SMEs. Specific objectives include at least the following activities: (i) to promote project participation of SMEs. The promotional activity should include participation in relevant events and organisation of workshops; (ii) to assist project participants through training activities,

⁴³ Innovative Medicines Initiative.

⁴⁴ European and Developing Countries Clinical Trials Partnership.

personalised tools and using new media; *(iii)* to provide support for consortium building and matchmaking for industry and academia preparing EU project proposals with the help of a matchmaking database; *(iv)* to provide tools (including an up-to-date database of health-related SMEs in Europe) to encourage cooperation between industry and academia and increase the participation rate of high-technology research-performing SMEs. *(v)* To provide support on IPR issues that may rise during funded projects' lifetime; *(vi)* to assist project participants with training activities and tools; *(vii)* to provide advice/information/training on valorisation of project results, knowledge transfer in view of future commercialisation covering for example business management, innovation financing sources, organisation of partnering events. The project will collaborate, complement and develop synergies with existing support structures such as National Contact Points, Enterprise Europe Network, knowledge-transfer networks, like the IPR helpdesk, EMA⁴⁵ SME Office etc.

Note: Limits on the EU financial contribution will apply and will be implemented strictly as eligibility criterion.

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

Only one proposal may be selected.

Expected impact: The promotional activity is expected to support the increase of industry, especially high-tech SMEs participation in EU-funded health research, enhancing Innovation Union and Lisbon objectives for contributing to technological evolution, innovation, competitiveness of European industry, economic growth and employment. Participation of industry, and high-technology research-intensive SMEs in particular, in health research projects will enhance innovation through the dissemination and exploitation of research results generated in EU funded health research activities with the political objective of giving to SMEs 15% or more of the EU contribution. The project is expected to help innovative SMEs in successfully participating into framework projects.

Additional eligibility criterion:

The **requested EU contribution** per project shall not exceed EUR 2 500 000.

HEALTH.2013.4.1-2: Interactions between EU legislation and health research and/or innovation and the effects of its application and implementation on health research and/or innovation. FP7-HEALTH-2013-INNOVATION-1. The action aims to analyse and evaluate the interactions between relevant EU legislation with related guidelines and health research and/or innovation, including but not limited to: the specific application and implementation of this legislation at national level in this field; developments in the application and implementation. Each action is expected to address a specific issue relating to one EU legislation of major importance for the research and outcome performed within the health area.

Note: Limits on the EU financial contribution will apply and will be implemented strictly as eligibility criterion.

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

One or more proposals may be selected.

Expected impact: to better assess the effects of and interactions between the relevant EU legislation and research activities and related developments supported within this area using

⁴⁵ European Medicines Agency.

scientific analysis based on facts and figures. In particular, such projects are expected to constitute the evidence base that will help the Commission to identify ways to optimise the innovative potential, the efficacy in the drafting and application of current or future EU legislation.

Additional eligibility criterion:

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

HEALTH.2013.4.1-3: Support for Presidency events: Organisation of supporting actions and events associated to the Presidency of the European Union. FP7-HEALTH-2013-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) will contribute to conferences or other appropriate events to be held in a MS which will hold a forthcoming Presidency of the European Union, specifically from mid-2013 to end 2014 Presidencies, in any area of the Health Theme. In order to ensure high political and strategic relevance, the active involvement of the relevant national authorities 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 or other specific audiences.

Note: Limits on the EU financial contribution will apply and will be implemented strictly as eligibility criterion.

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

One or more proposals may 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.2013.4.1-4: Preparing the future for health research and innovation. FP7-HEALTH-2013-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. 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 will have to 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 European innovation partnership. The expected work excludes research activities. 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 strategic research agendas or roadmap-oriented activities will be taken into account and - where relevant - coordination with these will allow for synergies and exclude competition or duplication. In addition, the proposal will have to 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.) will be clearly identified. The timeframe considered for implementation will also be duly justified.

Note: Limits on the EU financial contribution will apply and will be implemented strictly as eligibility criterion.

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

One or more proposals may be selected.

Expected impact: Projects will 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.

FP7-HEALTH.2013.4.1-5: Global initiative on gene-environment interactions in diabetes/obesity in specific populations. FP7-HEALTH-2013-INNOVATION-1. This action should support the coordination of research activities in the field of population research into diabetes and obesity that are currently funded by the European Commission, Members States and Associated Countries, together with other national funding agencies, notably in Mexico, New Zealand, Canada, the USA and Australia, as well as charities. It aims at aligning programmes and policies across Europe and the world, and contributing to increase sharing of best practice and best use of research and public health resources, including in associations with international initiatives such as the Global Alliance for Chronic Diseases⁴⁶. It should address the fragmentation of research activities develop synergies, and possible common strategic research agendas. It should integrate on-going and planned international projects, both EU funded and other, that address research on diabetes and obesity in specific populations. Part of the work to be undertaken is to convene international meetings as appropriate to follow up on the February 2012 Brussels conference "Diabesity – a world-wide challenge".

Note: Limits on the EU financial contribution will apply and will be implemented strictly as eligibility criterion.

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

Only one proposal may be selected.

Expected impact: This action should improve the linking and efficient integration and coordination of relevant and complementary EU funded and international/national/regional

⁴⁶ The European Commission proposes to take part in the Global Alliance for Chronic Diseases – see Other Activities page 67.

research activities. It should provide a forum for exchange of information and best practices between the projects involved and the funding bodies, helping to create a transparent, dynamic and effective governing mechanism. Funding agencies will retain the governance of their action. The inclusion of existing and future international projects on the subject is expected to leverage on resources and avoid duplication. The structure should be kept open to allow for extended involvement of other funding bodies' projects. Ultimately, this action should lead to a self-sustainable network of funders in the area of diabetes/obesity research in specific populations, and its prevention, enabling the translation of information gained from innovative research and experiences into policy, social and economic benefits.

