ORIENTATION PAPER

prepared in connection with the FP7 2013 Work Programme in the area of Health research

Important notice:
This paper is made public at an early stage in the adoption process of the work programme to provide potential applicants with the currently expected main lines of the 2013 work programme. It is a working document not yet endorsed by the Commission and its content does not in any way prejudge the subsequent modifications by the Commission, neither the subsequent formal opinion of the Programme Committee nor the final decision of the Commission. The final adoption and the publication of the later work programme by the Commission are expected in mid-July 2012 via the participant portal: *http://ec.europa.eu/research/participants/portal/page/cooperation*. Only the adopted work programme will have legal value.

Information and topic descriptions indicated in this orientation paper may not appear in the final work programme; and likewise, new elements may be introduced at a later stage. No essential information, such as indicative budgets per call/area, will be provided by the Commission until the final work programme is adopted. Any such information disclosed by any other party shall not be construed as having been endorsed by or affiliated to the Commission.

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Two health calls are proposed, following the two-stage procedure:

FP7-HEALTH-2013-INNOVATION-1 with 35 topics and

indicative deadline 2 October 2012

and

FP7-HEALTH-2013-INNOVATION-2 with 2 topics and

indicative deadline 25 September 2012

DRAFT VERSION 2 April 2012

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.

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**[1] including complementing efforts undertaken by the Innovation Union flagship initiative[2], the European Innovation Partnership (EIP) for "active and healthy ageing"[3]. Throughout this work programme, a set of approaches contribute to **bridging with 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.

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, 2009[6]) through large-scale collaborative research efforts.

Approach for 2013

[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;

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 ongoing public-private partnership with the pharmaceutical industry, the Innovative Medicine Initiative[7] (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 projects whose results are nearing market introduction, 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 access to the market of innovative solutions and thus help ensure the practical application of research results. As such, projects could strengthen future innovation in their projects by considering the inclusion of pre- and co-normative research tasks and the integration of standardisation organisations to support standardisation.

Key Challenges/objectives

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 2010[8].

Comparative Effectiveness Research (CER) has not been addressed in FP7 before and will bridge to planned activities of Horizon 2020 where CER will 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.

[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

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 Goals[9].

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.

- **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 topics[10] (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 must 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
- **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.
- **Dissemination actions:** The health market is highly fragmented in Europe, with different public health policies in Member States and Associated countries. To sustain the

[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.2013.0-1: 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.

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 previously FP-funded health research projects to address the innovation lifecycle by boosting the translation of FP 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 months[11].

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 NIH[12] programmes to European researchers, participants established in the *United States of America* are eligible for funding and participation 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 **broader topics** of which **many are tailored for SME participation** (bottom-up with a minimum

[11] Further information: http://cordis.europa.eu/fp7/find-doc_en.html
http://ec.europa.eu/research/sciencesociety/

[12] National Institutes of Health of the US Department of Health and Human Services

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.**

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 must be in line with the realistic planning of the project and so, can be quite short (e.g. 1-2 years), or long enough to achieve the goals of the project with the exception of topics 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 must also be in line with the needs of the respective consortium, within the maximum EU contribution but not necessarily at the maximum by default.

- ***Ethical issues:*** It is particularly important that applicants address the potential ethical issues of their proposals, both in the proposed methodology and the possible implications of the results. The specific requirements for addressing ethical issues[13] 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) must be considered where appropriate.
- ***Use of animals in research:*** Research activities should take into account the Protocol on the Protection and Welfare of Animals, and the use of animals in research and testing[14]. 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 Notes[15].
- ***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

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

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

[15] ftp://ftp.cordis.europa.eu/pub/fp7/docs/negotiation_en.pdf

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 must 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 must explain why.

  Innovative clinical trials[16] to verify safety and efficacy: The early involvement of patients[17] 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 must 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. More detailed information will be given in the relevant guide for applicants, to be published later.

[16] http://ec.europa.eu/health/human-use/clinical-trials/index_en.htm

[17] http://www.eu-patient.eu/Initatives-Policy/Projects/ValuePlus/

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 must 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 FP projects' results into innovative applications for health. FP7-HEALTH-2013-INNOVATION-2. The main aim of this topic is to build on the results of projects funded under the Health theme of the EU FP6 and FP7, to prove the viability of methodologies, processes, prototypes, models, technologies, clinical trials, etc. developed under these projects, with a potential for application. Eligible 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 must fit into the overall business and innovation needs of the partners involved and must demonstrate clear exploitation potential and socio-economic benefits for the patients, for them and the society at large. Applicants must have the freedom to exploit the results for commercial use. Applicants must 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 the Health theme, 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.
- SMEs will need to have a leading role in the project.
- Applicants invited to present a full proposal for stage 2 must submit a short business

plan clearly describing the valorisation of the technology(ies).