Additional eligibility criterion:

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

FP7-HEALTH.2013.4.1-6: Mapping chronic non-communicable diseases research activities. FP7-HEALTH-2013-INNOVATION-1. This action should identify and analyse current EU-funded, as well as national and regional research programmes and initiatives in the field of chronic non-communicable diseases, their implementation modalities, funding sources and overall investments and output. The objective will be to map the scale and scope of research activities in this area, including the research fields addressed, with a view to identify potential overlaps, synergies, gaps and opportunities for collaboration. Adequate comparison of data and results should be ensured through the use of common definition criteria and methodology(ies).

Note: Limits on the EU financial contribution will apply and will be implemented strictly as eligibility criterion.

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

Only one proposal may be selected.

Expected impact: This action should contribute to the development of evidence-based policies towards supporting coordinated approaches in chronic non-communicable diseases research.

Additional eligibility criterion:

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

4.2 RESPONDING TO EU POLICY NEEDS

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

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

HEALTH.2013.4.2-1: Investigator-driven clinical trials for off-patent medicines using innovative, age-appropriate formulations and/or delivery systems. FP7-HEALTH-2013-INNOVATION-1. Proposals will address one of the options below:

A) for use in children (Regulation (EC) No1901/2006⁴⁷): Projects are expected to contribute to expanding the availability of medicines for children. Particular attention will be paid to age-appropriate formulations and of specific delivery systems for children. Projects will conduct appropriate clinical trials in children, respecting the current legislation and considering the ethical aspects and the particular needs of children and their families. Patient advocacy groups should be involved where possible and appropriate. The aim is to conduct clinical trials with the view of obtaining a PUMA (Paediatric Use Marketing Authorisation). Priority will be given to following areas, as mentioned in the EMA list of priorities for paediatric medicines:

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

Or

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

Note: Limits on the EU financial contribution will apply and will be implemented strictly as eligibility criterion.

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

One or more proposals may be selected.

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

Additional eligibility criteria:

1. The **requested EU contribution** per project shall not exceed EUR 6 000 000.
2. The **estimated EU contribution going to industry including SMEs shall be 30% or more** of the total estimated EU contribution for the project as a whole. The SME status and the financial viability will be assessed at the end of the negotiation, before signature of the grant agreement.

HEALTH.2013.4.2-2: Adverse drug reaction research. FP7-HEALTH-2013-INNOVATION-1. Experiences with medicines that have been on the market for many years have shown that potentially serious adverse events may only become apparent long after their marketing authorisation. Projects to be funded in this topic will generate new knowledge on severe drug reactions and provide scientific evidence for post-authorisation risk assessment of medicinal products. Proposals will be based on pharmaco-epidemiological approaches focusing on adverse drug reaction research in one of the areas indicated below.

⁴⁷ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:378:0001:0019:en:PDF>

- Long term safety of antipsychotic medication in patients with dementia
- Genetic causes of adverse drug reactions: angiotensin-converting enzyme inhibitors and angioedema, and statin-induced myopathy
- Long-term adverse skeletal effects of bisphosphonates

Further details of the research objectives and expected deliverables are available on the website:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000322.jsp&mid=

Note: Limits on the EU financial contribution will apply and will be implemented strictly as eligibility criterion.

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

One or more proposals may be selected.

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

Additional eligibility criteria:

1. The **requested EU contribution** per project shall not exceed EUR 3 000 000.
2. The **estimated EU contribution going to SME(s) shall be 15 % or more** of the total estimated EU contribution for the project as a whole. The SME status and the financial viability will be assessed at the end of the negotiation, before signature of the grant agreement.

HEALTH.2013.4.2-3: New methodologies for clinical trials for small population groups. FP7-HEALTH-2013-INNOVATION-1. The objective is to develop new or improved statistical design methodologies for clinical trials aiming at the efficient assessment of the safety and/or efficacy of a treatment for small population groups in particular for rare diseases or personalised (stratified or individualised) medicine. Research should be multidisciplinary and should involve all relevant stakeholders including industry and patient advocacy groups as appropriate. Ideally, results would lead to improvement of clinical trial guidelines. Clinical trials as such are excluded from this topic. Collaboration with relevant organisations outside Europe is welcomed.

Note: Limits on the EU financial contribution will apply and will be implemented strictly as eligibility criterion.

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

One or more proposals may be selected.

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

Additional eligibility criterion:

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

III IMPLEMENTATION of CALLS

HEALTH-2013-INNOVATION

Call identifier: FP7-HEALTH-2013-INNOVATION-1

Proposal submission and evaluation: two-stage procedure.

Date of publication: 10 July 2012⁴⁸

Deadline for stage 1 proposals: 02 October 2012 at 17:00:00 (Brussels local time)⁴⁹

Indicative budget: EUR 679.3 million from the 2013 budget⁵⁰

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.

For description of the topics of the calls, please refer to section II 'Content of calls'

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	36
1.3 SUITABILITY, SAFETY, EFFICACY OF THERAPIES	60
1.4 INNOVATIVE THERAPEUTIC APPROACHES AND INTERVENTIONS	36
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 Functional validation in animal and cellular models of genetic determinants of diseases and ageing processes	36
2.1.1-2 High impact research initiative on metagenomics for personalised medicine approaches	30

⁴⁸ The Director-General responsible for this call may publish it up to one month prior to or after the envisaged date of publication.

⁴⁹ The Director-General responsible for this call may delay this deadline by up to two months.

⁵⁰ Under the condition that the draft budget for 2013 is adopted without modifications by the budgetary authority.

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2.2 RESEARCH ON THE BRAIN AND BRAIN-RELATED DISEASES, HUMAN DEVELOPMENT AND AGEING	
2.2.1 RESEARCH ON THE BRAIN AND BRAIN-RELATED DISEASES	
2.2.1-1 Traumatic brain injury	30
2.2.1-2, -3, -4, -5 Mental health, neurology and pain	96
2.3 TRANSLATIONAL RESEARCH IN MAJOR INFECTIOUS DISEASES: TO CONFRONT MAJOR THREATS TO PUBLIC HEALTH	
2.3.0 CROSS-CUTTING PRIORITIES	
2.3.1 ANTI-MICROBIAL DRUG RESISTANCE	24
2.3.3 EMERGING EPIDEMICS	24
2.3.4 NEGLECTED DISEASES	33
2.4 TRANSLATIONAL RESEARCH IN OTHER MAJOR DISEASES	
2.4.1 CANCER	72
2.4.2 CARDIOVASCULAR DISEASES	54
3 OPTIMISING THE DELIVERY OF HEALTHCARE TO EUROPEAN CITIZENS	
3.1 TRANSLATING THE RESULTS OF CLINICAL RESEARCH OUTCOME INTO CLINICAL PRACTICE INCLUDING BETTER USE OF MEDICINES, APPROPRIATE USE OF BEHAVIOURAL AND ORGANISATIONAL INTERVENTIONS AND NEW HEALTH THERAPIES AND TECHNOLOGIESHEALTH CARE SYSTEMS	30
3.3 HEALTH PROMOTION AND PREVENTION	24
4 OTHER ACTIONS ACROSS THE HEALTH THEME	
4.1 COORDINATION AND SUPPORT ACTIONS ACROSS THE THEME	10.3
4.2 RESPONDING TO EU POLICY NEEDS	42

Table 2: Topics called:

Activity/Area	Topics called	Funding Schemes and additional eligibility criteria
1 BIOTECHNOLOGY, GENERIC TOOLS AND MEDICAL TECHNOLOGIES FOR HUMAN HEALTH		
1.2 DETECTION, DIAGNOSIS & MONITORING		
1.2	HEALTH.2013.1.2-1: Development of imaging technologies for therapeutic interventions in rare diseases. <i>One or more proposals may be selected.</i>	<i>SME-targeted Collaborative Project (small or medium-scale focused research project). Additional eligibility criterion: Requested EU contribution per project: Maximum EUR 6 000 000. The estimated EU contribution going to SME(s) shall be 30% or more of the total estimated EU contribution for the project as a whole. The SME status and the financial viability will be assessed at the end of the negotiation, before signature of the grant agreement.</i>
1.3 SUITABILITY, SAFETY, EFFICACY OF THERAPIES		
1.3	HEALTH.2013.1.3-1: Modelling toxic	<i>Collaborative Project (large-scale integrating</i>

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	<p>responses in case studies for predictive human safety assessment.</p> <p><i>Only one proposal may be selected.</i></p>	<p><i>research project). Additional eligibility criterion: Requested EU contribution per project: Maximum EUR 12 000 000. The estimated EU contribution going to industry including SME(s) shall be 15% or more of the total estimated EU contribution for the project as a whole. The SME status and the financial viability will be assessed at the end of the negotiation, before signature of the grant agreement.</i></p>
1.3	<p>HEALTH.2013.1.3-2: Innovative approaches to address adverse immune reactions to biomedical devices, implants and transplant tissues.</p> <p><i>One or more proposals may be selected.</i></p>	<p><i>Collaborative Project (small or medium-scale focused research project). Additional eligibility criterion: Requested EU contribution per project: Maximum EUR 6 000 000. The estimated EU contribution going to industry including SME(s) shall be 30% or more of the total estimated EU contribution for the project as a whole. The SME status and the financial viability will be assessed at the end of the negotiation, before signature of the grant agreement.</i></p>
1.3	<p>HEALTH.2013.1.3-3: Safety and efficacy of therapeutic vaccines.</p> <p><i>One or more proposals may be selected.</i></p>	<p><i>Collaborative Project (small or medium-scale focused research project). Additional eligibility criterion: Requested EU contribution per project: Maximum EUR 6 000 000. The estimated EU contribution going to industry including SME(s) shall be 30% or more of the total estimated EU contribution for the project as a whole. The SME status and the financial viability will be assessed at the end of the negotiation, before signature of the grant agreement.</i></p>
1.3	<p>HEALTH.2013.1.3-4: Development of alternative <i>in vitro</i>, analytical, immunochemical, and other test methods for quality control of vaccines.</p> <p><i>One or more proposals may be selected.</i></p>	<p><i>Collaborative Project (small-scale focused research project). Additional eligibility criterion: Requested EU contribution per project: Maximum EUR 3 000 000. The estimated EU contribution going to industry including SME(s) shall be 30% or more of the total estimated EU contribution for the project as a whole. The SME status and the financial viability will be assessed at the end of the negotiation, before signature of the grant agreement.</i></p>
1.4 INNOVATIVE THERAPEUTIC APPROACHES AND INTERVENTIONS		
1.4	<p>HEALTH.2013.1.4-1. Controlling differentiation and proliferation in human stem cells intended for therapeutic use.</p> <p><i>One or more proposals may be selected.</i></p>	<p><i>Collaborative Project (small or medium-scale focused research project). Additional eligibility criterion: Requested EU contribution per project: Maximum EUR 6 000 000. The estimated EU contribution going to SME(s) shall be 15% or more of the total estimated EU contribution for the project as a whole. The SME status and the financial viability will be assessed at the end of the negotiation, before signature of the grant agreement.</i></p>
2 TRANSLATING RESEARCH FOR HUMAN HEALTH		
2.1 INTEGRATING BIOLOGICAL DATA AND PROCESSES: LARGE-SCALE DATA GATHERING,		