- Expected outcome must be 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 must fulfil the Commission applicable rules[18]. 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 must 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 is restricted** to entities established in EU Member States and Associated Countries. In addition, SMEs must 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

[18] ftp://ftp.cordis.europa.eu/pub/fp7/docs/rules-verif_en.pdf

diseases, and for support and guidance of therapeutic interventions. The focus will be on a multidisciplinary approach integrating areas such as: molecular and cellular biology, physiology, genetics, physics, chemistry, biomedical engineering, 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 must 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)[19].

Specific requirements to be considered under the evaluation:

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

[19] http://www.e-rare.eu/content/irdirc

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 must 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.

1.3 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 must 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 define and engage jointly on integrated research with shared goals 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 must 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 must 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 must 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 must 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 must 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 must 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 must 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 must 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 lead by regulatory 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 must 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 required[20].

Note: For all topics in this area applicants must 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

[20] 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

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 must include industry, especially from the SME sector from EU Member States and/or Associated.

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:

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

2. The **estimated EU contribution going to *SMEs must 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 must 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 must 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 must 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.
- Preference will be given to proposals demonstrating that research intensive SMEs play a leading role.
- The projects will be led by SMEs with R&D capacities but the coordinator does not need to be an SME.
- The expected project results must clearly be of 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 must 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 must 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 microflora 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)[21] and should include:

- **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 must 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

[21] http://www.human-microbiome.org/

(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 must 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 must 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)[22] that is being set up in cooperation with the US (NIH) and Canada.

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

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)[23], the data standards endorsed by the International Initiative for Traumatic Brain Injury Research (InTBIR). Applicants must 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 must 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 database[24]. 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 (NIH[25] and CIHR[26]) and the scientific community at large.

The management structure and provisions need to be adequate to the size and scope of the project. Following evaluation and negotiation the successful project(s) will be required to interact with other InTBIR funded projects.

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).

[22] Link to policy document to be added
[23] The TBI-CDE, listed by category, can be found at http://www.commondataelements.ninds.nih.gov/TBI.aspx
[24] http://www.nih.gov/news/health/aug2011/ninds-29.htm
[25] National Institutes of Health of the US Department of Health and Human Services
[26] Canadian Institutes of Health Research

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)[27]. 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 and the total budget available for this topic shall not exceed EUR 30 000 000.

HEALTH.2013.2.2.1-2: Development of effective imaging tools for diagnosis, monitoring and management of mental disorders[28]. 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 Health[29].

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 must 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

[27] http://www.internationalbrain.org/

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

[29] http://ec.europa.eu/health/ph_determinants/life_style/mental/docs/pact_en.pdf

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 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) must 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 put more effective therapeutics on the market. Research proposed may address key issues such as genomics of epilepsy and epileptiform disorders, mechanisms of ictiogenesis 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) must 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 must 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 must 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 must 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.
- Priority will be given to proposals demonstrating that research intensive SMEs play a leading role.

- The projects will be led by SMEs with R&D capacities, but the coordinator does not need to be an SME.
- The expected project results must clearly be of 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 must 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 resistance[30]. 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 must follow the rules for the **two-stage** submission procedure (see also respective call fiche in section III).

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. 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

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

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.
- SMEs must have a leading role in the project.
- Applicants invited to present a full proposal for stage 2 must submit a short business plan clearly describing the valorisation of the technology(ies).
- Expected project results must be 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 must fulfil the Commission applicable rules[31]. 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) must 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 is restricted** to entities established in EU Member States and Associated Countries. In addition, SMEs must 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 antibacterial and antifungal (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

[31] ftp://ftp.cordis.europa.eu/pub/fp7/docs/rules-verif_en.pdf

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 must 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 must 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 must 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)[32]. Research must 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 must 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 must 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 must already have undergone first-in-man testing.