SYSTEMS BIOLOGY		
2.1.1 Large-scale data gathering		
2.1.1	HEALTH.2013.2.1.1-1: Functional validation in animal and cellular models of genetic determinants of diseases and ageing processes. <i>One or more proposals may be selected.</i>	<i>SME-targeted Collaborative Project (large-scale integrating research project). Additional eligibility criterion: Requested EU contribution per project: Maximum EUR 12 000 000. The estimated EU contribution going to SME(s) shall be 30% or more of the total estimated EU contribution for the project as a whole. The SME status and the financial viability will be assessed at the end of the negotiation, before signature of the grant agreement.</i>
2.1.1	HEALTH.2013.2.1.1-2: High impact research initiative on metagenomics for personalised medicine approaches. <i>Only one proposal may be selected.</i>	<i>Collaborative Project (large-scale integrating research project). Additional eligibility criterion: Requested EU contribution per project: Maximum EUR 30 000 000. The estimated EU contribution going to industry including SME(s) shall be 30% or more of the total estimated EU contribution for the project as a whole. The SME status and the financial viability will be assessed at the end of the negotiation, before signature of the grant agreement.</i>
2.2 RESEARCH ON THE BRAIN AND RELATED DISEASES, HUMAN DEVELOPMENT AND AGEING		
2.2.1 Research on the brain and brain-related diseases		
2.2.1	HEALTH.2013.2.2.1-1: Prospective longitudinal data collection and Comparative Effectiveness Research (CER) for traumatic brain injury (TBI). <i>One or more proposals may be selected.</i>	<i>Collaborative Project (large-scale integrating research project). Additional eligibility criterion: The requested contribution per project shall not exceed EUR 30 000 000.</i>
2.2.1	HEALTH.2013.2.2.1-2: Development of effective imaging tools for diagnosis, monitoring and management of mental disorders ⁵¹ . <i>One or more proposals may be selected.</i>	<i>Collaborative Project (small or medium-scale focused research project). Additional eligibility criterion: Requested EU contribution per project: Maximum EUR 6 000 000. The estimated EU contribution going to industry including SME(s) shall be 30% or more of the total estimated EU contribution for the project as a whole. The SME status and the financial viability will be assessed at the end of the negotiation, before signature of the grant agreement.</i>
2.2.1	HEALTH.2013.2.2.1-3: Paediatric conduct disorders characterised by aggressive traits and/or social impairment: from preclinical research to treatment. <i>One or more proposals may be selected.</i>	<i>Collaborative Project (small or medium-scale focused research project). Additional eligibility criterion: Requested EU contribution per project: Maximum EUR 6 000 000. The estimated EU contribution going to SME(s) shall be 15% or more of the total estimated EU contribution for the project as a whole. The SME status and the financial viability will be assessed at the end of the negotiation, before signature of the grant agreement.</i>

⁵¹ As defined in the Diagnostic and Statistical Manual of Mental Disorders, 4th edition.

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2.2.1	HEALTH.2013.2.2.1-4: Patho-physiology and therapy of epilepsy and epileptiform disorders. <i>One or more proposals may be selected.</i>	<i>Collaborative Project (large-scale integrating research project). Additional eligibility criterion: Requested EU contribution per project: Maximum EUR 12 000 000. The estimated EU contribution going to SME(s) shall be 15% or more of the total estimated EU contribution for the project as a whole. The SME status and the financial viability will be assessed at the end of the negotiation, before signature of the grant agreement a whole.</i>
2.2.1	HEALTH.2013.2.2.1-5: Understanding and controlling pain. <i>One or more proposals may be selected.</i>	<i>Collaborative Project (small or medium-scale focused research project). Additional eligibility criterion: Requested EU contribution per project: Maximum EUR 6 000 000.</i>
2.3 TRANSLATIONAL RESEARCH IN MAJOR INFECTIOUS DISEASES: TO CONFRONT MAJOR THREATS TO PUBLIC HEALTH		
2.3.0 Cross-cutting priorities		
2.3.0	HEALTH.2013.2.3.0-1: Innovation in vaccines. <i>One or more proposals may be selected.</i>	<i>SME-targeted Collaborative Project (small or medium-scale focused research project). Additional eligibility criterion: Requested EU contribution per project: Maximum EUR 6 000 000. The estimated EU contribution going to SME(s) shall be 30% or more of the total estimated EU contribution for the project as a whole. The SME status and the financial viability will be assessed at the end of the negotiation, before signature of the grant agreement.</i>
2.3.1 Anti-microbial drug resistance		
2.3.1	HEALTH.2013.2.3.1-2: Stratified approaches to antibacterial and/or antifungal treatment. <i>One or more proposals may be selected.</i>	<i>Collaborative Project (small or medium-scale focused research project). Additional eligibility criterion: Requested EU contribution per project: Maximum EUR 6 000 000.</i>
2.3.3 Potentially new and re-emerging epidemics		
2.3.3	HEALTH.2013.2.3.3-1: Clinical management of patients in severe epidemics. <i>Only one proposal may be selected.</i>	<i>Collaborative Project (large-scale integrating research project). Only up to one proposal may be selected. Additional eligibility criterion: Requested EU contribution per project: Maximum EUR 24 000 000.</i>
2.3.4 Neglected infectious diseases		
2.3.4	HEALTH.2013.2.3.4-1: Neglected infectious diseases of Central and Eastern Europe. <i>One or more proposals may be selected.</i>	<i>Collaborative Project (small-scale focused research project). Additional eligibility criterion: Requested EU contribution per project: Maximum EUR 3 000 000.</i>
2.3.4	HEALTH.2013.2.3.4-2: Drug development for neglected parasitic diseases. <i>One or more proposals may be</i>	<i>SME-targeted Collaborative Project (small or medium-scale focused research project). Additional eligibility criterion: Requested EU contribution per project: Maximum EUR 6 000 000. The estimated EU contribution going to</i>

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	<i>selected.</i>	<i>SME(s) shall be 15% or more of the total estimated EU contribution for the project as a whole. The SME status and the financial viability will be assessed at the end of the negotiation, before signature of the grant agreement.</i>
2.4 TRANSLATIONAL RESEARCH IN OTHER MAJOR DISEASES		
2.4.1 Cancer		
2.4.1	HEALTH.2013.2.4.1-1: Investigator-driven treatment trials to combat or prevent metastases in patients with solid cancer. <i>One or more proposals may be selected.</i>	<i>Collaborative Project (small-scale focused research project). Additional eligibility criterion: Requested EU contribution per project: Maximum EUR 6 000 000.</i>
2.4.1	HEALTH.2013.2.4.1-2: Strengthening the cancer patient's immune system. <i>One or more proposals may be selected.</i>	<i>Collaborative Project (small or medium-scale focused research project). Additional eligibility criterion: Requested EU contribution per project: Maximum EUR 6 000 000. The estimated EU contribution going to industry including SME(s) shall be 30% or more of the total estimated EU contribution for the project as a whole. The SME status and the financial viability will be assessed at the end of the negotiation, before signature of the grant agreement.</i>
2.4.1	HEALTH.2013.2.4.1-3: Investigator-driven supportive and palliative care clinical trials and observational studies. <i>One or more proposals may be selected.</i>	<i>Collaborative Project (small or medium-scale focused research project). Additional eligibility criterion: Requested EU contribution per project: Maximum EUR 6 000 000.</i>
2.4.2 Cardiovascular diseases		
2.4.2	HEALTH.2013.2.4.2-1: Discovery research to reveal novel targets for cardiovascular disease treatment. <i>One or more proposals may be selected.</i>	<i>Collaborative Project (small or medium-scale focused research project). Additional eligibility criterion: Requested EU contribution per project: Maximum EUR 6 000 000. The estimated EU contribution going to SME(s) shall be 30% or more of the total estimated EU contribution for the project as a whole. The SME status and the financial viability will be assessed at the end of the negotiation, before signature of the grant agreement.</i>
2.4.2	HEALTH.2013.2.4.2-2: Comparative effectiveness research of existing technologies for prevention, diagnosis and treatment of cardiovascular diseases. <i>One or more proposals may be selected.</i>	<i>Collaborative Project (small or medium-scale focused research project). Additional eligibility criterion: Requested EU contribution per project: Maximum EUR 6 000 000.</i>
2.4.2	HEALTH.2013.2.4.2-3: Optimising lifestyle interactions in the prevention and treatment of cardiovascular disease across the lifespan.	<i>Collaborative Project (small-scale focused research project). Additional eligibility criterion: Requested EU contribution per project: Maximum EUR 3 000 000.</i>

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	<i>One or more proposals may be selected.</i>	
3. OPTIMISING THE DELIVERY OF HEALTHCARE TO EUROPEAN CITIZENS		
3.2 TRANSLATING THE RESULTS OF CLINICAL RESEARCH OUTCOME INTO CLINICAL PRACTICE INCLUDING BETTER USE OF MEDICINES, APPROPRIATE USE OF BEHAVIOURAL AND ORGANISATIONAL INTERVENTIONS AND NEW HEALTH THERAPIES AND TECHNOLOGIES.		
3.1	HEALTH.2013.3.1-1: Comparative Effectiveness Research (CER) in health systems and health services interventions. <i>One or more proposals may be selected.</i>	<i>Collaborative Project (small or medium-scale focused research project). Additional eligibility criterion: Requested EU contribution per project: Maximum EUR 6 000 000.</i>
3.3 HEALTH PROMOTION AND PREVENTION		
3.3	HEALTH.2013.3.3-1: Social innovation ⁵² for health promotion. <i>One or more proposals may be selected.</i>	<i>Collaborative Project (small or medium-scale focused research project). Additional eligibility criterion: Requested EU contribution per project: Maximum EUR 6 000 000. The estimated EU contribution going to SME(s) shall be 15% or more of the total estimated EU contribution for the project as a whole. The SME status and the financial viability will be assessed at the end of the negotiation, before signature of the grant agreement.</i>
4 OTHER ACTIONS ACROSS THE HEALTH THEME		
4.1 COORDINATION AND SUPPORT ACTIONS ACROSS THE THEME		
4.1	HEALTH.2013.4.1-1: Supporting industrial participation in EU-funded research in the Health sector. <i>Only up to one proposal may be selected.</i>	<i>Coordination and Support Action (coordinating action). Additional eligibility criterion: Requested EU contribution per action: Maximum EUR 2 500 000.</i>
4.1	HEALTH.2013.4.1-2: Interactions between EU legislation and health research and/or innovation and the effects of its application and implementation on health research and/or innovation. <i>One or more proposals may be selected.</i>	<i>Coordination and Support Action (supporting action). Additional eligibility criterion: Requested EU contribution per action: Maximum EUR 500 000.</i>
4.1	HEALTH.2013.4.1-3: Support for	<i>Coordination and Support Action (supporting</i>

⁵² Social innovations are new ideas (products, services and models) that simultaneously meet social needs (more effectively than alternatives) and create new social relationships or collaborations. In other words they are innovations that are not only good for society but also enhance society's capacity to act.
http://ec.europa.eu/enterprise/policies/innovation/policy/social-innovation/index_en.htm

It covers wide fields which range from new models of child care to web-based social networks, from the provision of domestic healthcare to new ways of encouraging people to exchange cars for bicycles in cities, and the development of global fair-trade chains. It may be a new product, service, initiative, organisational model or approach to the delivery of public services.