[32] 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 ongoing 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.
- Priority will be given to proposals demonstrating that research intensive SMEs play a leading role.
- The projects will be led by SMEs with R&D capacities but the coordinator does not need to be an SME.
- The expected project results must 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 *SMEs must 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 must 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 must 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 must be clearly described. The primary endpoint should be overall survival. The outcome of this research must be relevant for patients and have a potential to lead to changes in clinical practice. Applicants must demonstrate that clinical trials are appropriately powered to produce statistically significant evidence. Gender aspects and differences related to age groups must be appropriately considered. The clinical trials to be supported must be registered in a publicly accessible clinical trials registry and their results published in peer-reviewed journals. The applications must consider the relevant governance issues for clinical trials such as good clinical practice and respect of the appropriate international, European and national legislation and guidelines. Patient advocacy groups which can contribute to the quality, feasibility and impact of clinical trials, 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 projec**t 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 reverse translate clinical observations concerning cancer immunotherapy into improving 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. Appropriate tumour response criteria must be implemented and existent or newly developed assays harmonised while validating 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) must 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 must be clearly described. The outcome of this research must be relevant for patients or survivors and have a potential to lead to changes in clinical practice. Applicants must 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 must be registered in a publicly accessible clinical trials registry and their results published in peer-reviewed journals. The applications must consider the relevant governance issues for clinical trials such as good clinical practice and respect of the appropriate international, European and national legislation and guidelines. Patient advocacy groups, which can contribute to the quality, feasibility and impact of clinical trials, 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 must 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 must 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.
- Priority will be given to proposals demonstrating that research intensive SMEs play a leading role.
- The projects will be led by SMEs with R&D capacities, but the coordinator does not need to be an SME.
- The expected project results must clearly be of interest and potential benefit to SMEs.

Additional eligibility criteria:

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

2. The **estimated EU contribution going to *SMEs must 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 must 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 must 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 must 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 projec**t 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 projec**t 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 must be appropriately considered.

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

HEALTH.2013.3.3-1: Social innovation[33] 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 ongoing 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 must 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 must 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.

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.

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[33] 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.

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 *must 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 must 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 (including IMI[34] and EDCTP[35]), with focus on industry, especially European research performing SMEs. It will also promote and support successful participation, with focus on industry and especially research performing SMEs, in health-related areas of planned activities under Horizon 2020. Specific objectives include all 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 proposals' participants through training activities, 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

[34] Innovative Medicines Initiative.
[35] European and Developing Countries Clinical Trials Partnership.

database*; (iv)* to provide tools (including an up-to-date database of health-related SMEs in Europe) and advice to improve the quality of research proposals submitted, to encourage cooperation between industry and academia and increase the participation rate of high-technology research-performing SMEs. *(v)* To provide support, tools and training to facilitate and speed-up negotiation of grant agreements*; (vi)* to provide support on IPR issues that may rise during negotiation or during funded projects' lifetime; *(vii)* to assist project participants with training activities and tools; *(viii)* 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 must collaborate, complement and develop synergistic approach with existing support structures such as National Contact Points, Enterprise Europe Network, knowledge-transfer networks, like the IPR helpdesk, EMA[36] 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).

[36] European Medicines Agency.

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 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 must clearly be discernible. Under this topic activities will be supported with the aim of assessing profoundly the research and/or innovation resources, gaps and needs of the thematic target area, and to evaluate its potential as a focal area for a future 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 must be taken into account and - where relevant - coordination with these will allow for synergies and exclude competition or duplication. In addition, the proposal must 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.) must be clearly identified. The timeframe considered for implementation must 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 Diseases[37]. . It should address the fragmentation of research activities develop synergies, and possible common

[37] The European Commission proposes to take part in the Global Alliance for Chronic Diseases – see Other Activities page 65.

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 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 1 000 000.

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 must 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 must address one of the options below:

A) for use in children (Regulation (EC) No1901/2006[38]): Projects are expected to contribute to expanding the availability of medicines for children. Particular attention must be paid to age-appropriate formulations and of specific delivery systems for children. Projects must 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

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.

[38] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:378:0001:0019:en:PDF

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 must 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 must generate new knowledge on severe drug reactions and provide scientific evidence for post-authorisation risk assessment of medicinal products. Proposals must be based on pharmaco-epidemiological approaches focusing on adverse drug reaction research in one of the areas indicated below.

- 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 biphosphonates

Further details of the research objectives and expected deliverables are available on the website: (to be defined).

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) must 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 will not be funded. 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.