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	<p>Presidency events: Organisation of supporting actions and events associated to the Presidency of the European Union.</p> <p><i>One or more proposals may be selected.</i></p>	<p><i>action). Additional eligibility criterion: Requested EU contribution per action: Maximum EUR 100 000.</i></p>
4.1	<p>HEALTH.2013.4.1-4: Preparing the future for health research and innovation.</p> <p><i>One or more proposals may be selected.</i></p>	<p><i>Coordination and Support Action (supporting action). Additional eligibility criterion: Requested EU contribution per action: Maximum EUR 500 000.</i></p>
4.1	<p>HEALTH.2013.4.1-5: Global initiative on gene-environment interactions in diabetes/obesity in specific populations.</p> <p><i>Only up to one proposal may be selected.</i></p>	<p><i>Coordination and Support Action (coordinating action). Additional eligibility criterion: Requested EU contribution per action: Maximum EUR 2 000 000.</i></p>
4.1	<p>HEALTH.2013.4.1-6: Mapping chronic non-communicable diseases research activities.</p> <p><i>Only up to one proposal may be selected.</i></p>	<p><i>Coordination and Support Action (coordinating action). Additional eligibility criterion: Requested EU contribution per action: Maximum EUR 2 000 000.</i></p>
4.1		
4.2 RESPONDING TO EU POLICY NEEDS		
4.2	<p>HEALTH.2013.4.2-1: Investigator-driven clinical trials for off-patent medicines using innovative, age-appropriate formulations and/or delivery systems.</p> <p><i>One or more proposals may be selected.</i></p>	<p><i>Collaborative Project (small or medium-scale focused research project). Additional eligibility criterion: Requested EU contribution per project: Maximum EUR 6 000 000. The estimated EU contribution going to industry including SME(s) shall be 30% or more of the total estimated EU contribution for the project as a whole. The SME status and the financial viability will be assessed at the end of the negotiation, before signature of the grant agreement.</i></p>
4.2	<p>HEALTH.2013.4.2-2: Adverse drug reaction research.</p> <p><i>One or more proposals may be selected.</i></p>	<p><i>Collaborative Project (small-scale focused research project). Additional eligibility criterion: Requested EU contribution per project: Maximum EUR 3 000 000. The estimated EU contribution going to SME(s) shall be 15% or more of the total estimated EU contribution for the project as a whole. The SME status and the financial viability will be assessed at the end of the negotiation, before signature of the grant agreement.</i></p>
4.2	<p>HEALTH.2013.4.2-3: New methodologies for clinical trials for small population groups.</p> <p><i>One or more proposals may be selected.</i></p>	<p><i>Collaborative Project (small-scale focused research project). Additional eligibility criterion: Requested EU contribution per project: Maximum EUR 3 000 000.</i></p>

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It is important to note that the basic conditions for eligibility shall be met, such as the minimum number of participants (in most cases 3 from different MS or AC, except for supporting actions) or the budget ceiling for the maximum requested EU contribution. 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** shall be in line with the realistic planning of the project. The size of the **EU contribution** to the budget shall also be in line with the needs of the consortia, within the maximum EU contribution, but does not necessarily need to be 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.

In recognition of the opening of NIH⁵³ programmes to European researchers, participants established in the *United States of America* are entitled to participate and to receive funding⁵⁴ in all topics under this call.

Eligibility criteria for each proposal are checked by Commission staff before the evaluation begins. Proposals which do not fulfil any of the criteria will not be evaluated.

Eligibility criteria (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 ⁵⁵
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 legal entity

⁵³ National Institutes of Health of the US Department of Health and Human Services

⁵⁴ In accordance with Article 29 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).

⁵⁵ These can differ for specific topics, please consult always the topic description in section II

The eligibility criteria will 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 criteria.

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 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 criterion will be verified: 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 respective topic description in section II. *The SME status and the financial viability will be finally assessed during the negotiation, before signature of the grant agreement. Proposals not fulfilling this criterion will not be funded.*

Evaluation procedure:

- The evaluation criteria and scoring scheme are set out in annex 2 to the work programme and the guide for applicants.
 - Proposal page limits: Applicants will 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 electronic Submission Services of the Commission. No annexes are allowed to the proposal.
- 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, and 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.
- **For the evaluation of topics "HEALTH.2013.2.1.1-2: High impact research initiative on metagenomics for personalised medicine approaches", "HEALTH.2013.2.2.1-1: Prospective longitudinal data collection and Comparative Effectiveness Research (CER) for traumatic brain injury (TBI)" and "HEALTH.2013.2.3.3-1: Clinical management of patients in severe epidemics", the Commission will organise hearings⁵⁶ at stage 2 with applicants as part of the panel deliberations for all proposals above threshold.**

⁵⁶ Details about the procedure are provided in an explanatory memorandum on the call web page.

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 will need to 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. The SME status and the financial viability 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 will need to 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 shall be submitted by the deadline mentioned above.*
- *Stage 1 proposals shall follow the instructions set out in the guide for applicants and in the proposal part B template available through electronic Submission Services of the Commission. Proposals should focus on the overall scientific and technological content and on clear identification of the milestones and deliverables to be reached (intended results), the intended use of the results 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)**. **No annexes are allowed to the proposal i.e. applicants have to strictly follow the template for part B and may not create more sections or annexes within this document.** The maximum page limits of each section shall 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 will need to 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. Successful proposals will not receive an ESR⁵⁷.*
- *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 section II of 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 the beginning of February 2013.*
- *Stage 2 proposals shall follow the instructions set out in the guide for applicants and in the proposal part B template available through electronic Submission Services of the Commission. **No annexes are allowed to the proposal i.e. applicants have to strictly follow the template for part B and may not create more sections or annexes within this document.** The maximum page limits of each section shall 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 2 proposals are evaluated on the basis of the following three criteria: **Scientific/technological quality, 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*

⁵⁷ See annex C of the "Rules for submission of proposals, and the related evaluation, selection and award procedures"; COMMISSION DECISION C(2011)1132 of 28 February 2011.

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 will need to pass the minimum thresholds as follows:

Table 5: Thresholds for evaluation criteria for second stage

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

- *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.

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.

- *The SME and/or industrial status of participants and their financial viability will be checked definitively at the end of any negotiation of any kind of collaborative project requiring a certain SME and/or industrial participation.*

Proposal ranking at stage 2:

- *There will be differing numbers of proposals short-listed according to the topic description in section II and the available budget.*
- *However, there may be topics for which no proposals are of sufficient quality to be selected for funding, as there will be competition within topics and between topics on the basis of the quality of the proposals.*
- *The Commission ranked lists of proposals to be retained for negotiation will be based on the priority list established by the panel of independent external experts at stage 2 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 2012. The deadline for stage 2 proposals will be in the beginning of February 2013. The evaluation of the stage 2 is expected to take place in March 2013. Overall evaluation results are 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 begin in May 2013.

Consortium agreements: Participants in collaborative are required to conclude a consortium agreement. 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 on the Participant Portal at: https://ec.europa.eu/research/participants/portal/page/fp7_documents under 'Guidance documents for FP7/Financial issues/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-2013-SMES-FOR-INNOVATION

Call identifier: FP7-HEALTH-2013-INNOVATION-2

Proposal submission and evaluation: two-stage procedure.

Date of publication: 10 July 2012⁵⁸

Deadline for stage 1 proposals: 25 September 2012 at 17:00:00 (Brussels local time)⁵⁹

Indicative budget: EUR 140 million from the 2013 budget⁶⁰

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.

For description of the topics of the calls, please refer to section II 'Content of calls'

Table 1: Indicative budget lines

ACTIVITY/AREA	Indicative budget (EUR million)
0. HORIZONTAL TOPICS FOR COLLABORATIVE PROJECTS RELEVANT FOR THE WHOLE OF THEME HEALTH	95
2. TRANSLATING RESEARCH FOR HUMAN HEALTH	
2.3. TRANSLATIONAL RESEARCH IN MAJOR INFECTIOUS DISEASES: TO CONFRONT MAJOR THREATS TO PUBLIC HEALTH	
2.3.1 ANTI-MICROBIAL DRUG RESISTANCE	45

⁵⁸ The Director-General responsible for this call may publish it up to one month prior to or after the envisaged date of publication.

⁵⁹ The Director-General responsible for this call may delay this deadline by up to two months.

⁶⁰ Under the condition that the draft budget for 2013 is adopted without modifications by the budgetary authority.

Table 2: Topics called:

Activity/Area	Topics called	Funding Schemes
0. HORIZONTAL TOPICS FOR COLLABORATIVE PROJECTS RELEVANT FOR THE WHOLE OF THEME HEALTH		
0.1	HEALTH.2013.0-1: Boosting the translation of health research projects' results into innovative applications for health. <i>One or more proposals may be selected.</i>	<i>Collaborative Project (small or medium-scale focused research project).</i>
2.3. TRANSLATIONAL RESEARCH IN MAJOR INFECTIOUS DISEASES: TO CONFRONT MAJOR THREATS TO PUBLIC HEALTH		
2.3.1 Anti-microbial drug resistance		
2.3.1	HEALTH.2013.2.3.1-1: Drugs and vaccines for infections that have developed or are at risk of developing significant anti-microbial resistance. <i>One or more proposals may be selected.</i>	<i>Collaborative Project (small or medium-scale focused research project).</i>

Conditions for FP7-HEALTH-2013-INNOVATION-2:

It is important to note that once the basic criteria 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 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 its 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. However, a proposal can be declared ineligible at any time of the process.

Specific requirements to be considered under the evaluation:

- Specific innovation initiative designed to encourage strong SME efforts towards the translation of research results into innovative applications for health.
- Leading role of SMEs in the project.
- Developing a short business plan as part of the proposal clearly describing the valorisation of the technology(ies) when presenting a full proposal at stage 2.
- Expected outcomes of clear interest and potential benefit to SMEs.

Eligibility criteria (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 this call. Please note that the completeness criterion also includes that part B of the proposal shall be readable, accessible and printable.

Table 3: Minimum number of participating legal entities for the funding scheme used in this call, in line with the Rules for Participation.

Funding scheme	Minimum conditions
Collaborative Project	At least 3 independent legal entities, each of which is established in a EU Member State (MS) or Associated Country (AC), and no 2 of which are established in the same 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 criteria.

- The **requested EU contribution** per project shall 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 may not exceed 3 years.
- **The number of participants is restricted** from 3 to 5 entities⁶¹, where **SME or SME joint venture participation is restricted** to entities established in EU Member States and Associated Countries.

In addition only at stage 2:

- **Participating SME(s) or SMEs joint venture** 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.
- The **estimated EU contribution going to SME(s) or SME joint venture shall be 50% or more** of the total estimated EU contribution to the project as a whole. The SME status and the financial viability will be assessed at the end of the negotiation, before signature of the grant agreement.
- The **financial viability of all partners** in selected projects needs to fulfil the Commission requirements. *The SME status and the financial viability will be checked definitively at the end of any negotiation.*

⁶¹ For minimum conditions please refer to table 3

Applicants invited to present a full proposal for stage 2 are requested to submit within the proposal a short business plan, clearly describing the valorisation of the technology. The short business plan is part of the proposal content within its page limitations given in the guide for applicants and the electronic Submission Services template.

Evaluation procedure for stage 1 and 2:

- The evaluation criteria and scoring scheme are set out in annex 2 to the work programme and the guide for applicants.
- 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 will need to 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 shall be submitted by the deadline mentioned above.*
- *Stage 1 proposals shall follow the instructions set out in the guide for applicants and in the proposal part B template available through electronic Submission Services of the Commission. Proposals will need to describe the overall scientific and technological content and clearly identify the milestones and deliverables to be reached (intended results), the intended use of the results and the expected impact (scientific, economic, social, environmental, etc.) and as set out in section II under each topic with a total maximum of 6 pages (excluding the cover page and the required tables). The maximum page limits of each section will need to be respected. No annexes are allowed to the proposal i.e. applicants have to strictly follow the template for part B and may not create more sections or annexes within this document. 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 will need to 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. Successful proposals will not receive an ESR⁶².*
- *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 2012.*
- *Stage 2 proposals shall respect the maximum of 20 pages (excluding the cover page and the required tables) and shall follow the instructions set out in the guide for applicants and in the proposal part B template available through electronic Submission Services of the Commission. **The maximum page limits of each section will need to be respected. No annexes are allowed to the proposal i.e. applicants have to strictly follow the template for part B and may not create more sections or annexes within this document.** Proposals will need to describe the overall scientific and technological content and clearly identify the milestones and deliverables. A proper statistical section for clinical trials or experimental design will need to be provided where appropriate. In the section implementation the capacity to carry out the work and the leading role of the SMEs need to be described. In the section expected impact the intended results (scientific, economic,*

⁶² See annex C of the "Rules for submission of proposals, and the related evaluation, selection and award procedures"; COMMISSION DECISION of 28 February 2011

social, environmental, etc. and as set out in section II under each topic) are to be described.

- *Proposal page limits: Applicants shall 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 electronic Submission Services of the Commission. **No annexes are allowed.***
- *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, and 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 will need to 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 from EU Member States or Associated Countries. Applicants and evaluators should note that only proposals which fulfil these conditions will be eventually selected. The SME status and the financial viability 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 6 000 000, 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 evaluations.*

➔ *At stage 2 evaluators will also consider whether the participants will have the capacity to carry out the proposed short business plan.*

Proposal ranking at stage 2:

- *Proposals will be ranked 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 upon 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 2012. The deadline for stage 2 proposals is expected to be mid December 2012. The evaluation of the stage 2 is expected to take place in January 2013. 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 2013.

Consortium agreements: Participants are required to conclude a consortium agreement. Even if an SME is not the coordinator, the protection of interests of the participating SMEs shall 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 on the Participant Portal at: https://ec.europa.eu/research/participants/portal/page/fp7_documents under 'Guidance documents for FP7/Financial issues/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 ACTIVITIES⁶³ (NOT IMPLEMENTED THROUGH CALLS FOR PROPOSALS)

Human Frontier Science Programme Organisation

An annual subscription to the international Human Frontier Science Programme Organisation (HFSP)⁶⁴ 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 4 672 000 for 2013, EUR 2 803 000 will be paid from this theme, and the remainder from the ICT Theme.

Funding scheme: CSA – subscription.

Conference: International efforts in rare diseases research

The aim of this conference is to increase the impact of EU-funded research in the context of the International Rare Diseases Research Consortium. Participants will be leading scientists from public and private sectors, representativeness of patient organisations, regulatory bodies and funding agencies.

Funding scheme: Coordination and Support Action – public procurement⁶⁵ to be implemented through a Framework Contract in 2013..

EU contribution (indicative budget: EUR 300 000).

Support for the organisation of conferences related to the Month of the Brain in 2013

Support is planned for two conference events for the Month of the Brain 2013, including one expected to be organised in association with the Irish Presidency. The objectives of those conferences are to mobilise stakeholders on the need to coordinate and optimise resources allocated to brain research and to raise awareness on the importance of brain health. Participants will be policy makers, funding agencies, scientists (private and public), patient organisations, citizens and employers.

⁶³ In accordance with Article 14, 17 and 27 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).

⁶⁴ The European Union is a member of the HFSP Organisation (HFSP) and has funded HFSP under previous Framework Programmes.

⁶⁵ In accordance with Art 14(b) of Regulation (EC) No 1906/2006 of 18 December 2006 laying down the rules for the participation of undertakings, research centres and universities in actions under the Seventh Framework Programme and for the dissemination of research results (2007-2013).

Funding scheme: Coordination and Support Action – public procurement⁶⁶: to be implemented through a Framework Contract in 2012/2013.

EU contribution (indicative budget: EUR 500 000).

Global Alliance for Chronic Diseases

The European Commission will make a contribution towards activities of the Global Alliance for Chronic Diseases (GACD). This will enable the European Commission to take part in GACD, which brings together leading health research funding agencies of key countries (currently USA, Australia, UK, Canada, China and South Africa) to coordinate research activities addressing on a global scale the prevention and treatment of chronic, non-communicable diseases such as cardiovascular diseases (mainly heart disease and stroke), diabetes and mental health. Recommendations of GACD are expected to have a fundamental value for future orientation of public health research policy. Funding will be provided through an action grant to: the secretariat of the GACD, hosted by University College London (UCL), Gower Street 1, WC1E 6BT, London, UK.

Funding scheme: CSA – named beneficiary

EU contribution (indicative budget: EUR 120 000).

European registry for human embryonic stem cell lines

A contribution will be made to ensure the continued registration of human embryonic stem cell (hESC) lines in a European registry maintained by Charité Universitätsmedizin Berlin. The aim is to gather and make available detailed information on the different hESC lines derived in Europe and beyond, thereby also avoiding needless creation of new cell lines. This registry operates through an internet website that will continue to provide high quality data about the lines (e.g. cell characteristics), details regarding their source and contact information regarding their location. Funding will be provided through an action grant to: Berlin-Brandenburg Centre for Regenerative Therapies – BCRT Charité - Universitätsmedizin Berlin, Augustenburger Platz 1, D-13353 Berlin, Germany.

Funding scheme: CSA – named beneficiary

EU contribution (indicative budget: EUR 500 000).

⁶⁶ In accordance with Art 14(b) of Regulation (EC) No 1906/2006 of 18 December 2006 laying down the rules for the participation of undertakings, research centres and universities in actions under the Seventh Framework Programme and for the dissemination of research results (2007-2013).

V BUDGET

THEME HEALTH - INDICATIVE BUDGET

Activities	2013⁶⁷ Budget EUR million⁶⁸
CALL FP7-HEALTH-2013-INNOVATION-1	679.30
CALL FP7-HEALTH-2013-INNOVATION-2	140.00
General activities (cf Annex) (details below)	8.94
OTHER ACTIVITIES: <ul style="list-style-type: none"> • Evaluations-Reviews (EUR 6.00 million) • HFSPO (EUR 2.803 million) • Actions implemented through public procurements and grants to identified beneficiaries (EUR 1.42 million) 	10.22
Estimated total budget	838.46

⁶⁷ Under the condition that the draft budget for 2013 is adopted without modifications by the budgetary authority.

⁶⁸ The Budget figures given in this table are rounded to two decimals points.

GENERAL ACTIVITIES - INDICATIVE BUDGET

Activities⁶⁹	2013⁷⁰ Budget EUR million
CORDIS	1.40
Experts (evaluators and reviewers)	0.02
COST	7.45
EUREKA	0.07
Total	8.94

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.

⁶⁹ For more details see annex 4 of the work programme.

⁷⁰ Under the condition that the draft budget for 2013 is adopted without modifications by the budgetary authority.